

Adverse Illness Event Series/Lentil and Leek Crumbles/Jun 2022 (CARA #1076) Incident Summary Report

October 18, 2022

Lead CORE Coordinators:

CORE Signals & Surveillance Team: Ashley Grant

CORE Response Team 2: Tem Jemaneh

ABSTRACT

On 6/21/2022, CORE Signals was notified by ORA partners about several illnesses associated with Daily Harvest's French Lentil and Leek Crumbles. The implicated food product associated with the illness series was identified as a frozen ready-to-cook product manufactured by Stone Gate Foods dba Second Bite Foods. Daily Harvest's French Lentil and Leek Crumbles was noted to be sold nationwide via online subscriptions and were also distributed through traditional retail channels. In response to consumer complaints submitted to the company, on 6/23/2022 Daily Harvest issued a voluntary recall of the French Lentil and Leek Crumbles product. At the time of transfer on 6/23/2022, this incident consisted of 35 complaint-based illnesses from 12 states: CA (6), CO (1), CT (6), IL (2), MA (4), NJ (4), NY (3), OR (1), RI (1), TX (2), VA (1), WI (3), and Unknown (1) with 20 hospitalizations. It should be noted that this information was obtained from FDA CFSAN Adverse Events Reporting System (CAERS) and Consumer Complaint (CC) reports. In response to submitted CC and CAERS reports reporting complaints of illness, on 6/22/2022, ORA HAFW1 initiated a joint inspection with the Minnesota Department of Agriculture (MDA) at Stone Gate Foods dba Second Bite Foods, Inc in Shakopee, MN. No significant observations were noted and no 483 was issued. No major deviations were observed during MDA's PC inspection. FDA collected 32 finished product and ingredient samples of Daily Harvest French Lentil and Leek Crumbles and findings were unable to determine a potential causative agent for this incident. Based on component ingredient analysis, FDA identified tara protein flour and sacha inchi powder as ingredients of interest. Analyses of collected samples of these ingredients did not identify any results of public health significance that could be definitively linked to reported illnesses for non-specific toxin tests, mycotoxin tests, and microbial tests. Similarly, no results of public health significance were obtained from testing of finished French Lentil and Leek Crumbles and (b)(4) product collected from warehouses and/or consumers. As of 10/18/2022, there were 393 adverse illness reports in 39 states with 133 hospitalization and 0 deaths. Based on CC and CAERS reports, the estimated illness onset dates range from 4/19/2022 – 9/4/2022. Information from reported adverse illness events identified French Lentil and Leek Crumbles manufactured by Stone Gate Foods dba Second Bite Foods and distributed by Daily Harvest as the confirmed vehicle in this incident, however, the specific cause or route of contamination could not be determined.

SIGNALS AND SURVEILLANCE ACTIVITIES

On 6/21/2022, CORE Signals was notified by ORA partners about several illnesses associated with Daily Harvest's French Lentil and Leek Crumbles. This notification did not mention a specific diagnosis or etiology and only described complaint-based illness reports. Daily Harvest is a subscription-based food delivery service that delivers frozen, easy to prepare foods. The implicated food product associated with the illness series was identified as a frozen ready-to-cook product, French Lentil and Leek Crumbles, manufactured by Stone Gate Foods dba Second Bite Foods (4218 Valley Industrial Blvd S. Shakopee MN 55379: FEI 3003908115). Daily Harvest's French Lentil and Leek Crumbles was noted to be sold nationwide via online subscriptions and were distributed through some traditional retail channels. Daily Harvest Corporate is located at 99 Hudson, St., New York City, NY 10013 (FEI: 3016119687).

Daily Harvest operates a direct-to-consumer business model, and on 6/17/2022 directly contacted all customers (via email), notifying them of a recall and potential issue with the French Lentil and Leek Crumbles product. On 6/20/2022, Stone Gate Foods filed a Reportable Food Registry (RFR; EON-494212) for the French Lentil and Leek Crumbles. Based on the RFR, the recall was issued due to customer complaints of gastrointestinal illness related to consumption of the product. Several customers reported hospital visits after consuming the French Lentil and Leek Crumbles. At the time the RFR was filed, all finished goods were put on hold and Daily Harvest stopped shipping the product.

Six implicated lots were included in the recall, with production dates occurring between 3/31/2022 and 5/19/2022. Recalled lots included: L02-VEGBN French Lentil + Leek Crumbles 9/27/2022; L5-A L02-VEGBN French Lentil + Leek Crumbles 10/10/2022; L5-A L02-VEGBN French Lentil + Leek Crumbles 10/23/2022; L5-A L02-VEGBN French Lentil + Leek Crumbles 11/6/2022; L5-A L02-VEGBN French Lentil + Leek Crumbles 11/14/2022; and L5-A L02-VEGBN French Lentil + Leek Crumbles 11/15/2022.

On 6/22/2022, ORA Human and Animal Foods (HAF) Division W1 (HAFW1; MIN-DO) initiated a joint inspection with the Minnesota Department of Agriculture (MDA) at Stone Gate Foods dba Second Bite Foods, Inc. During the inspection, Stone Gate Foods was noted as a Manufacturer/Re-packer/Packer of the product and was also noted to be registered as a dual jurisdiction USDA facility. Per the investigators who conducted the inspection, Stone Gate also manufactures (b)(4)

Prior to and during the inspection, Daily Harvest and Stone Gate Foods were simultaneously conducting their own investigation, which included product testing to determine the root cause of illness. According to Stone Gate Foods, finished product sample reports indicated product was tested for several bacteria, yeasts and molds, allergens, and aflatoxin. All tests were negative.

On 6/23/2022, at the time of transfer, this incident consisted of 35 complaint-based illnesses from 12 states: CA (6), CO (1), CT (6), IL (2), MA (4), NJ (4), NY (3), OR (1), RI (1), TX (2), VA (1), WI (3), and Unknown (1). Estimated illness onset dates ranged from 5/9/2022 to

6/18/2022, and approximately 20 cases had been hospitalized. It should be noted that this information was obtained from FDA CFSAN Adverse Events Reporting System (CAERS) and Consumer Complaint (CC) Reports.

At the time of transfer, 20 CAERs reports had been received from ill people. All 20 reports referenced Daily Harvest, and specifically mentioned the French Lentil and Leek Crumbles. Among the CAERS reports, 13 mentioned various liver-associated ailments and 16 noted gastrointestinal ailments. In addition to the CAERS reports, 13 FDA CCs had been received from ill patients. All 13 complaints referenced Daily Harvest French Lentil and Leek Crumbles. Among the CC reports, 10 reported various liver-associated ailments and 11 reported gastrointestinal ailments.

Medical records associated with the CAERS, and CCs reports were reviewed by CFSAN Medical Officers and were found to be suggestive of symptoms consistent with toxin poisoning, directly impacting the liver. Product testing was advised and included mass spectrometry for liver toxins, aflatoxins, ochratoxin, deoxynivalenol, CBD derivatives, mycotoxins, microcystins, and pyrrolizidine alkaloids.

At the time of transfer, information related to Daily Harvest's French Lentil and Leek Crumbles had become heavily publicized. Reports pertaining to the adverse events were circulated online via social media platforms and across various reporting agencies. This incident was transferred to CORE Response Team 2 on 6/23/2022 based on the following rationale:

- An FDA regulated product, Daily Harvest's French Lentil and Leek Crumbles, was linked to a series of adverse events reported to FDA as consumer complaints.
- Response coordination was needed for sampling and inspectional activities, public messaging and coordination of consumer complaint follow up.
- This was an incident of significant public interest and warranted additional follow-up by FDA.
- An FDA CORE coordinated response was requested by ORA.

RESPONSE ACTIVITIES

ADVERSE ILLNESS EVENT SERIES SUMMARY

ADVERSE ILLNESS EVENT CASE FINDING THROUGH CONSUMER COMPLAINTS (CC) AND CFSAN ADVERSE EVENS REPORTING SYSTEM (CAERS) REPORTS

FDA received adverse illness event reports via the National Consumer Complaint Coordinator and also via CAERS. The CCs and CAERS reports were sent to CORE on daily basis for review and CFSAN Medical Officers used this information to follow up to collect additional medical records for select adverse illness events of interest.

4

As of 10/18/2022, this incident included 393 adverse illness reports from complainants in 39 states: AZ (3), CA (75), CO (5), CT (14), DE (1), FL (9), GA (7), IL (11), IN (2), IA (2), KS (1), ME (1), MD (6), MA (19), MN (8), MS (2), MI (2) MO (2), MT (1), NV (1), NH (3), NJ (29), NM (1), NY (48), NC (14), OH (6), OK (2), OR (12) PA (10), RI (4), SC (3), SD (1), TN (4), TX (13), UT (1), VT (1), VA (9) WA (20), WI (9), and Unk (31) with 133 hospitalization and 0 deaths. Based on CC and CAERS reports, the estimated illness onset dates range from 4/19/2022 – 9/4/2022. The adverse illness events associated with the Daily Harvest French Lentil and Leek Crumbles were reported to FDA between 6/18/2022 to 10/5/2022.

The 393 adverse event reports received (comprising 175 CCs and 215 CAERS reports) were reviewed during the period 6/18/2022 to 10/5/2022. Symptoms, as reported by complainants, included gastrointestinal illness, such as vomiting (54/393), diarrhea (24/393), and nausea (99/393) reports); fatigue, body aches, fever, elevated liver enzymes (193/393), jaundice (23/393), and liver damage were also reported. Some adverse event reports also resulted in gallbladder removal. Twenty-three medical records associated with CAERS, and CC reports were reviewed by CFSAN Medical Officers.

Medical Records Review

As of 10/6/2022, 23 cases who had adverse events attributed to Daily Harvest were released for medical review. Twenty-two cases ate French Lentil and Leek Crumbles. Eighteen were female (78%) and the average age was 42.7 years (range 29 - 62 years).

A typical presentation of cases involving dietary exposure to Daily Harvest Lentil and Leek Crumbles and higher-level medical care would be an individual who complained of sharp epigastric or right upper quadrant pain, often with nausea and vomiting, within 24 hours after consuming the product the first or second time. Fever, rigors and fatigue frequently follow the abdominal pain, and within a few days, many develop jaundice, scleral icterus, and dark urine (presumably bilirubinuria). Symptoms would improve slowly once consumption of the crumbles stopped (dechallenge). However, 10 cases reported the rapid recurrence of symptoms (rechallenge) upon resuming the consumption of the crumbles.

Initial lab work typically identified a hyperbilirubinuria with elevated total bilirubin (mean 2.9 mg/dL, range 0.2 – 8 mg/dL) and transaminitis with elevated ALTs (mean 315.3 U/L, range 0.3 – 8.7 U/L, and mean 7.3 times upper limit [x UL], range 0.3 – 8.7 x UL) with general downward trends for those who avoided re-exposure to the product. R factors ranged from mid ones up to the low teens, with a majority in the 2-8 range. Some of the patients with higher R factors appeared to have a borderline leukopenia and/or high-normal eosinophil counts. Some of the patients with lower R factors had some trace hematuria and/or trace proteinuria. Most cases had extensive work-up to rule out hepatitis from infectious diseases or autoimmune diseases. Nearly all had imaging (ultrasound, cat scan [CT], magnetic resonance imaging [MRI]) of the abdomen to rule out obstruction of bile ducts or other gallbladder or liver pathology. Six cases had cholecystectomies, although only one had imaging suggesting a biliary obstruction. The gallbladder pathology diagnosis for the five other cases were chronic cholecystitis (n=4) and

5

cholesterosis (gallbladder polyps) (n=1). Four had upper endoscopies, partly to rule out *Helicobacter pylori* infection: chronic gastritis was the typical pathology diagnosis. Two cases had liver biopsies. One liver biopsy result identified "liver-mixed portal and lobular inflammation with prominent portal eosinophils in keeping with injury secondary to drug/herbal supplements". The other liver biopsy showed "bland cholestasis, [with] no evidence of acute cholangitis or significant ductular reaction... The differential includes drug-induced cholestasis."

Complaints associated with other Daily Harvest Products

Between 6/21/2022 - 9/6/2022, FDA received 24 CCs and 16 CAERS reports indicating adverse illness events associated with Daily Harvest products other than the Lentil and Leek Crumbles. All 40 adverse illness complaints referenced various Daily Harvest products as a cause for their illness. As demonstrated Table 1, no single product stood out or received a comparable number of complaints compared to the French Lentil and Leek Crumbles product.

Table 1: Other Daily Harvest Products Reported by Consumers Through CC and CAERS Reports

Daily Harvest Product Name		Number of products reported by	
	CC	CAERS	
Smoothies (various, including, but not limited to,	5	11	
Strawberry Peach, Mint cacao)			
Flatbreads (various)	5	4	
Other products (bowls, Squash and Wild Rice Gratin,		9	
soups, Hazelnut Chocolate Bites, mixed meals, pizza)			
Unspecified Daily Harvest products	1	1	

Of the 40 CC and CAERS reports, 10 mentioned various liver-associated ailments and 21 noted gastrointestinal ailments.

(b)(4)

Between 4/4/2022 - 10/18/2022, **(b)(4)** received 24 complaints associated with Daily Harvest product. Among the consumer complaints reports, 10 (42%) reported various liver associated ailments and 14 (58%) reported gastrointestinal ailments. Of these complaints, 7 mentioned French Lentil and Leek Crumbles, 8 various Daily Harvest products, and 9 unspecified products. Complaints reported to **(b)(4)** were also reported through CAERS/CC to FDA.

Revive Superfoods

Between 7/5/2022 - 10/7/2022, FDA received 9 CCs and 10 CAERS reports associated with Revive Superfoods products. Of the 19 CCs and CAERS reports, 9 (47%) complaints referenced

Revive Mango & Pineapple Smoothies, and 10 (53%) referenced multiple other flavors of Revive smoothie products as a cause for their illness. The Revive Superfoods Mango & Pineapple Smoothie also contained tara protein flour as a component ingredient, which was also used in the Daily Harvest product of interest. However, the number of reported illnesses for Revive Superfoods products was not comparable to those reported for the Daily Harvest Lentil and Leek Crumbles.

Minnesota Department of Health Epidemiological Study

The Minnesota Department of Health (MDH) conducted an epidemiologic investigation related to adverse illness events reported after consumption of Daily Harvest products from 4/1 to 7/20/2022. Multiple analytical studies were conducted, including a case-control study at the category, product, and ingredient levels. French Lentil and Leek Crumbles were statistically associated with illness. Ingredient-level analyses did not statistically implicate tara protein flour or sacha inchi powder but did find a statistical association between (b)(4) and illness, though analyses were limited by the small number of cases. Their investigation provides further evidence that the French Lentil and Leek Crumbles were the source of illness.

LABORATORY

FDA Samples

Between 6/21/2022 and 8/18/2022, investigators from ORA HAF East 2 (NWJ-DO), HAF East 6 (CHI-DO), HAF West 2 (KAN-DO), and HAF West 5 (SAN-DO) collected six samples of finished French Lentil and Leek Crumbles from several warehouses and 16 samples of leftover French Lentil and Leek Crumbles from complainants that had filed CC and CAERS reports. Investigators also collected 10 samples of raw ingredient used to make the product of interest, including cremini mushrooms, red lentils, French green lentils, hemp hearts (two samples), sacha inchi powder, tara protein flour (two samples), quinoa, and butternut squash. All samples were analyzed for general toxins, including metals, pesticides, cannabinoids, poison, etc, using nontargeted methods, a variety of mycotoxins and bacteria pathogens. The toxic metals screen included the following metals above the reporting limit (200 ng/g): vanadium, chromium, cobalt, nickel, arsenic, selenium, cadmium, mercury, thallium, and lead. No additional results of public health significance that could be definitively linked to reported illnesses were noted from the analysis of these samples. In addition to the above analyses, two finished product samples tested negative for mycotoxins and microbes including Salmonella spp., Listeria spp., Hepatitis A virus, and norovirus. Given the rapid onset of symptoms and frequent reports of liver injury for reported adverse events, microbiological testing of collected samples was not further pursued.

Six samples of Daily Harvest (b)(4) and five samples of French Lentil and Leek Crumbles finished product were submitted to FDA's National Center for Toxicological Research (NCTR), and one sample of sacha inchi was to CFSAN/ORS for further analytical

studies to try and determine/characterize the causative agent of illness for these adverse events. The proposed studies include, but are not limited to, in vitro and in vivo toxicological studies.

Based on CCs and CAERS reports, FDA investigators collected three samples of leftover Revive Superfoods Mango and Pineapple smoothie finished products from complainants. All Revive Superfoods product samples were analyzed for general toxins, including metals, pesticides, cannabinoids, poison, etc, using non-targeted methods. No results of public health significance that could be definitively linked to reported illnesses were reported from the analysis of these samples.

Firm Samples

Prior to and during HAFW1's joint inspection, Daily Harvest and Stone Gate Foods were simultaneously conducting their own investigation, which included product testing to determine the root cause of reported illnesses. According to Daily Harvest, between 6/22/2022 and 8/16/2022, the firm tested 10 finished products and seven ingredients (cremini mushrooms, red lentils, French green lentils, sacha inchi powder, tara protein flour, quinoa, butternut squash) of the French Lentils and Leek Crumble for mycotoxins, *Salmonella* spp., *Listeria* spp., *E. coli*/Coliforms, and yeast and mold. All results for these samples were reported as negative.

Canadian Samples

Canada indicated they had received six adverse illness reports associated with Revive Superfoods products. Due to one Revive Superfoods product (e.g., Revive Superfoods Mango & Pineapple Smoothie) containing tara protein flour, an ingredient in common with the Daily Harvest product of interest, the Canadian Food Inspection Agency (CFIA) began an investigation of Revive Superfoods. CFIA collected two samples of tara protein flour sourced from (b)(4)

(b)(4) via (b)(4) different suppliers from Revive and submitted them to FDA for further analysis. These samples will be subjected to the same analyses described previously and may be used for additional research purposes.

TRACEBACK

Formal traceback was not conducted during this investigation, but CORE Response Team 2 did review collected information to narrow down the ingredients in the Daily Harvest Lentil and Leek Crumbles that were unique to this product or seldom used in other products manufactured at the same facility. The thought was that if an ingredient was unique or used in very few other Daily Harvest products that it was more likely to have been the source of reported adverse illness events. HAFW1 collected a list of ingredients used in the product of interest and information on which ingredients were used in other Daily Harvest products. Through this information, it was determined that tara protein flour was an ingredient unique to the product of interest and sacha inchi powder was only used in a maximum of two (one being the (b)(4) other Daily Harvest products. This information, combined with the relatively limited amount of

information about the characteristics of these specific ingredients, led to these two products being identified as ingredients of interest.

While contamination could have occurred in the manufacturing facility (Second Bite Foods Inc dba Stone Gate Foods), there were many other products also being manufactured at the same facility that were not linked to reported adverse illness events. This led to the decreased likelihood of contamination occurring during the manufacturing process and this route was not pursued further. Additionally, HAFW1 did not note any observations during the inspection of the facility that could have led to potential contamination. ORA HAF East 1 (NYK-DO) also obtained information about the packaging used for products from Daily Harvest headquarters (New York, NY), which indicated packaging used for the product of interest was also used for multiple Daily Harvest products, none of which were linked to multiple reported adverse illness events. FDA thus considered contamination may have occurred upstream in the supply chain and began an investigation into the ingredients used to manufacture the product of interest.

Tara Protein Flour

Second Bite Foods Inc dba Stone Gate Foods (Shakopee, MN; FEI: 3003908115)

Tara protein flour was identified as an ingredient of interest early in the investigation because it was the only unique ingredient used in the product of interest. Documents received from HAFW1 indicated three lots of tara protein flour were used across all "Best By Dates" (BBD). The product of interest was made over the course of six production dates and the BBD was used as the lot code for the finished product. There were two lots of tara protein flour used in all the BBDs of finished product (Table 2). Based on documentation provided by HAFW1, it was determined that all three lots of tara protein powder were supplied by the importer (b)(4) (b)(4) , CO).

(b)(4) (b)(4) , CO; FEI: (b)(4))

It was indicated on labels of the tara protein flour at Second Bite Inc dba Stone Gate Foods (Shakopee, MN) that (b)(4) . ((b)(4) , CO) sourced the tara protein flour used in the product of interest from a (b)(4) , (b)(4) . The Division of Southwest Imports (DSWI) was able to perform a Foreign Supplier Verification Program (FSVP) inspection at the importing firm and learned that they only sold tara protein flour to the Daily Harvest manufacturer for use in the product of interest and (b)(4) was the sole supplier. The importer did not manipulate or take possession of product, instead sending it directly to the manufacturer. While the importer did have an FSVP plan in place for tara protein flour, more information was needed for the investigation.

(b)(4) , (b)(4); (b)(4))

The processor and manufacturer of the tara protein flour was determined to be (b)(4) , (b)(4). Although this firm was located in (b)(4), a country that the FDA does not have an information sharing agreement with, DSWI was able to facilitate communication with this supplier via (b)(4) , CO). These conversations revealed that the tara crop utilized by (b)(4) is only sourced from (b)(4) and adjacent countries and that some of the fields appeared to be controlled by (b)(4) . The firm reported that tara

protein flour has only been on the market for about two years, making it a relatively new product for the firm. The firm also manufactures several other products from the tara crop, not all of which are food grade, though they reported these products were made on different lines. However, it was unable to be determined which regions, countries, or fields the tara protein flour lot codes used in the Daily Harvest Lentil and Leek Crumbles products were sourced from.

Table 2: Lot Codes for the Ingredients of Interest Used in the Finished Product by Best By Date

Product	Finished Product Best By Date					
Product	9/27/2022	10/10/2022	10/23/2022	11/6/2022	11/14/2022	11/15/2022
Tara Protein	GP-211003,	GP-211211	GP-211211,	GP-220401	GP-220401,	GP-211003
Flour	GP-211211		GP-220401		GP-211003	
Sacha Inchi	PPSO-	PPSO021	PPSO-	PPSO021	PPSO021	PPSO021
Powder	040520007,		040520007,			
	PPSO021		PPSO021			

Sacha Inchi Powder

Second Bite Foods Inc dba Stonegate Foods (Shakopee, MN; FEI: 3003908115)

While sacha inchi powder was not unique to the product of interest, its limited use in other Daily Harvest products also made it an ingredient of interest in the investigation. Documents received from HAFW1 indicated that two lots of sacha inchi powder were used in the product of interest. However, it should be noted these same lots were also used in other Daily Harvest products, making neither lot code unique to the any products. The product of interest was made over the course of six production dates and BBDs were used as the lot codes for the finished product. One lot of sacha inchi powder was used in all the BBDs and the other was only used in two BBDs (Table 2). Based on documentation provided by HAFW1, it was determined that both lots of sacha inchi powder were imported by (b)(4)

(b)(4)

Traceback Limitations

There were a number of limitations encountered during this investigation. While there was a strong signal and distinctive symptomology reported by adverse illness events related to the Daily Harvest Lentil and Leek Crumbles product, FDA and CDC were unable to determine the cause of the adverse illness events (toxin, chemical, etc). This inability to identify a causative agent meant that nonspecific testing had to be used on all samples, and ultimately it was unclear where in the supply chain contamination may have occurred. Some ingredients were able to be ruled out based on their use in other products, but thus far analytical testing of ingredients have not revealed a substance that would explain the adverse illness events reported. Both ingredients of interest were also imported from (b)(4), a country that does not have an information sharing agreement or systems recognition with FDA. The lack of such an agreement or equivalency meant that FDA could only share public information with the (b)(4) authorities and were unable to provide additional investigational details. The location of both suppliers also meant that inspections could not be conducted as quickly. However, inspection assignments were

issued for both the sacha inchi powder and tara protein flour manufacturing firms in (b)(4) and will likely be initiated after CORE Response activities ends due to timeline constraints.

Traceback Conclusions

The information and records provided to CORE indicated two ingredients of interest could be the potential source of adverse illnesses events associated with the Daily Harvest Lentil and Leek Crumbles. These ingredients were both supplied by (b)(4) companies and were used in a maximum of two other Daily Harvest products (sacha inchi powder supplied by (b)(4) or were unique (tara protein powder supplied by (b)(4)) to the Lentil and Leek Crumbles. All other component ingredients were used across numerous other Daily Harvest products and no issues that could result in contamination were found at the manufacturing facility or with the packaging. FDA will conduct inspections at the manufacturing firms in (b)(4) for both tara protein flour and sacha inchi powder after the CORE Outbreak Close-Out meeting with the Office of Food Safety and CORE Outbreak Evaluation to determine if a source of contamination for either ingredient can be determined. Based on information from reported adverse illness events and traceback data, it was determined that consumption of Daily Harvest Lentil and Leek Crumbles was the likely source of adverse illness events during this incident, but a cause or source of contamination could not be identified.

ESTABLISHMENT INSPECTIONS & INVESTIGATIONS

On 6/22/2022, HAFW1 conducted a joint inspection with the MDA at Stone Gate Foods dba Second Bite Foods, Inc (4218 Valley Industrial Blvd S. Shakopee MN 55379: FEI 3003908115). Daily Harvest French Lentils and Leek Crumbles is manufactured at Stone Gate Foods dba Second Bite Foods. Environmental monitoring records from the production run timeframes of interest were reviewed and no deviations were noted. Investigators conducted a walkthrough of the facility and determined that intentional adulteration was unlikely.

The FDA inspection was closed on 7/7/2022 and no 483 was issued. Minnesota Department of Agriculture closed out their PC inspection on 6/23/2022.

The following are the details for ten records/information, inspection, and sample collection assignments in order of issuance:

On 6/28/2022, CORE issued eNspect Assignment #225608 for Daily Harvest French Lentil and Leek Crumbles information collection from Daily Harvest headquarters (New York, NY) to ORA HAFE1; records and information collected by HAFE1 related to this request were received on 6/29/2022, 7/11/2022, 7/14/2022, 7/21/2022, 8/4/2022, 8/9/2022 and 8/25/2022.

On 6/28/2022, CORE issued FACTS Assignment #12216624 (Op ID 11588255) for Daily Harvest French Lentil and Leek Crumbles raw ingredient sample collection from Second Bite Foods Inc. dba Stone Gate Foods (Shakopee, MN) to ORA HAF West 1 (MINDO); on 6/29/2022 16 ingredient samples of Lentil and Leek Crumbles product were collected by MIN-DO related to this request.

On 6/29/2022, CORE issued FACTS Assignment # 12216858 (Op ID 11590248) for Daily Harvest French Lentil and Leek Crumbles sample collection from (b)(4)

, IL) to ORA HAF East 6 (CHI-DO); on 7/1/2022 four samples of French Lentil and Leek Crumbles product were collected by CHI-DO related to this request.

On 6/29/2022, CORE issued FACTS Assignment # 12216864 (Op ID 11590311), for Daily Harvest French Lentil and Leek Crumbles sample collection from (b)(4), NJ) to ORA HAF East 2 (NWJ-DO); on 6/30/2022 two samples of French Lentil and Leek Crumbles product were collected by HAFE2 related to this request.

On 6/29/2022, CORE issued FACTS Assignment # 12216880 (Op ID 11590348), for Daily Harvest French Lentil and Leek Crumbles sample collection from (b)(4) City, KS) to HAF West 2 (KAN-DO); on 7/6/2022 three samples of French Lentil and Leek Crumbles product were collected by HAFW2 related to this request.

On 7/14/2022, CORE issued eNSpect Assignment #226310 for tara protein flour information and records collection from (b)(4) , CO) to DSWI; records and information collected by DSWI related to this request were received on 7/22/2022, 7/28/2022 and 9/14/2022.

On 8/1/2022, CORE issued FACTS assignment # 12222989, Op ID 11625568, for tara protein flour sample collection from (b)(4) , NV) to HAF West 5 (SAN-DO); on 8/4/2022 samples of tara protein flour were collected by SAN-DO related to this request.

On 8/16/2022, CORE issued FACTS assignment # 12225955, Op ID 11642679, for sacha inchi sample collection from (b)(4) , NJ) to HAFE2; On 8/18/2022, HAFE2 collected three samples of sacha inchi powder related to this request.

On 8/31/2022, CORE issued FACTS assignment # 12229287, Op ID 11660026, for Daily Harvest finished product sample collection from (b)(4) , IL) to HAFE6; On 9/6/2022, HAFE6 collected six samples of (b)(4) and five samples of French Lentil and Leek Crumbles related to this request.

On 9/7/2022, CORE issued eNSpect Assignment #228223 for inspection and sampling at (b)(4), (b)(4) to the ORA Foreign Office.

On 9/7/2022, CORE issued eNSpect Assignment #228222 for inspection and sampling at (b)(4)) to the ORA Foreign Office.

PRODUCT/FIRM ACTIONS

On 6/23/2022 Daily Harvest issued a voluntary recall of all French Lentil and Leek Crumbles product distributed from 4/28/2022 to 6/17/2022.

12

On 7/19/2022, (b)(4)) was added to Import Bulletin 99-B54 for tara protein flour.

COMMUNICATIONS

On 6/30/2022, FDA issued a Consumer Advisory related to the ongoing incident. Webpost updates were issued on 7/14/2022, 7/28/2022 and 8/25/2022.

CDC did not issue any communications about this incident.

CONCLUSIONS

All 393 adverse illness event reports received by FDA from consumers indicated that ill people consumed Daily Harvest French Lentil and Leek Crumbles, manufactured at the Stone Gate, MN facility, prior to illness. In response to illness complaints submitted to the company, on 6/23/2022, Daily Harvest initiated a voluntary recall of the French Lentil and Leek Crumbles. In response to numerous reports of adverse illness events submitted to FDA via CCs and CAERS, on 6/22/2022, HAFW1 initiated an inspection at Stone Gate Foods Shakopee, MN, the manufacturer of the French Lentil and Leek Crumbles product for Daily Harvest. In addition to component ingredient samples collected during the inspection at Stone Gate Foods, finished French Lentil and Leek and (b)(4) , leftover French Lentil and Leek Crumbles obtained from consumers reporting adverse illness events, and additional samples of both tara protein flour and sacha inchi flour were collected and analyzed. To date, all product samples tested negative for mycotoxins, and no results of public health significance that could be definitively linked to reported illnesses were identified for the non-specific toxin analyses conducted. Additionally, two product samples tested for microbiological pathogens were also reported as negative. Tara protein flour was an ingredient unique to the product of interest and sacha inchi powder was only used in a maximum of two other products. This information, combined with the relatively limited amount of information about these specific ingredients, led to these two products them being identified as ingredients of interest. The information and records provided to CORE indicated two ingredients of interest could be the potential source of adverse illnesses events associated with the Daily Harvest French Lentil and Leek Crumbles. Foreign inspection assignments including sample collection for the (b)(4) suppliers of tara protein flour and sacha inchi powder are anticipated to be initiated in November 2022.

Adverse illness event series information suggested the Daily Harvest French Lentil and Leek Crumbles manufactured by Stone Gate Foods dba Second Bite Foods was the source of reported adverse events during this incident. However, a definitive source or single point of contamination was not identified.

This incident was transferred to the CFSAN, Office of Food Safety on 10/18/2022.

ACKNOWLEDGMENTS

FDA/CORE would like to acknowledge the thorough response activities conducted by local/county and state partners from AZ, CA, CO, CT, DE, FL, GA, IL, IN, IA, KS, ME, MD, MA, MN, MS, MI, MO, MT, NV, NH, NJ, NM, NY, NC, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, WI and by FDA/ORA staff from HAFE1, HAFE2, HAFE6, HAFW1, HAFW3, and HAFW4, HAFW5, HAFW6 and DSWI. Additionally, the contributions and guidance provided by subject matter experts from CDC, FDA's Center for Food Safety and Applied Nutrition, National Center for Toxicological Research (NCTR) and Office of Regulatory Affairs were also appreciated; given the level of analytical resources required during this incident, the coordination and/or assistance provided by CFSAN, and ORA Office of Regulatory Science was also appreciated.

INCIDENT COORDINATION GROUP

FDA/Office of Coordinated Outbreak Response & Evaluation (CORE)

CORE Signals & Surveillance Team – Ashley Grant, Tyann Blessington

CORE Response Team 2 – Tem Jemaneh, Margaret Kirchner, Pamela Mokoko, Marvin Mitchell, Asma Madad, Natalie Cotaldo and Monique Salter

CORE Outbreak Evaluation Team – Karunya Manikonda

CORE Communications – Julia Mangia

FDA/Office of Regulatory Affairs (ORA)

ORA HQ Division of Domestic Human and Animal Food Operations (DDHAFO) (Program Operation Branch) – Linda Stewart, Nicole Clausen, Martha Myrick

ORA HQ Division of Foreign Human and Animal Food Operations (DFHAFO) - Vinetta Howard King, Yvette Arline, Roxanne Adeuya

ORA/OEIO/DE/ROB (Recall Operations Branch) - Lisa Gilliam

Senior Emergency Response Coordinators – Kim Livsey, Chris Yee.

Produce Safety Network – Shannon Hoehna, Alex Goodman, Kate Allen.

Office of Regulatory Science – Angela Swinford, Jennifer Kinney, Yanxuan Tina Cai, (Program coordinator for Mycotoxins) Mohamed Islam. Hawk, Heather D.

Division of Import Operations – Jeffery Hilgendorf, Ashley Abraham

Forensic Chemistry Center - Doug Hietkemper, Catherine Dasenbrock, Jonathan Litzau

Office of Human and Animal Foods Operations –

Human and Animal Foods (HAF) Divisions/District Offices:

- HAFE1 (New York, New England) Nicole Vaught, Kimberly Langello, Maura Squire,
 DIB Lori Holmquist, Ronald Pace, Scott Izyk
- HAFE2 (Baltimore, New Jersey, Philadelphia) Valerie Moore, Linda Price (CCC), William Muszynski, Bradley Bensautti
- HAFE6 (Chicago)/Detroit Joe Cooper, Marlon Turner
- HAFW1 (Minneapolis) Sana Elassar, Kristy Zuroski, DRC (Stone Gate/DH Recall)
- HAFW3 (Dallas)-Travis Hunt
- HAFW4 (Denver) Holly Miller
- HAFW5 (Los Angeles, San Francisco) Linda Gilchrist (CCC), Steven Galvez, Nicole Yuen, Hermie Francisco
- HAFW6 (Seattle) Kelsey Volkman
- DSWI (Southwest Imports) Lawrence Harmon, CAPT Monique Frazier, Mary Reed

FDA/Center for Food Safety and Applied Nutrition (CFSAN)

Office of Compliance – Marco Esteves, Rose Sexton, Lisa Thursam, Renu Kapoor, Leslie Hintz

15

Office of the Center Director – Dr. Suzanne Fitzpatrick, Dr. Steve Hermansky – Toxicologist

Office of Food Additive Safety

- Dr. Troy Hubbard Toxicologist
- Dr. Renata Kolanos Chemist, Natural Food Expert
- Dr. Mical Honigfort Regulatory Review Branch Chief
- Dr. Jason Downey Compliance expert, Toxicology
- Mary Ditto,
- Susan Carlson,
- Kristi Muldoon

Office of Food Safety – Jenny Scott, Tim Jackson

- OFS/Plant Products Branch Lauren Robin, Anthony Adeuya
- OFS/Division of Produce Safety Gordon Davidson
- OFS/Multi Commodity/Refrigerated Frozen Foods Andreas Keller, Diane Jeang, Guy Skinner, Brett Podoski

Office of Analytics and Outreach – Medical Officers - Karl Klontz, Cecile Punzalan, Andrew Karasick.

Office of Analytics and Outreach – CAERs – Oliver Ou, Nichole Nolan, Stephanie Kenez

Office of Regulatory Science – Christine Parker, Shaun MacMahon Office of Applied Research and Safety Assessment – Zhihui Yang Office of International Engagement – Teresa Fox, Jeffrey Read, Ken Nieves

FDA/Office of the Commissioner (OC)

Office of the Chief Counsel – Becky Goldberg, Vivian (Shiyu) Tao, Carie Jasperse Office of Emergency Operations/National Consumer Complaint Coordinator – Sheila vanTwuyer

Latin American Office - Nicole Conklin, Michelle Rodriguez

National Center for Toxicological Research (NCTR)

Goncalo Gamboa, Donna Mendrick

Centers for Disease Control and Prevention (CDC)

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)- Megan Hofmeister.

National Center for Emerging and Zoonotic Infectious Diseases/ORPB- Laura Gieraltowski, Colin Schwensohn, Ben Schneider

National Center for Environmental Health/CDC Health Studies - Fuyuen Yip, Johnni Daniel, Erik Svendsen, Art Chang, Michael Yeh

State/Local Regulatory Partners

16

AZ, CA, CO, CT, DE, FL, GA, IL, IN, IA, KS, ME, MD, MA, MN, MS, MI, MO, MT, NV, NH, NJ, NM, NY, NC, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, VA, WA, and WI

CTU No.: FDA-CDER-CTU-2022-4h313 | Department: GFSAN | RCT No.: RCT-1028563 | DTU Triage Date: 21-Jun-2022 | Total Pag-

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	12.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	18-Jun-2022	CTU Received Date	18-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact			10 To	2000		
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
Section A	- About the Problem					
	ind of problem was it? all that apply)	Used a product incorrectly w	effect (including new or worsening symptor which could have or led to a problem quality of the product g from one product maker to another maker			
Date the problem occurred		12-May-2022				
Serious		Yes				
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect				

Other serious/important medical incident(Please Describe Below)

4 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Death

I ate a meal consuming Crumbles from Daily Harvest and I ended up in the hospital with severe pains and other symptoms. My liver enzymes and other enzymes were extremely elevated and I was hospitalized for 3 days. I am still battling these symptoms and seeing many different doctors to figure out what's going on. I've heard that many people have had the same issues after consuming these Crumbles.

Relevant Test/Laboratory Data		1 of	1
Test Name	Test Date	12-May-2022	
Test Result	Test Unit		
Low Test Range	High Test Range	-44	
More Information Available?			

Generated by: SYSTEM Generated on: 18-Jun-2022 12:16:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48313 | Department: CFSAN | RCT No.: RCT-1023563 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Ad	lditional Comments				
	I can send all of my relevant lab re	eports if requested. There are	too many to input here.		
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Crumbles			
	Name of the company that makes (or compounds) the roduct				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of he product				

Generated by: SYSTEM Generated on: 18-Jun-2022 12:16:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48313 | Department: CFSAN | RCT No.: RCT-1023563 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	Give best estimate of duration		
	Is therapy still on-going?		
Wŀ	ny was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
			<u> </u>
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Otl	her identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast mplants, etc.)	
	ate the implant was put in	Date the implant was taken out (If	
		relevant)	
Se	ction E - About the Person Wh	no Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)	29 Year(s)	
	Date of Birth		
	Weight	49.5 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White	

Generated by: SYSTEM Generated on: 18-Jun-2022 12:16:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48313 | Department: CFSAN | RCT No.: RCT-1023563 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	Hypothyroidism		
lPle	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	<u> </u>		
ll is	any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
	t arry other important imorniat	ion about the person (sach as moning, pregnancy, alcohol ase, etc.)	
II ic	et all aurrant properintian modic	cations and medical devices b ng used.	
	Levothyroxine	Lations and medical devices by hig used.	
	LevolityToxille		
II is	t all aver the equator modicati	and any vitamina mineral asymptoments and borbal remadica being used	
LIS	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
Se	ction F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	-
	Number/Street	(b) (6)	
	Number/Street	(b) (6)	
	Number/Street City	(b) (6) (b) (6)	
	Number/Street City State/Province	(b) (6) (b) (6)	
	Number/Street City State/Province Country	(b) (6) (b) (6) UNITED STATES	
	Number/Street City State/Province Country ZIP or Postal code	(b) (6) (b) (6) UNITED STATES (b) (6)	

Generated by: SYSTEM Generated on: 18-Jun-2022 12:16:22 Page 4 of 5

Reporter Organization

CTU No.: FDA-CDER-CTU-2022-48313 | Department: CFSAN | RCT No.: RCT-1023563 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Department		
Reporter Speciality		
Today's date	18-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 18-Jun-2022 12:16:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-48357 | Department: CFSAN | RCT No.: RCT-1023627 | CTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Deta	ils						
Company U	nit	CDER-CTU	Origii	nating Ac ount		FAERS	
Source Medium		MWO (Drug)	Source	ce Form Type		E2B XML 3500B	
Priority		Routine	Routine				
Override Au	ito Calculation Rule	No					
FDA Received Date		19-Jun-2022	CTU	Received Date		19-Jun-2022	-
CTU Triage Date			CTU	Data Entry Date			
Report Type		Spontaneous	Repo	rt Classification		Drug	
Assign To		User	,				
User/Group							
Forward to I	Department						
Case Priorit	y	Direct	Direct				
Contact							
Case Reporter	First Name	Last Name		Email Address		Phone	
✓	(b) (6)	(b) (6)		(b) (6)		(b) (6)	
Section A -	About the Problem						
	nd of problem was it? all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker					
Date the	problem oc urred	31-May-2022					
Serious		Yes					
	of the following happen? all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem					

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

Other serious/important medical incident(Please Describe Below)

Birth defect
Life-threatening

I was admitted to the ER on May 31 after a few days of horrible abdominal pain and bloating in my upper right quadrant, and developed a 101.7 fever. Abnormally high AST and ALT levels (above 500s) everything else was fairly normal and the ultrasound, CT and MRI were all normal outside of a slightly swollen liver. Negative for Hep A/B/C. I am healthy and fit 31-year old female without any prior liver issues in my life. My doctor has absolutely no clue what caused this and it has been terrifying. I ate the Daily Harvest French Lentil + Leek Crumbles back in May right before getting sick and received the two emails on 6/17 and 6/19 this week from Daily Harvest about not eating them due to causing gastrointestinal issues despite already eating hem. I'm concerned I was poisoned by Daily Harvest.

R	Relevant Test/Laboratory Data 1 of 8					
	Test Name	AST	Test Date	31-May-2022		
	Test Result	593	Test Unit	CELLS PER MICROLITR E		
	Low Test Range	0	High Test Range	34		

Generated by: SYSTEM Generated on: 19-Jun-2022 16:16:23 Page 1 of 6

CTU No.: FDA-CDER-CTU-2022-48357 | Department: CFSAN | RCT No.: RCT-1023627 | CTU Triage Date: 21-Jun-2022 | Total Pag

es: 6

More Information Available?			
Relevant Test/Laboratory Data			2 of 8
Test Name	ALT	Test Date	31-May-2022
Test Result	538	Test Unit	CELLS PER MICROLITR E
Low Test Range	3	High Test Range	52
More Information Available?			
Relevant Test/Laboratory Data			3 of 8
Test Name	MDW	Test Date	31-May-2022
Test Result	30.2	Test Unit	
Low Test Range	0	High Test Range	23
More Information Available?			
Relevant Test/Laboratory Data			4 of 8
Test Name	WBC	Test Date	31-May-2022
Test Result	2.8 K/mcL	Test Unit	
Low Test Range	4.5	High Test Range	11
More Information Available?			
Relevant Test/Laboratory Data			5 of 8
Test Name	C REACTIVE PROT	Test Date	31-May-2022
Test Result	14.5	Test Unit	MILLIGRAMS PER LITRE
Low Test Range	0.0	High Test Range	5.0
More Information Available?			
Relevant Test/Laboratory Data			6 of 8
Test Name	LYMPHOCYTES	Test Date	31-May-2022
Test Result	9	Test Unit	W/VOL%
Low Test Range	16	High Test Range	44
More Information Available?			
Relevant Test/Laboratory Data			7 of 8
Test Name	NEUTROPHILS	Test Date	31-May-2022
Test Result	78	Test Unit	W/VOL%
Low Test Range	44	High Test Range	77
More Information Available?			
Relevant Test/Laboratory Data			8 of 8
Test Name	MONO ABSOLUTE	Test Date	31-May-2022
Test Result	.2 K/mcL	Test Unit	
Low Test Range	.3	High Test Range	1.0
1 1			

Generated by: SYSTEM Generated on: 19-Jun-2022 16:16:23 Page 2 of 6

CTU No.: FDA-CDER-CTU-2022-48357 | Department: CFSAN | RCT No.: RCT-1023627 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

Ad	lditional Comments		
Se	ection B - Product Availability		
	Do you still have the product in case we need to evaluate it?	No	
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No	
Se	ection C - About the Products	1 of 1	
	Suspect	Yes	_
	Primary?	Yes	
	Туре	Drug/Biologi	_
	This report is about	Food/Medical food	_
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek Crumbles	
	Name of the company that makes (or compounds) the roduct	Daily Harvest	
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar	
	Strength	If Other	
	NDC number		
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No	
	Did the problem return if the rson started taking or using the roduct again?	Yes	
Dr	ug Therapy	1 of 1	
	Expiration date		
	Lot number		
	Dosage Form		
	Quantity	If Other	
	Frequency	If Other	
	How was it taken or used	If Other	
	Date the person first started aking or using the product		
	Date the person stopped taking or using the product		
	Date the person reduced dose of he product		

Generated by: SYSTEM Generated on: 19-Jun-2022 16:16:23 Page 3 of 6

CTU No.: FDA-CDER-CTU-2022-48357 | Department: CFSAN | RCT No.: RCT-1023627 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Give best estimate of duration	1 Week			
	Is therapy still on-going?				
WI	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
	It was a meal for lunch				
	Returned to Manufacturer On				_
					_
Se	ction D - About the Medical De	evice			
	Name of medical device				_
	Name of the company that makes the medical device				
Ot	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if	you can	
loc	cate them)				
					_
	Model Number				_
	Catalog Number				_
	Lot Number				_
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem				
	oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast mplants, etc.)		
	ate the implant was put in	(222 22)	Date the implant was taken out (If		_
			relevant)		_
Se	ction E - About the Person Wh	o Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)	31 Year(s)			
	Date of Birth				
	Weight	62.55 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati	ve		_
		Native Hawaiian or Other Pacif			
		Asian			
		White			
		Black or African American			

Generated by: SYSTEM Generated on: 19-Jun-2022 16:16:23 Page 4 of 6

CTU No.: FDA-CDER-CTU-2022-48357 | Department: CFSAN | RCT No.: RCT-1023627 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

		in the life (O to the life to				
Lis	st known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)				
Ple	ease list all allergies (such as	to drugs, foods, pollen or o hers)				
l is	et any other important informat	tion about the person (such as moking pregnancy alcohol use etc.)				
LIC	st all current prescription medications and medical devices b ng used.					
Please list all allergies (such as to drugs, foods, pollen or o hers) List any other important information about the person (such as moking, pregnancy, alcohol use, etc.) List all current prescription medications and medical devices b ng used. List all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used. Section F - About the Person Filling Out This Form 1 of 1 Primary? Yes Reporter is Patient? Title Last name (b) (6) Middle Name First name (b) (6) Number/Street City						
Lis	t all over-the-counter medicat	ions and any vitamins, mineral, supplements, and herbal remedies being used.				
Se	ection F - About the Person Fil	ling Out This Form 1 of 1				
	Primary?	Yes				
	Reporter is Patient?					
$\overline{}$	Title					
		(b) (6)				
	Last name	(b) (6)				
	Last name Middle Name					
	Last name Middle Name First name					
	Last name Middle Name First name					
	Last name Middle Name First name Number/Street					
	Last name Middle Name First name Number/Street City	(b) (6)				
	Last name Middle Name First name Number/Street City State/Province	(b) (6)				
	Last name Middle Name First name Number/Street City State/Province Country	(b) (6) UNITED STATES (b) (6)				
	Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code	(b) (6) UNITED STATES (b) (6) (b) (6)				
	Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number	(b) (6) UNITED STATES (b) (6)				

Generated by: SYSTEM Generated on: 19-Jun-2022 16:16:23 Page 5 of 6

CTU No.: FDA-CDER-CTU-2022-48357 | Department: CFSAN | RCT No.: RCT-1023627 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

Department		
Reporter Speciality		
Today's date	19-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 19-Jun-2022 16:16:23 Page 6 of 6

CTU No.: FDA-CDER-CTU-2022-4h389 | Department: GFSAN | RCT No.: RCT-1023760 | GTU Thage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST/GMT-05:00) time zone

Basic Details				
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No		the second of	
FDA Received Date	20-Jun-2022	CTU Received Date	20-Jun-2022	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department				
Case Priority	Direct			

Contact	ontact					
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b) (6)	(b) (6)	(b) (6)	(b) (6)		

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	4.
Date the problem occurred	15-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I awoke in the early morning 6/15/22 with intractable nausea and vomiting, diarrhea after eating fully cooked daily harvest lentil protein crumbles for lunch on 6/14/22. I was unable to hold food or water down, unable to report to work or care for my child, had weakness, fever, sweating and fatigue in addition to nausea/vomiting during this episode of illness. I was unable to get to the ER as I did not have transportation or someone to care for my child. The vomiting stopped by 10pm on 6/15, but I still felt otherwise ill (low grade nausea, pain and fatigue) through the end of the week. On 6/17 I rec'd a recall email from daily harvest about the crumbles and realize that is what made me sick (as I ate them on 6/14). The e-mail from DH blamed customers for not cooking thoroughly enough and offered a \$10 credit. As other users of this product have reported liver damage, I plan to follow up with my doctor to ask for labs to make sure I did not have permanent damage. I saved the bag of crumbles in the event they are needed for testing.

Relevant Test/Laboratory Data		1 of 1
Test Name	Test Date	1.1.
Test Result	Test Unit	4 1

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48389 | Department: CFSAN | RCT No.: RCT-1023760 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Low Test Range		High Test Range		
	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it? Do you have a picture of the	Yes			
	roduct? (check yes if you are ncluding a picture)				_
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily harvest French lentil a	and leek crumbles		
	Name of the company that makes (or compounds) the roduct	Daily harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	10-Oct-2022			
	Lot number	L5-A 14:47			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started	14-Jun-2022			

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48389 | Department: CFSAN | RCT No.: RCT-1023760 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Date the person stopped taking or using the product	14-Jun-2022		
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
WI	hy was the person using the pr	oduct? (such as what co	ndition was it supposed to treat) 1 of 1
	Nutrition			
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that			
Ot	makes the medical device her identifying information (The	l e model catalog lot seri	al, or UDI number, and the exp	iration date if you can
loc	cate them)			mation date, in you can
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the			
	medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemake	ers. breast_mplants. etc.)	
	ate the implant was put in		Date the implant was taken out (If	
			relevant)	
Se	ection E - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Cisgender woman/girl		
	Please Specify Other Gender			
	Age (specify unit of time for age)	50 Year(s)		
	Date of Birth			
	Weight	91.8 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Na	tive	
		Native Hawaiian or Other Pac	ific Islander	

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48389 | Department: CFSAN | RCT No.: RCT-1023760 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

		Asian White Black or African American	
Lis	st known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
	Multiple sclerosis on a disease m	nodifying treatment, hypertension, obese, migraines, depression	
Ple	ease list all allergies (such as	to drugs, foods, pollen or o hers)	
	NKA		
Lis	st any other important informa	tion about the person (such as moking, pregnancy, alcohol use, etc.)	
	Immune compromised		
Lis	st all current prescription medi	cations and medical devices b ng used.	
	· · · · · · · · · · · · · · · · · · ·	ICTZ, modafinil, baclofen, sumatriptan, emgality	
Lis	st all over-the-counter medical	tions and any vitamins, mineral , supplements, and herbal remedies being used.	
		detox vitamins while I awai lab results from my PCP	
Se	ection F - About the Person Fil		
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Telephone number	(b) (6)	

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48389 | Department: CFSAN | RCT No.: RCT-1023760 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	20-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:22 Page 5 of 5

BEST BY: 10/10/2022 15-4 14:47

ERNO SEEN SE ARA

aring Crumbles:

leat a lightly oiled skillet or non-stick pan over medium-high dd the desired

CTU No.: FDA-CDER-CTU-2022-48385 | Department: CFSAN | RCT No.: RCT-1023743 | CTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details											
Company Unit			CDER-CTU		Originating Ac ount		FAERS				
Source Medium			MWO (Drug)		Source Form Type		E2B XML 3500B				
Priority			Routine								
Override Auto Calculation Rule			No								
FDA Received Date			20-	lun-2022	CTU	Received Date	20-Jun-2022				
CTU Triage Date					CTU	Data Entry Date					
Report Type			Spontaneous		Report Classification		Drug				
Assign To			User								
User/Group											
Forward to Department											
Са	Case Priority			Direct							
Со	ntact										
Case Reporter		First Name		Last Name		Email Address	Phone				
\square		(b) (6)		(b) (6)		(b) (6)	(b) (6)				
Section A - About the Problem											
		d of problem was it?	<u>.</u>								
	(Check all that apply)		Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem								
			Noticed a problem with the quality of the product								
			Had problems after switching from one product maker to another maker								
	Date the problem oc urred Serious		06-Jun-2022								
			Yes								
Did any of the following happen? (Check all that apply)			Hospitalization - admitted or stayed longer								
			Required help to prevent permanent harm								
			Disability or health problem								
			Birth defect								
			Life-threatening								
			Death								
			Other serious/important medical incident(Please Describe Below)								
4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)											
After eating Daily Harvest French Leek and Lentils Crumbles, I felt incredibly sick and was hospitalized. My bilirubin and liv r nzymes were elevated and I had gatrointenstinal symptoms. I wa in the hospital for 3 nights, 4 days and the doctors ran many tests and were not able to figure out what caused it. Daily harvest sent an email on Friday June 17th letting people know heir product might be causing "some gastrointensinal discomfor." However, there are hundreds of other people reporting similar side effects as mine including elevated liver enzymes. These reports date back to a month ago and no one was											
	ntormed	l until recently.									
Re	levant T	est/Laboratory Data					1 of 1				
	Test Name				Test	Date					
Test Result				Test	Unit						
Low Test Range				High	Test Range						
More Information Available?											

Generated by: SYSTEM Generated on: 20-Jun-2022 11:16:26 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48385 | Department: CFSAN | RCT No.: RCT-1023743 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

Ac	lditional Comments						
Se	ection B - Product Availability						
	Do you still have the product in case we need to evaluate it?	Yes					
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes					
Se	ection C - About the Products			1 of 1			
	Suspect	Yes					
	Primary?	Yes					
	Туре	Drug/Biologi					
	This report is about	Food/Medical food					
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil and Leek Crumbles					
	Name of the company that makes (or compounds) the roduct	Daily Harvest					
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar					
	Strength		If Other				
	NDC number						
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No					
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply					
Dr	ug Therapy	1 of 1					
	Expiration date	10-Oct-2022					
	Lot number						
	Dosage Form						
	Quantity		If Other				
	Frequency		If Other				
	How was it taken or used		If Other				
	Date the person first started aking or using the product	02-Jun-2022					
	Date the person stopped taking or using the product	03-Jun-2022					
	Date the person reduced dose of he product						

Generated by: SYSTEM Generated on: 20-Jun-2022 11:16:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48385 | Department: CFSAN | RCT No.: RCT-1023743 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 7

Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you callocate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (if relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman(girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Net Hispanic/Latino Native Haveiuro ro Other Pacific Islander Native Haveiuro ro Other Pacific Islander		Give best estimate of duration		
Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you callocate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem occurred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight Bas Sb kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native Native Havariian or Other Pacific Islander		Is therapy still on-going?	Yes	
Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you cal locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (if relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight Section I - American Indian or Alaska Native Native Havaiian or Other Pacific Islander	Wł	ny was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you cal locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (if relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight Section I - American Indian or Alaska Native Native Havaiian or Other Pacific Islander				
Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you callocate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 66.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native		Returned to Manufacturer On		
Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you cat locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native	Se	ction D - About the Medical De	evice	
makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you cal locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight 68.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Aleska Native Native Hawaiian or Other Pacific Islander		Name of medical device		
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred?				
Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight G8.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander			e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical devices when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight (b) (6) Weight Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		ate trismy		
Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight 68.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Model Number		
Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Catalog Number		
UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Lot Number		
Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Serial Number		
Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		UDDI Number		
medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast implants, etc.) Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Expiration date		
Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight 68.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) Mative Hawaiian or Other Pacific Islander		medical device when the problem		
Date the implant was put in Date the implant was taken out (If relevant) Section E - About the Person Who Had the Problem Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight 68.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) Mative Hawaiian or Other Pacific Islander	Fo	r implanted medical devices O	NLY (such as pacemakers, breast mplants, etc.)	
Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		•	Date the implant was taken out (If	
Person's Initials Sex Female Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	Se	ction E - About the Person Wh	o Had the Problem	
Gender Cisgender woman/girl Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander				
Please Specify Other Gender Age (specify unit of time for age) Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Sex	Female	
Age (specify unit of time for age) Date of Birth (b) (6) Weight Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Gender	Cisgender woman/girl	
Date of Birth (b) (6) Weight 68.85 kg Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Please Specify Other Gender		
Weight 68.85 kg Ethnicity (Choose only one) Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Age (specify unit of time for age)		
Ethnicity (Choose only one) Not Hispanic/Latino Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Date of Birth	(b) (6)	
Race (Check all that apply) American Indian or Alaska Native Native Hawaiian or Other Pacific Islander		Weight	68.85 kg	
Native Hawaiian or Other Pacific Islander		Ethnicity (Choose only one)	Not Hispanic/Latino	
		Race (Check all that apply)	Native Hawaiian or Other Pacific Islander Asian	

Generated by: SYSTEM Generated on: 20-Jun-2022 11:16:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48385 | Department: CFSAN | RCT No.: RCT-1023743 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 7

Lis	List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)					
	N/A					
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o	hers)			
	N/A					
Lis	st any other important informat	on about the person (such	ı as moking, pregna	ncy, alcohol use, etc.)		
	N/A					
Lis	st all current prescription medic	ations and medical device	s b ng used.			
	N/A					
Lis	st all over-the-counter medicati	ons and any vitamins, min	eral , supplements, a	and herbal remedies being u	sed.	
	Zyrtec, Hippo Vitamins, Ibuprofen					
0	ection F - About the Person Fill	ing Out This Form		1.	of 1	
SE	Primary?	Yes		1 (OI I	
	Reporter is Patient?	163				
	Title					
_	Last name	(b) (6)				
	Middle Name					
	First name	(b) (6)				
	Number/Street	(b) (6)				

Middle Name

First name

(b) (6)

Number/Street

(b) (6)

City

(b) (6)

State/Province

Country

UNITED STATES

ZIP or Postal code

(b) (6)

Telephone number

(b) (6)

Email address

(b) (6)

Fax

Reporter Organization

Generated by: SYSTEM Generated on: 20-Jun-2022 11:16:26 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48385 | Department: CFSAN | RCT No.: RCT-1023743 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

Department		
Reporter Speciality		
Today's date	20-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 20-Jun-2022 11:16:26 Page 5 of 5

CRUMBLES

ssinatortilla. Crumble on top of a Flatbread. Seve elettuce wrap. Layer into lasagna. Upgrade your ppy Joes. Dare we say stuff into an empanada Se French Lentil + Leek Crumbles truly work will evening Oh, don't forget to add into your chill or even shepherd's pie. We could go on.

KEEP FROZEN, COOK THOROUGHLY

CTU No.: FDA-CDER-CTU-2022-48394 | Department: CFSAN | RCT No.: RCT-1023765 | CTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	iyed in the report are in EST(G	IVI I -US.						
Basic Deta		000	D OTH	0	tio A t	FAEDO		
Company L			ER-CTU		nating Ac ount	FAERS		
Source Medium			O (Drug)	Sour	ce Form Type	E2B XML 3500B		
Priority			Routine					
	uto Calculation Rule	No						
FDA Recei		20-J	lun-2022		Received Date	20-Jun-2022		
CTU Triage	e Date				Data Entry Date			
Report Typ	e	Spo	ntaneous	Repo	ort Classification	Drug		
Assign To		Use	r					
User/Group)							
Forward to	Department		I					
Case Priori	ty	Dire	ct					
Contact								
Case Reporter	First Name		Last Name		Email Address	Phone		
	(b) (6)		(b) (6)		(b) (6)	(b) (6)		
	- About the Problem							
	nd of problem was it?							
	all that apply)				uding new or worsening sympto	ms)		
			Used a product incorrectly which could have or led to a problem					
			Noticed a problem with th					
Data the	e problem oc urred			hing from one	product maker to another make	!r		
Serious	-	17-Jun-2022 Yes						
	of the following happen?	 						
	all that apply)	Hospitalization - admitted or stayed longer						
		Required help to prevent permanent harm						
			☐ Disability or health problem					
			Birth defect					
			ife-threatening					
			Death	nadical incida	nt(Please Describe Below)			
4 Tell us w	hat hannened and ho					DA may reach out to you for		
	onal documents if nece			o do man	, ac and as possible i	Briting readined to you for		
oint I ha	ad trouble breathing. Calle	ed an a	ambulance and was	s test d for	a cardiac event, but no e	sed for about two hours to the evidence was found. Was g home, and continued in waves		
Relevant T	est/Laboratory Data					1 of 1		
Test Na	me			Test	Date			
Test Re				Test	Unit			
Low Tes	st Range			Hiah	Test Range			
	formation Available?							

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:49 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48394 | Department: CFSAN | RCT No.: RCT-1023765 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			_
	Primary?	Yes	-		_
	Туре	Drug/Biologi			_
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek Crumbles	3		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Generi Biosimilar	n Outsourcing Facility		
	Strength	If	Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity	If	Other		
	Frequency	If	Other		
	How was it taken or used	Oral If	Other		
	Date the person first started aking or using the product	16-Jun-2022			
	Date the person stopped taking or using the product	16-Jun-2022			
	Date the person reduced dose of he product				

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:49 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48394 | Department: CFSAN | RCT No.: RCT-1023765 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 7

	Give best estimate of duration		
	Is therapy still on-going?		
WI	ny was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device	yvioc	
	Name of the company that makes the medical device		
Ot	her identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
100	cate them)		
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast mplants, etc.)	
	ate the implant was put in	Date the implant was taken out (If	
		relevant)	
Se	ction E - About the Person Wh	o Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Male	
	Gender	Cisgender man/boy	
	Please Specify Other Gender		
	Age (specify unit of time for age)	36 Year(s)	
	Date of Birth		
	Weight	69.75 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White	

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:49 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48394 | Department: CFSAN | RCT No.: RCT-1023765 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 7

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)						
Please list all allergies (such as to drugs, foods, pollen or o hers)						
List any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)					
	ion about the person (such as moving, pregnancy, alcohol ase, etc.)					
List all current prescription medic	cations and medical devices bing used.					
Liet air carrent procenption mount	sations and medical devices a rig deed.					
List all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.					
Cannabis, daily multivitamin, mela						
Section F - About the Person Filling Out This Form 1 of 1						
Primary?	Yes					
Reporter is Patient?						
Title						
Last name	(b) (6)					
Middle Name						
First name	(b) (6)					
Number/Street	(b) (6)					
City	(b) (6)					
State/Province	(b) (6					
Country	UNITED STATES					

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:49 Page 4 of 5

(b) (6)

(b) (6)

(b) (6)

ZIP or Postal code

Telephone number

Reporter Organization

Email address

Fax

CTU No.: FDA-CDER-CTU-2022-48394 | Department: CFSAN | RCT No.: RCT-1023765 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

Department			
Reporter Speciality			
Today's date	20-Jun-2022		
Did you report this company that make (the manufacturer/o			
If you do NOT want dentity disclosed to manufacturer, pleas box (Confidentiality	o the se mark this		

Generated by: SYSTEM Generated on: 20-Jun-2022 11:46:49 Page 5 of 5

DAILY HARVEST

CRUMBLES

hatortilla. Crumble on top of a Flatbread. Sene stuce wrap. Layer into lasagna. Upgrade you loes. Dare we say stuff into an empanada hench Lentil + Leek Crumbles truly work with the look of the look

NET WT. 1207 (340a)

CTU No.: FDA-CDER-CTU-2022-45407 | Department: GPSAN | RCT No.: RCT-1028825 | DTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	-1.00
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	20-Jun-2022	CTU Received Date	20-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	A	A		F 7 - 7
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem)		

ction A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	18-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I ate Daily Harvest's Lentils + French Level Crumbles product at 6/18/22 at 8pm cooking it as instructed. By 4am 6/19/22, I was very sick. Nausea, diarrhea, 101°F fever, body aches, and dizziness. I was sick all Sunday and continue to be sick today 6/20. I have never gotten this sick from food. I noted that Daily Harvest had sent out an email hours before regarding this product advising to throw it away but making no mention of contacting FDA or doing testing on the product. I only made half of the crumble in. The rest is still in my freezer and I'm trying to reach out to labs to test it for listeria.

Relevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	

CTU No.: FDA-CDER-CTU-2022-48407 | Department: CFSAN | RCT No.: RCT-1023828 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Low Test Range		High Test Range		
	More Information Available?				
Ad	Iditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it? Do you have a picture of the	Yes			
	roduct? (check yes if you are ncluding a picture)				
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek Crumb	bles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	23-Oct-2022			
	Lot number	L02-VEGBN			
	Dosage Form				
	Quantity	Other	If Other 12	2 Ounce(s)	
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started	18-Jun-2022			

Generated by: SYSTEM Generated on: 20-Jun-2022 13:46:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48407 | Department: CFSAN | RCT No.: RCT-1023828 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Date the person stopped taking or using the product	18-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?	_			
Wł	ny was the person using the pr	oduct? (such as what con	dition was it supposed to treat)	1 of 1	
	Food				
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that				
	makes the medical device		1 1151		
Otl	her identifying information (The ate them)	e model, catalog, lot, seria	l, or UDI number, and the expira	tion date, if you can	
	Model Number				
	Catalog Number				
	Lot Number		-		
	Serial Number	_			
	UDDI Number				
	Expiration date	_			
	Was someone operating the medical device when the problem				
	oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ction E - About the Person Wh	o Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)	32 Year(s)			
	Date of Birth	-			
	Weight	67.5 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nativ	ve		
		Native Hawaiian or Other Pacific			

Generated by: SYSTEM Generated on: 20-Jun-2022 13:46:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48407 | Department: CFSAN | RCT No.: RCT-1023828 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

		Asian White Black or African American	
Lis	st known medical conditions (S	such as diabetes, high blood pre ure, cancer, heart disease, or others)	
	None		
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	Suc inylcholine		
Lis	st any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
	N/a		
Lis	st all current prescription medic	cations and medical devices b ng used.	
	None		
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
	None		
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	_
	ZIP or Postal code	(b) (6)	-
	Telephone number	(b) (6) (b) (6)	_
ı	Email address	(0) (0)	1

Generated by: SYSTEM Generated on: 20-Jun-2022 13:46:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48407 | Department: CFSAN | RCT No.: RCT-1023828 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	20-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 20-Jun-2022 13:46:25 Page 5 of 5

CRUMBLES

ha tortilla. Crumble on top of a Flatbread lequice wrap. Layer into lasagna. Upgrade Joes. Dare we say stuff into an employench Lentil + Leek Crumbles truly have could go an employed by the could go

NET WE 1202 (340g)
KEEP FROZEN, COOK THOROUGHEY

CTU No.: FDA-CDER-CTU-2022-48412 | Department: GPSAN | RCT No. RCT-1023639 | CTU Trage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	
FDA Received Date	20-Jun-2022	CTU Received Date	20-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	16	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	27-May-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I ate Daily Harvest lentil and leek crumbles 3 times for lunch over the week before my illness. Overnight on 5.27.22, I had severe abdominal pain for 3 hours. The pain resolved and then I had fever and drenching sweats, severe fatigue, and myalgias. On about the 5th day of my illness, I started itching, severely. My PCP ordered bloodwork and my liver enzymes were markedly elevated. I immediately had an ultrasound to look for gallstones, which did not reveal any. I went to the emergency department and had an MRCP (MRI) and a bunch of labs including a hepatitis panel, auto immune workup, all of which were unremarkable. My symptoms and lab abmornalities persisted, promptimg be to see a GI doctor, who then sent me to a hepatologist. I also saw an infectious disease doctor who sent of an extensive panel (adenovirus, cmv, babesia, and many many more) which was all negative. The hepatologist recommended an ERCP, which I had on 6/13/22. There were no stone or other biliary obstruction noted. I had a liver biospy which showed "bland cholestasis" which I was told is some sort of toxic event, usually from a prescription medication. I do not take any prescription medications. I received an email from daily Harvest about the crumbles, the first email was not alarming (consumers had GI discomfort) but the second email mentions an investigation is ongoing. I am reaching out because my liver test are still abnormal, almost a month into my illness, I still have extreme fatigue and malaise.

Relevant Test/Laboratory Data

1 of 1

Generated by: SYSTEM Generated on: 20-Jun-2022 14:16:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48412 | Department: CFSAN | RCT No.: RCT-1023839 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Test Name	BILIRUBIN	Test Date	08-Jun-2022
Test Result	4.6	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	0.2	High Test Range	1.2
More Information Available?			
ditional Comments			
I had liver enzymes tested in De	cember 2021 (prior to t	his even) and they were all norma	I
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
ction C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologi		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	french lentil and lee	k crumble plant protein crumbles	
Name of the company that makes (or compounds) the roduct	Daily Harvest		
Product Type(check all that apply)	Over-the-Counter Compounded by a P Generi Biosimilar	harmacy or an Outsourcing Facility	
Strength		If Other	
NDC number			
Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No		
Did the problem return if the rson started taking or using the	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date

Lot number

Dosage Form

Quantity If Other

roduct again?

Generated by: SYSTEM Generated on: 20-Jun-2022 14:16:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48412 | Department: CFSAN | RCT No.: RCT-1023839 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	16-May-2022			
	Date the person stopped taking or using the product	20-May-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
W	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to t	reat) 1 of 1	
	Meal (lunch)				
	Returned to Manufacturer On				
0 -	ation D. Alexandria Madical D.				
Se	ection D - About the Medical De Name of medical device	evice			
	Name of the company that				
	makes the medical device				
Ot loc	her identifying information (The cate them)	e model, catalog, lot, seri	al, or UDI number, and the	expiration date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken or relevant)	ut (If	
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Not selected			
	Please Specify Other Gender				
	Age (specify unit of time for age)	43 Year(s)	_	_	
	Date of Birth				

Generated by: SYSTEM Generated on: 20-Jun-2022 14:16:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48412 | Department: CFSAN | RCT No.: RCT-1023839 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	Weight	62.1 kg	
	Ethnicity (Choose only one)		
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
ll is	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
Lic	NONE	aon de diabetee, mgn bioed pro dre, editeer, medit dieedee, et etitere/	T
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	NONE		
l ic	t any ather inspectant informat	an about the never (auch as making programmy sleekelings at a)	
LIS	NONE	on about the person (such as moking, pregnancy, alcohol use, etc.)	T
	NONE		
Lis	st all current prescription medic	ations and medical devices b ng used.	
	Ursodiol		
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
Se	ection F - About the Person Fill		
	Primary? Reporter is Patient?	Yes	
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	

Generated by: SYSTEM Generated on: 20-Jun-2022 14:16:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48412 | Department: CFSAN | RCT No.: RCT-1023839 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	20-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 20-Jun-2022 14:16:25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-45418 | Department: CFSAN | RCT No.: RCT-1028854 | DTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	12.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		the format of
FDA Received Date	20-Jun-2022	CTU Received Date	20-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

S	ection A - About the Problem		Li Li
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
	Date the problem occurred	04-Jun-2022	
Ī	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Read today about the recall on Daily Harvest Lentil Crumbles. The day before my ER visit- I began to experience significant abdominal pain following eating the crumbles with my breakfast. As the night went on I began to develop a fever, muscle aches, tingling, and increased pain. I was in so much discomfort there was not a single position I could assume for any significant relief. It worsened overnight- I woke up in a pool of sweat in addition to passing dark urine. I took myself to the ER Saturday morning and spent 8 hours there. I multiple lab tests completed including testing negative for Hepatitis Panel & Mono. I received a CT Abdomen Pelvis with contrast, ECG 12 lead, and a chest X-Ray. Findings include increased liver enzymes, mild peripheral and pericholecystic edema, and thickening of distal stomach/pylorus. I left the doctor with no answers recommended to return if I feel worse. I am a healthy young individual and have never had any health concerns. My experience matched those discussed online. I still have the opened bag of lentil crumbles.

Relevant Test/Laborato	ry Data		1 of 2
Test Name	CMP: AST	Test Date	04-Jun-2022
Test Result	Increased liver enzymes	Test Unit	INTERNATIONAL UNITS PER LITRE

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48418 | Department: CFSAN | RCT No.: RCT-1023854 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Low Test Range	0	High Test Range	462			
	More Information Available?						
Re	elevant Test/Laboratory Data			2 of 2			
	Test Name	CMP: ALT	Test Date	04-Jun-2022			
	Test Result	560	Test Unit	INTERNATIONAL UNITS PER LITRE			
	Low Test Range	0	High Test Range	560			
	More Information Available?						
Ac	Iditional Comments						
Se	ection B - Product Availability						
	Do you still have the product in case we need to evaluate it?	Yes					
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes					
Se	ection C - About the Products			1 of 1			
	Suspect	Yes					
	Primary?	Yes					
	Туре	Drug/Biologi					
	This report is about	Food/Medical food					
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	FRENCH LENTIL + LEEK (CRUMBLES				
	Name of the company that makes (or compounds) the roduct	DAILY HARVEST					
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility				
	Strength		If Other				
	NDC number						
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?						
	Did the problem return if the rson started taking or using the						
	roduct again?						
Dr				1 of 1			

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48418 | Department: CFSAN | RCT No.: RCT-1023854 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Lot number		
	Dosage Form		
	Quantity	If Other	
	Frequency	If Other	
	How was it taken or used	If Other	
	Date the person first started aking or using the product		
	Date the person stopped taking or using the product		
	Date the person reduced dose of he product		
	Give best estimate of duration		
	Is therapy still on-going?		
Wł	ny was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Ot	her identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
loc	cate them)		
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		
Fo			
	r implanted medical devices O	NLY (such as pacemakers, breast mplants, etc.)	
Da	r implanted medical devices O ate the implant was put in	DNLY (such as pacemakers, breast implants, etc.) Date the implant was taken out (If relevant)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
	•	Date the implant was taken out (If relevant)	
	ate the implant was put in	Date the implant was taken out (If relevant) no Had the Problem	

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48418 | Department: CFSAN | RCT No.: RCT-1023854 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Please Specify Other Gender		
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	
	Weight	57.15 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	Birth control		
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	Penicillin		
Lis	st any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
	About 3 drinks a week. Does not s	smoke.	
Lis	st all current prescription medic	ations and medical devices b ng used.	
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
		(b) (6)	+-

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48418 | Department: CFSAN | RCT No.: RCT-1023854 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

Number/Street	(b) (6)	
City	(b) (6)	Г
State/Province	(b) (6)	Ī
Country	UNITED STATES	Ī
ZIP or Postal code	(b) (6)	Ī
Telephone number	(b) (6)	Ī
Email address	(b) (6)	ľ
Fax		ľ
Reporter Organization		Ī
Department		Ī
Reporter Speciality		Ī
Today's date	20-Jun-2022	Ī
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:22 Page 5 of 5

NET WT. 12oz (340g)

DAILY HARVEST

RUMBLES

oss in a tortilla. Crumble on top of a Flatbread. Sent pppy Joes. Dare we say stuff into an empanadi a lettuce wrap. Layer into lasagna. Upgrade 10 se French Lentil + Leek Crumbles truly working

ing Oh, don't forget to add into your officer hepherd's pie. We could go on.

CTU No.: FDA-CDER-CTU-2022-48452 | Department: CFSAN | RCT No.: RCT-1023930 | CTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

ls			
nit	CDER-CTU	Originating Ac ount	FAERS
ium	MWO (Drug)	Source Form Type	E2B XML 3500B
	Routine		
to Calculation Rule	No		
ed Date	20-Jun-2022	CTU Received Date	20-Jun-2022
Date		CTU Data Entry Date	
	Spontaneous	Report Classification	Drug
	User	·	
Department	Ø		
/	Direct		
(b) (6)	(b) (6)	(b) (6)	(b) (6)
(b) (6)	(b) (6)	(b) (6)	(b) (6)
About the Problem	(b) (6)	(b) (6)	(b) (6)
About the Problem d of problem was it?		(b) (6)	
About the Problem	Were hurt or had a bad s		
About the Problem d of problem was it?	Were hurt or had a bad s	side effect (including new or worsening symptom	
About the Problem d of problem was it? Il that apply)	Were hurt or had a bad s Used a product incorrect Noticed a problem with t Had problems after switch	side effect (including new or worsening symptom	
About the Problem d of problem was it?	Were hurt or had a bad s Used a product incorrect Noticed a problem with t Had problems after swite 07-Jun-2022	side effect (including new or worsening symptom ly which could have or led to a problem he quality of the product	
About the Problem d of problem was it? Il that apply) problem oc urred	Were hurt or had a bad s Used a product incorrect Noticed a problem with t Had problems after switch	side effect (including new or worsening symptom ly which could have or led to a problem he quality of the product	
About the Problem d of problem was it? Il that apply) problem oc urred of the following happen?	Were hurt or had a bad s Used a product incorrect Noticed a problem with t Had problems after swite 07-Jun-2022	side effect (including new or worsening symptom ly which could have or led to a problem he quality of the product ching from one product maker to another maker	
About the Problem d of problem was it? Il that apply) problem oc urred	Were hurt or had a bad s Used a product incorrect Noticed a problem with t Had problems after swite 07-Jun-2022 Yes	side effect (including new or worsening symptom ly which could have or led to a problem the quality of the product thing from one product maker to another maker	
About the Problem d of problem was it? Il that apply) problem oc urred of the following happen?	Were hurt or had a bad s Used a product incorrect Noticed a problem with t Had problems after swite 07-Jun-2022 Yes Hospitalization - admitted Required help to prevent Disability or health problems	side effect (including new or worsening symptom ly which could have or led to a problem the quality of the product thing from one product maker to another maker d or stayed longer	
About the Problem d of problem was it? Il that apply) problem oc urred of the following happen?	Were hurt or had a bad s Used a product incorrect Noticed a problem with t Had problems after swite 07-Jun-2022 Yes Hospitalization - admitted Required help to prevent Disability or health problems Birth defect	side effect (including new or worsening symptom ly which could have or led to a problem the quality of the product thing from one product maker to another maker d or stayed longer	
About the Problem d of problem was it? Il that apply) problem oc urred of the following happen?	Were hurt or had a bad s Used a product incorrect Noticed a problem with t Had problems after swite 07-Jun-2022 Yes Hospitalization - admitted Required help to prevent Disability or health problems	side effect (including new or worsening symptom ly which could have or led to a problem the quality of the product thing from one product maker to another maker d or stayed longer	
t	nit ium to Calculation Rule ed Date Date Department /	nit CDER-CTU ium MWO (Drug) Routine to Calculation Rule No ed Date 20-Jun-2022 Date Spontaneous User Department Direct	nit CDER-CTU Originating Ac ount ium MWO (Drug) Source Form Type Routine to Calculation Rule ed Date Date Spontaneous User Department Direct CDER-CTU Originating Ac ount Originatin

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

My 26 year old son ate the product which was Daily Harvest French Lentil and Leek Crumbles either Sunday night 6/5 or Monday 6/6. He woke up at 3 am on Tuesday with severe stomach cramps. Later that day (6/7) he developed a 103 fever and had ongoing severe stomach pain. He went to an urgent care cent r and they sent him to the emergency room at New York (b) (6)

They took his bloodwork which indicated elevated liver enzyme and thought he had gallstones and would need to have his gallstone removed. They did an ultra ound, MRI and ultimately conducted an endoscopy. They did not see any gallstones or indications of gallstone issues. He r mained in the hospital until Friday, 6/10. During this time thy did a lot of bloodwork to ensure his liver enzymes decreased whin they did but slowly. They were much better but not back to normal when he was discharged. They could not give him a diagno.

Relevant Test/Laboratory I	Data		1 of 5
Test Name	ASPARTATE AMINOTRA NSFERASE	Test Date	08-Jun-2022
Test Result	215	Test Unit	

Generated by: SYSTEM Generated on: 20-Jun-2022 17:16:39 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48452 | Department: CFSAN | RCT No.: RCT-1023930 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

	Low Test Range	<=34 U/L	High Test Range	
	_	V=34 0/L	Tilgii Test Kalige	
D	More Information Available? elevant Test/Laboratory Data			2 of 5
Re	-			
	Test Name	ALANINE AMINOTRANSF ERASE	Test Date	08-Jun-2022
	Test Result	399	Test Unit	
	Low Test Range	10 U/L	High Test Range	49 U/L
	More Information Available?			
Re	elevant Test/Laboratory Data			3 of 5
	Test Name	BILIRUBIN TOTAL	Test Date	08-Jun-2022
	Test Result	3.2	Test Unit	MILLIGRAMS PER DECIL ITRE
	Low Test Range	0.3	High Test Range	1.2
	More Information Available?			
Re	elevant Test/Laboratory Data			4 of 5
	Test Name	HEPATITIS A	Test Date	08-Jun-2022
	Test Result	Reactive (A)	Test Unit	
	Low Test Range	Non reactive	High Test Range	
	More Information Available?			
1				
Re	elevant Test/Laboratory Data			5 of 5
Re		URINE PROTEIN	Test Date	5 of 5 07-Jun-2022
Re	elevant Test/Laboratory Data	URINE PROTEIN 30(A)	Test Date Test Unit	
Re	elevant Test/Laboratory Data Test Name			07-Jun-2022 MILLIGRAMS PER DECIL
Re	Test Name Test Result	30(A)	Test Unit	07-Jun-2022 MILLIGRAMS PER DECIL ITRE
	Test Name Test Result Low Test Range	30(A)	Test Unit	07-Jun-2022 MILLIGRAMS PER DECIL ITRE
	Test Name Test Result Low Test Range More Information Available?	30(A) Negative	Test Unit High Test Range	07-Jun-2022 MILLIGRAMS PER DECIL ITRE
Ac	Test Name Test Result Low Test Range More Information Available?	30(A) Negative	Test Unit High Test Range	07-Jun-2022 MILLIGRAMS PER DECIL ITRE
Ac	Test Name Test Result Low Test Range More Information Available? Iditional Comments On 6/8 AM, he tested reactive for	30(A) Negative	Test Unit High Test Range	07-Jun-2022 MILLIGRAMS PER DECIL ITRE
Ac	Test Name Test Result Low Test Range More Information Available? Iditional Comments On 6/8 AM, he tested reactive for ection B - Product Availability Do you still have the product in	30(A) Negative Hepatitis A. This changed by	Test Unit High Test Range	07-Jun-2022 MILLIGRAMS PER DECIL ITRE
Se	Test Name Test Result Low Test Range More Information Available? Iditional Comments On 6/8 AM, he tested reactive for Comments On 6/8 and he tested reactive for Comments C	30(A) Negative Hepatitis A. This changed by Yes	Test Unit High Test Range	07-Jun-2022 MILLIGRAMS PER DECIL ITRE
Se	Test Name Test Result Low Test Range More Information Available? Iditional Comments On 6/8 AM, he tested reactive for Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture)	30(A) Negative Hepatitis A. This changed by Yes	Test Unit High Test Range	07-Jun-2022 MILLIGRAMS PER DECIL ITRE Negative
Se	Test Name Test Result Low Test Range More Information Available? Iditional Comments On 6/8 AM, he tested reactive for ection B - Product Availability Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture)	30(A) Negative Hepatitis A. This changed by Yes No	Test Unit High Test Range	07-Jun-2022 MILLIGRAMS PER DECIL ITRE Negative

Generated by: SYSTEM Generated on: 20-Jun-2022 17:16:39 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48452 | Department: CFSAN | RCT No.: RCT-1023930 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

	This report is about	Food/Medical food	Food/Medical food				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Crumbles - French Lentil an	d Leek				
	Name of the company that makes (or compounds) the roduct	Daily Harvest					
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy o Generi Biosimilar	or an Outsourcing Facility				
	Strength		If Other				
	NDC number						
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?						
	Did the problem return if the rson started taking or using the roduct again?						
Dr	ug Therapy			1 of 1			
	Expiration date	10-Oct-2022					
	Lot number	L5-A					
	Dosage Form						
	Quantity		If Other				
	Frequency		If Other				
	How was it taken or used		If Other				
	Date the person first started aking or using the product	05-Jun-2022					
	Date the person stopped taking or using the product	06-Jun-2022					
	Date the person reduced dose of he product						
	Give best estimate of duration						
	Is therapy still on-going?				_		
VVI	ny was the person using the pr	oduct? (such as what cor	idition was it supposed to tr	reat) 1 of 1			
	Returned to Manufacturer On				_		
Se	ection D - About the Medical De	evice					
	Name of medical device						
	Name of the company that makes the medical device						
Ot	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the e	expiration date, if you can			

Generated by: SYSTEM Generated on: 20-Jun-2022 17:16:39 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48452 | Department: CFSAN | RCT No.: RCT-1023930 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	Model Number			-
	Catalog Number			
	Lot Number			
	Serial Number			\vdash
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemake	s, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Male		
	Gender	Not selected		
	Please Specify Other Gender			
	Age (specify unit of time for age)	26 Year(s)		
	Date of Birth			
	Weight	83.25 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif Asian White Black or African American		
Lis	t known medical conditions (S	uch as diabetes, high blo	od pre ure, cancer, heart disease, or others)	
	None			
PΙε	ease list all allergies (such as t	o drugs, foods, pollen or	hers)	
	N/A			
Lic	t any other important informati	on about the person (suc	h as moking, pregnancy, alcohol use, etc.)	

Generated by: SYSTEM Generated on: 20-Jun-2022 17:16:39 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48452 | Department: CFSAN | RCT No.: RCT-1023930 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	N/A				
Lis	st all current prescription medications and medical devices b ng used.				
Lis	List all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.				

ction F - About the Person Fil	ling Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	20-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 20-Jun-2022 17:16:39 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-45423 | Department: GPSAN | RCT No.: RCT-1028856 | DTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	A 1 1 1 1 1 1	220000000000000000000000000000000000000	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		the second second
FDA Received Date	20-Jun-2022	CTU Received Date	20-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	Ø		
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)	

Section A - About the Problem				
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker		
	Date the problem occurred	06-Jun-2022		
	Serious	Yes		
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)		
	Other serious/important medical incident(Please Describe Below)			

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

After consuming Daily Harvest's French Lentil & Leek Crumbles, I fell extremely ill with liver pain and resulted in an ER visit and ongoing medical uncertainty. Daily Harvest Order Number: S-115275037 Daily Harvest Lentil & Leek Crumbles Batch Number: Best By 10/10/2022 L5-A 09:37 Here is a timeline of when it was consumed and my symptoms: May 27/28, 2022 - Consumption of French Lentil crumbles May 28 to June 4, 2022 - Gastrointestinal distress and fatigue June 5, 2022 - 102.5 degree Fever and intense upper abdominal pain June 6, 2022 - Doctor visit and bloodwork (b) (6) June 8, 2022 - Itchy rash all over body, doctor's bloodwork showed extremely high liver enzyme levels (AST 572, ALT 700, ALP 187). Doctor prescribed hydroxyzine hcl and triamcinolone lotion for symptom relief. June 9, 2022 ? Emergency Room ER visit for organ imaging and further medical testing. (b) (6) Liver enzyme levels still high (AST 64, 217, ALP 147). Negative for Hepatitis panel and other viruses. June 9 to current (June 20) ? Ongoing fatigue and ache in liver area

Relevant Test/Laboratory Data		1 of 1
Test Name	Test Date	

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:41 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48423 | Department: CFSAN | RCT No.: RCT-1023858 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Test Result		Test Unit		
	Low Test Range		High Test Range		
	More Information Available?				
Λα	ditional Comments				
Au	ditional Comments				
	I can provide medical documentate crumbles. I have extra that I am w	tion of all my ER/doctor visits villing to give to FDA to test fo	and tests, and videos of me holding toxicity. Please contact me ASA	ng the bag of Daily Harvest P.	
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest Lentil and Lee	aily Harvest Lentil and Leek Crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	Compounded by a Pharmacy or an Outsourcing Facility Generi		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	10-Oct-2022			
	Lot number	L5-A 09:37			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:41 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48423 | Department: CFSAN | RCT No.: RCT-1023858 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Date the person first started aking or using the product	28-May-2022		
	Date the person stopped taking or using the product	28-May-2022		
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?	Yes		
WI	hy was the person using the pr	roduct? (such as what cor	ndition was it supposed to treat) 1 of 1	
	Food			
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if you can	
100	cate tnem)			
	Madal Novalage			
	Model Number			
	Catalog Number			-
	Lot Number			-
	Serial Number			-
	UDDI Number			-
	Expiration date			-
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)	
Date the implant was put in			Date the implant was taken out (If relevant)	
80	ection E - About the Person Wh	o Had the Problem		
00	Person's Initials	(b) (6)		
	Sex	Female		-
	Gender	Cisgender woman/girl		-
	Please Specify Other Gender	Glogoridor Wornariygiri		+
	Age (specify unit of time for age)	31 Year(s)		
	Date of Birth	0 / 1 Car(3)		-
	Weight	46.35 kg		_
	Ethnicity (Choose only one)	Not Hispanic/Latino		-
	_ ==::::0::, (=:::===============================			1

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:41 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48423 | Department: CFSAN | RCT No.: RCT-1023858 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
l is	at known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
		After consuming, I had liver pa n, fever, and extremely elevated liver enzymes	T
	Trone belore eating the product.	and concurring, Frida liver part, level, and extremely elevated liver enzymes	
וח	and list all allerains (auch as t	a device foods nallon as a hoss)	
PI	None	o drugs, foods, pollen or o hers)	
	None		
Lis		ion about the person (such as moking, pregnancy, alcohol use, etc.)	
	None		
Lis	st all current prescription medic	cations and medical devices b ng used.	
	None		
Lis	t all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
	None		
Se	ction F - About the Person Fill		
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6) ,	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:41 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48423 | Department: CFSAN | RCT No.: RCT-1023858 | CTU Triage Date: 21-Jun-2022 | Total Pages: 6

Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	20-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 20-Jun-2022 14:46:41 Page 5 of 5

(1 Compost Mo

HARVEST

REST BY: 10/10/2022 LS-A 09:37

uparing Crumbles:

- Hest a lightly oiled skillet or non-stick pan over medium-high heat.
- uthe desired amount of frozen Crumbles to the pan, breaking up m large clusters.
- string frequently, sauté until nicely browned and thoroughly cooked transitional temperature of 165°F, about 5-6 minutes.
- Lastand for 1-2 minutes. Enjoy on their own or add to your favorite

WALE STORE FROZEN. Do not thaw or refreeze. Cook thoroughly mal temperature of 165°F. Fill level and cook time may vary. Tacks 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290 [as Salurated Fat 2g (10% DV), Trans Fat 0g, Cholesterol Omg (0% DV), Sodium 430mg (19% DV) at 19g (10% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added Sugars, 0% DV) (10% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% DV), Potas Nou how much a nutrient in a serving of food contributes to a daily diet 2,000 calories admin on advice butternut squash, organic hemp seeds, organic cauliflower rice, organic extra viginals organic red lentils, organic tri-colored quinoa, organic cremini mushrooms, organic mushrooms, organic cremini crem The parsley, water, organic cassava root flour, organic flax seeds, organic sacha inchi Powder, himalayan sea salt, organic apple cider vinegar, organic onion powder, organic to provide the organic apple cider vinegar, organic onion powder, organic organ reganic tomato powder, organic apple cider vinegar, organic onion pomenta organic coriander seeds of

MARVEST INC. NEW YORK, NY 10013

CTU No.: FDA-CDER-CTU-2022-48466 | Department: CFSAN | RCT No.: RCT-1023972 | CTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Ba	Basic Details						
С	ompany U	nit	CDI	ER-CTU	Origin	nating Ac ount	FAERS
S	ource Med	ium	MW	O (Drug)	Sourc	ce Form Type	E2B XML 3500B
Pı	riority		Rou	ıtine			
0	verride Au	to Calculation Rule	No				
FI	DA Receiv	ed Date	20-	1un-2022	CTU	Received Date	20-1un-2022
C.	TU Triage	Date			CTU	Data Entry Date	
R	eport Type)	Spc	ntaneous	Repo	rt Classi8 ation	Drug
A	ssign To		Use	r			
U:	serJGroup						
Fo	orf ard to I	Department	$\overline{\mathcal{L}}$]			
C	ase Priorit	у	Dire	ect			
		,					
Co	ontact						
-	ase eporter	First Name		Last Name		Email Address	Phone
$\overline{\mathbf{v}}$	3	(b) (6)		(b) (6)		(b) (6)	(b) (6)
Se	ection A -	A?out the Pro?lem					
9w̄	Date the Serious Did any (Checq a	nal documents i8nece		Used a product incorrectly f hick Noticed a pro?lem f ith the Yua 4 ad pro?lems a8 r sf itching 8 1 un-2022 4 ospitalization - admitted or sta ReYuired help to prevent perma Disa?ility or health pro?lem Birth de8 Li8-threatening Death Other seriousJmportant medical appened (xnclude as y)	ch could lity o8th om one ayed long anent ha	product maq r to another maq r	
Re	elevant T	estLa?oratory Data					k o8k
	Test Nar				Test	Date	
	Test Res				Test		
	Lof Tes	t Range			4 gh	Test Range	
	More xn8	brmation Availa?leH		•		,	

Generated ?y: SI STEM G nerated on: 20-1un-2022 20:k6:22 Page k o85

CTU No.: FDA-CDER-CTU-2022-48466 | Department: CFSAN | RCT No.: RCT-1023972 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Ad	ditional Comments				
Se	ction B - Product Availa?ility				
	Do you still have the product in case f need to evaluate itH	No			
	Do you have a picture o8the productH (checq yes i8you are ncluding a picture)	No			
Se	ction C - A?out the Products			k o8k	
	Suspect	le			
	PrimaryH	le			
	Туре	Drug.Biologic			
	This report is a?out	Food Medical & ood			
	Name o8the product as it appears on the ?ox' ?ottle' or pacqage (xnclude as many names as you see)	Daily harvest lentil and leaq	crum?les		
	Name o8the company that maq (or compounds) the roduct	Daily harvest			
	Product Type(checq all that apply)	Over-the-Counter Compounded ?y a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		x8Other		
	NDC num?er				
	Did the pro?lem stop a8 r the rson reduced the dose or opped taq ng or using the roductH				
	Did the pro?lem return i8the rson started taq ng or using the roduct againH				
Dr	ug Therapy			k o8k	
	Expiration date				
	Lot num?er				
	Dosage Form	-			
	, uantity		x8Other		
	FreYuency		x8Other		
	4 of f as it taq n or used		x8Other		
	Date the person 8rst started aq ng or using the product	03-1un-2022			
	Date the person stopped taq ng or using the product	03-1un-2022			
	Date the person reduced dose o8 he product				

Generated ?y: SI STEM G nerated on: 20-1un-2022 20:k6:22 Page 2 o85

CTU No.: FDA-CDER-CTU-2022-48466 | Department: CFSAN | RCT No.: RCT-1023972 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	Give ?est estimate o8duration		
	x therapy still on-goingH		
Wŀ	ny f as the person using the pr	oductH(such as f hat condition f as it supposed to treat) k o8k	
	Returned to Manu&cturer On		
Se	ction D - A?out the Medical De	evice	
	Name o8medical device		
	Name o8the company that maq the medical device		
Otl	her identi&ing in&rmation (The ate them)	e model' catalog' lot' serial' or UDxnum?er' and the expiration date' i8you can	
	Model Num?er		
	Catalog Num?er		
	Lot Num?er		
	Serial Num?er		
	UDDxNum?er		
	Expiration date		
	Was someone operating the medical device f hen the pro?lem oc urredH		
Fo	r implanted medical devices O	NLI (such as pacemagers' ?reast implants' etcw)	
	ate the implant f as put in	Date the implant f as tagen out (x8	
		relevant)	
Se	ction E - A?out the Person Wh	o 4 ad the Pro?lem	
	Person@ xnitials	(b) (6)	
	Sex	Female	
	Gender	Cisgender f oman birl	
	Please Speci8y Other Gender		
	Age (speci8y unit o8time & age)	30 I ar(s)	
	Date o8Birth		
	Weight	. 9v6 qg	
	Ethnicity (Choose only one)	4 ispanicLatino	
	Race (Checq all that apply)	American xndian or Alasqa Native Native 4 af aiian or Other Paci8 x lander Asian White	

Generated ?y: SI STEM G nerated on: 20-1un-2022 20:k6:22 Page 3 o85

CTU No.: FDA-CDER-CTU-2022-48466 | Department: CFSAN | RCT No.: RCT-1023972 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

List	qnof n medical conditions (S	Such as dia?etes' high ?lood pressure' cancer' heart disease' or others)	
Plea	ase list all allergies (such as t	to drugs' &ods' ollen or others)	
List	any other important in&rmat	ion a?out the person (such as smoqing' pregnancy' alcohol use' etcv)	
List	all current prescription medic	cations and medical devices? ng usedw	
List	all over-the-counter medicat	ions and any vitamins' minerals' supplements' and her?al remedies ?eing use	wb
0			
_	tion F - A?out the Person Fill		
	PrimaryH Reporter is PatientH	le	
	Title		
	111110		
		(b) (6)	
	Last name	(b) (6)	
	Last name Middle Name		
	Last name Middle Name First name	(b) (6) (b) (c)	
	Last name Middle Name First name Num?er.S reet		
	Last name Middle Name First name Num?er.S reet City		
	Last name Middle Name First name Num?er,S reet City State,Province	(b) (6)	
	Last name Middle Name First name Num?er,S reet City State,Province Country		
	Last name Middle Name First name Num?er,S reet City State,Province Country ZxP or Postal code	(b) (6) UNXTED STATES	
	Last name Middle Name First name Num?er,S reet City State,Province Country ZxP or Postal code Telephone num?er	(b) (6) UNXTED STATES (b) (6)	
	Last name Middle Name First name Num?er,S reet City State,Province Country ZxP or Postal code	(b) (6) UNXTED STATES	

Generated ?y: SI STEM G nerated on: 20-1un-2022 20:k6:22 Page 9 o85

CTU No.: FDA-CDER-CTU-2022-48466 | Department: CFSAN | RCT No.: RCT-1023972 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

Department		
Reporter Speciality		
Today@ date	20-1un-2022	
Did you report this pro?lem to the company that maq the product (the manu&cturer&compounder)H		
x8you do NOT f ant your dentity disclosed to the manu&cturer' please marq this ?ox (Con8dentiality ReYuested):	No	

Generated ?y: SI STEM G nerated on: 20-1un-2022 20:k6:22 Page 5 o85

CTU No.: FDA-CDER-CTU-2022-48463 | Department: CFSAN | RCT No.: RCT-1023959 | CTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone						
Basic De	tails					
Company	Unit	CDER-CTU	Originating Ac ount	FAERS		
Source M	edium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority		Routine				
Override	Auto Calculation Rule	No				
FDA Received Date		20-Jun-2022	CTU Received Date	20-Jun-2022		
CTU Tria	ge Date		CTU Data Entry Date			
Report Ty	/pe	Spontaneous	Report Classification	Drug		
Assign To)	User				
User/Gro	up					
Forward t	o Department					
Case Pric	prity	Direct				
		I.				
Contact						
Case	First Name	Last Name	Email Address	Phone		
Reporter	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
\square		(6) (6)	(b) (b)	(6) (6)		
Section A	A - About the Problem					
What kind of problem was it? (Check all that apply) Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker Date the problem oc urred 18-Jun-2022 Serious Pes Did any of the following happen? (Check all that apply) Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below) 4. Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary) After eating a full bag of Daily Harvest Lentil and Leek crumbl on 6/16/2022, I developed severe stomach pains, intermittent				tomach pains, intermittent d after many blood tests		
Relevant	fever, nausea, extreme fatigue, and very dark urine. I visited an emergency room on 6/18/2022, and after many blood tests and an ultrasound, they determined there was a problem with my liver and gallbladder, but could not identify the cause. Relevant Test/Laboratory Data 1 of 5					
Test N	lame	SGPT/ALT	Test Date	18-Jun-2022		

K	Relevant Test/Laboratory Data					
	Test Name	SGPT/ALT	Test Date	18-Jun-2022		
	Test Result	308	Test Unit	INTERNATIONAL UNITS PER LITRE		
	Low Test Range	10	High Test Range	35		
	More Information Available?					

Generated by: SYSTEM Generated on: 20-Jun-2022 19:16:28 Page 1 of 5 CTU No.: FDA-CDER-CTU-2022-48463 | Department: CFSAN | RCT No.: RCT-1023959 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Relevant Test/Laboratory Data			2 of 5
Test Name	SGOT/AST	Test Date	18-Jun-2022
Test Result	101	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	14	High Test Range	50
More Information Available?			
Relevant Test/Laboratory Data			3 of 5
Test Name	ALKALINE PHOSPHATAS E	Test Date	18-Jun-2022
Test Result	206	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	53	High Test Range	128
More Information Available?			
Relevant Test/Laboratory Data			4 of 5
Test Name	TOTAL BILIRUBIN	Test Date	18-Jun-2022
Test Result	3.4	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	0.3	High Test Range	1.2
More Information Available?			
Relevant Test/Laboratory Data			5 of 5
Test Name	CREATINE PHOSPHOKIN ASE	Test Date	18-Jun-2022
Test Result	1387	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	35	High Test Range	232
More Information Available?			
Additional Comments			
Section B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Section C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologi		
This report is about			

Generated by: SYSTEM Generated on: 20-Jun-2022 19:16:28 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48463 | Department: CFSAN | RCT No.: RCT-1023959 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil & Leek Crum	bles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date		_		
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	15-Jun-2022			
	Date the person stopped taking or using the product	16-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration		_		
	Is therapy still on-going?				
WI	ny was the person using the pr	oduct? (such as what co	ondition was it supposed to	treat) 1 of 1	
	It is a food				
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device			_	
Ot	her identifying information (The	e model, catalog, lot, ser	ial, or UDI number, and the	expiration date, if you can	

Generated by: SYSTEM Generated on: 20-Jun-2022 19:16:28 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48463 | Department: CFSAN | RCT No.: RCT-1023959 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number		-	
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Male		
	Gender	Cisgender man/boy		
	Please Specify Other Gender			
	Age (specify unit of time for age)	30 Year(s)		
	Date of Birth			
	Weight	69.75 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif Asian White Black or African American		
Lis	t known medical conditions (S	uch as diabetes, high blo	od pre ure, cancer, heart disease, or others)	
PΙε	ease list all allergies (such as t	o drugs, foods, pollen or o	o hers)	
Lic	t any other important informati	on about the person (suc	h as moking, pregnancy, alcohol use, etc.)	

20-Jun-2022 19:16:28

Page 4 of 5

Generated on:

Generated by: SYSTEM

CTU No.: FDA-CDER-CTU-2022-48463 | Department: CFSAN | RCT No.: RCT-1023959 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Lis	st all current prescription medications and medical devices b ng used.	
Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	

tion F - About the Person Fil	ling Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	Portland
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	20-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 20-Jun-2022 19:16:28 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-46478 | Department: GFSAN | RCT No. RCT-1023979 | CTU Trage Date: 21∈Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		220000000000000000000000000000000000000	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	the format of
FDA Received Date	20-Jun-2022	CTU Received Date	20-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	-6	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

ction A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	31-May-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Hi and thanks in advance. I saw that the Daily Harvest company has food recalls and I had no idea the cause of my sickness was me eating their food - I kept thinking it was something else "unhealthy" but I have consumed their now recalled Crumbles. Here is a summary: My box arrived on May 20 and I ate crumbles in a couple different items during the following week because I wanted to "eat healthy" before I enjoyed Memorial Day BBQ (smh at that thought now!) I had it in pasta and I had it in lettuce wraps. I am single with 1 kid who doesn't eat what I eat so I had plenty left overs and just kept eating what all I had cooked. By the next week so starting May 30th I had fever, throwing up etc. May 31st still had a fever and was in pain; I thought maybe I had COVID so I asked for a COVID test. When it came back negative they started to investigate, why was I not able to keep food down, had a fever and abdominal pain. Xrays, then Ultrasound, then transfer to different facility then CAT SCAN then heart monitoring - all kept coming back OK plus blood and urine tests. They mentioned the liver results were concerning and said I should see a GI person for follow-up. I couldn't get anyone any sooner than tomorrow, 6/21 so I have printed out all of this stuff to take to them in the morning. I seriously can't believe this! I have all of this in my medical charts , I missed work and was feeling terrible for a week + due to this. I took a picture of one of with (b) (6) the bags before tossing it out. All DailyHarvest did was email me on June 17th to say they were giving me a credit for \$10 a bag purchased and I should toss the bags out. Now I see people on Reddit saying don't throw the bags away because the FDA might come collect them. I technically have them in my garbage bin in the garage but I don't know if your staff would want

Generated by: SYSTEM Generated on: 20-Jun-2022 21:46:23 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-4N478 | Department: GFSAN | RCT No.: RCT-1023979 | CTU Thage Date: 21-Jun-2022 | Total Pag

to dig that out. Anyway, I would still have it until this Friday coming up. I thought I had COVID, then I was scared something was wrong with one of my other organs, I was at the hospital over 8 hours and I think I said already how this impacted my job too. Just a huge mess, thank you for your time and attention to helping all of the consumers impacted by this. I do have a 3rd picture but couldn't upload it because of the file size limit. It shows the stamp on the bag which says: BEST BUY 10/10/2022 L5-A 07:52

R	elevant Test/Laboratory Data			1 of 1	
	Test Name		Test Date	31-May-2022	П
	Test Result		Test Unit		
	Low Test Range		High Test Range		
Ī	More Information Available?				
Ar	dditional Comments				
Se	(b) (6) JanMay 31, 2022 Ima AUTOMATED DIFFERENTIALOR METABOLIC PANELOrdered by JanMay 31, 2022 Lab CBC WITH action B - Product Availability Do you still have the product in case we need to evaluate it? Do you have a picture of the	(6) May 31, 2022 Lab LIPAS FLEXOrdered by (b) (6) May 3 022 The result is abnormalLaging XR ABDOMEN 2 VWOrdered by (b) (6) Brian L JanBrian L JanMay	31, 2022 Lab TROPO 022 Other type of result Election EOrdered by (b) (6) May 3 31, 2022 Lab URINE, BACT ab POCT PERFORM URIN ordered by(b) (6) JanMay 31, 2022 The results 31, 2022 Lab Covid Testing	NIN I POINT OF CAREOrdered ctrocardiogram (ECG)Ordered May 31, 2022 11, 2022 Imaging Abdominal ERIAL CULTUREOrdered by EDIPSTICKOrdered by JanMay 31, 2022 Lab CBC WITH lis abnormalLab COMPREHENSIVE Ordered by (b) (6)	
	product? (check yes if you are including a picture)				
Se	ection C - About the Products			1 of 1	
-	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologic			
	This report is about	Food/Medical food	_		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest Crumbles F	rench Lentil + Leek		
	Name of the company that makes (or compounds) the product	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generic Biosimilar	y or an Outsourcing Facility		
	Strength		If Other		
	NDC number		`		
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes			

Generated by: SYSTEM Generated on: 20-Jun-2022 21:46:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48478 | Department: CFSAN | RCT No.: RCT-1023979 | CTU Triage Date: 21-Jun-2022 | Total Pag

roduct again?		Did the problem return if the rson started taking or using the	Doesn't Apply			
Expiration date Lot number Dosage Form Quantity Frequency Hother Frequency Hother Date the person first started aking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Be that person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of medical device Name of medical device Name of the company that makes the medical device Name of the company that makes the medical device Name of the company that makes the medical device Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem or urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (if		roduct again?				
Lot number Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person educed dose of he product Date the person educed dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) I was trying to eat healthy food. Returned to Manufacturer On Section D - About the Medical Device Name of the company that makes the medical device Name of medical device Name of supplies information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Dost Number Serial Number UDDI Number Expiration date Was someone operating the medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was staken out (if	Dr				1 of 1	
Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Oatie the person stopped taking or using the product Oatie the person stopped taking or using the product Oatie the person stopped taking or using the product Office best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was saken out (if		Expiration date	10-Oct-2022			
Quantity If Other Frequency If Other Frequency If Other How was it taken or used 21-May-2022 aking or using the product 28-May-2022 Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person using the product Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) I was trying to eat healthy food. Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? From Implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was staken out (if		Lot number				
Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of the product Date the person reduced dose of the product Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) I was trying to eat healthy food. Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can ideate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical dedices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was put in If Other If Ot		Dosage Form				
How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) I was trying to eat healthy food. Returned to Manufacturer On Section D - About the Medical Device Name of the company that makes the medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device on the problem oc urred? For implanted medical device ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was put in		Quantity		If Other		
Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) I was trying to eat healthy food. Returned to Manufacturer On Section D - About the Medical Device Name of the company that makes the medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device on the problem oc urred? For implanted medical device ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was put in Date the implant was put in		Frequency		If Other		
aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) I was trying to eat healthy food. Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was put in		How was it taken or used		If Other		
or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) I was trying to eat healthy food. Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical device ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If			21-May-2022			
he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1			28-May-2022			
Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat)						
Why was the person using the product? (such as what condition was it supposed to treat) I was trying to eat healthy food. Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (if		Give best estimate of duration				
Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		• • •				
Returned to Manufacturer On Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If	W	ny was the person using the pr	oduct? (such as what c	ondition was it supposed to t	reat) 1 of 1	
Section D - About the Medical Device Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If						
Name of medical device Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		Returned to Manufacturer On				
Name of the company that makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If	Se	ction D - About the Medical De	evice			
makes the medical device Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them) Model Number Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical devices when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		Name of medical device				
Model Number						
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If	Ot	her identifying information (The cate them)	e model, catalog, lot, se	rial, or UDI number, and the	expiration date, if you can	
Catalog Number Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If						
Lot Number Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		Model Number				
Serial Number UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		Catalog Number				
UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		Lot Number				
Expiration date Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		Serial Number				
Was someone operating the medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		UDDI Number				
medical device when the problem oc urred? For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.) Date the implant was put in Date the implant was taken out (If		Expiration date				
Date the implant was put in Date the implant was taken out (If		medical device when the problem				
	Fo	r implanted medical devices O	NLY (such as pacemak	ers, breast mplants, etc.)		
	D	ate the implant was put in			ut (If	

Generated by: SYSTEM Generated on: 20-Jun-2022 21:46:23 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48478 | Department: CFSAN | RCT No.: RCT-1023979 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 7

Se	ction E - About the Person Wh	io Had the Problem				
	Person's Initials	(b) (6)				
	Sex	Female				
	Gender	Cisgender man/boy				
	Please Specify Other Gender					
	Age (specify unit of time for age)					
	Date of Birth	(b) (6)				
	Weight	87.75 kg				
	Ethnicity (Choose only one)	Not Hispanic/Latino				
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American				
Lis	t known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)				
	I have Multiple Sclerosis, diagnos					
PIE	,	o drugs, foods, pollen or o hers)				
	Seasonal allergies					
Lis	t any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)				
	None that I can think of.					
Lis	t all current prescription medic	cations and medical devices b ng used.				
	I have a Mirena IUD, I have a monthly injection for the MS call d Kesimpta.					
Lis		ons and any vitamins, mineral , supplements, and herbal remedies being used.				
	I take over the counter allergy medicine like Claritin quick di olve tablets.					
Se	ction F - About the Person Fill	ing Out This Form 1 of 1				
	Primary?	Yes				

Generated by: SYSTEM Generated on: 20-Jun-2022 21:46:23 Page 4 of 5

Reporter is Patient?

CTU No.: FDA-CDER-CTU-2022-48478 | Department: CFSAN | RCT No.: RCT-1023979 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(0) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	20-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 20-Jun-2022 21:46:23 Page 5 of 5

numbles:

the desired amount of frozen Crumbles to the pan, breaking up alightly oiled skillet or non-stick pan over medium-high heat

gfrequently, sauté until nicely browned and thoroughly cooked nternal temperature of 165°F, about 5-6 minutes

stand for 1-2 minutes. Enjoy on their own or add to your favorited

BLE STORE FROZEN. Do not thaw or refreeze. Cook thorough maltemperature of 165°F. Fill level and cook time may vary

Nouhow much a nutrient in a serving of food contributes to a daily diet 2000 advice. 187% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Addeds 18, Donco (no. DV), Potassium win Domes (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), potassium with the control of the co Seturated For 5 ontainer, Serv size: 4 oz (113g), Amount per serving

uls, organic red lentils, organic tri-colored quinoa, organic cremini mushing parsley, water seeds, organic tri-colored quinoa, organic cremini mushing parsley, water Parsley, water, organic cassava root flour, organic flax seeds, organic organi hic butternut squash, organic hemp seeds, organic cauliflower rice, organic red in mush mush organic cremini mush

powder, himalayan sea salt, organic apple cider vinegar, ordanic corlander organic tomater to sea salt, organic apple cider vinegar, organic corlander tomate. Mer, organic tomato powder, organic white pepper, organic coriander

CTU No.: FDA-CDER-CTU-2022-48858 | Department: CFSAN | RCT No.: RCT-1024069 | CTU Triage Date: 21-Jun-2022 | Total Pag

asic Details ompany Unit						
ompany Unit						
	CDER-CTU	Originating Ac ount	FAERS			
ource Medium	MWO (Drug)	Source Form Type	E2B XML 3500B			
riority	Routine	,				
verride Auto Calculation Rule	No					
DA Received Date	21-Jun-2022	CTU Received Date	21-Jun-2022			
TU Triage Date		CTU Data Entry Date				
eport Type	Spontaneous	Report Classification	Drug			
ssign To	User					
ser/Group						
orward to Department						
ase Priority	Direct					
ase First Name eporter (b) (6)	Last Name (b) (6)	Email Address (b) (6)	Phone (b) (6)			
ection A - About the Probler	n					
(Check all that apply) Date the problem oc urred	Noticed a problem w	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker 31-May-2022				
Serious	Yes	Yes				
Did any of the following happe (Check all that apply)	Required help to preduce the properties of the p	nitted or stayed longer vent permanent harm roblem ant medical incident(Please Describe Below)				
Tell us what happened and y additional documents if n	how it happened (Incl	ude as many de ails as possible l	FDA may reach out to you for			
3 hours. I tried other-the-cour leep that night due to the pair and was still experiencing pair care and they remarked that I other than a suspected infection I received an email from Daily experienced gastrointestinal coff the crumbles and not to ear	ter products but could not	nbles. I arted experiencing excruciating the find any relief; it felt like my esophague for app roximately 12 hours. The next of the severe as the first night. A couple in and that my heart was racing but were are negative. It took about a week of be garding the crumbles which said that a deceived a second email from Daily Harports I've read since, this matter seems a produc. I have saved the crumbles for	us was on fire. I was unable to day I developed a fever of 102.6 of days later I went to urgent e unable to pinpoint a problem edrest before I felt back to normal. small number of customers had evest instructing me to dispose s to be much more serious than			
elevant Test/Laboratory Da	ta		1 of 1			
Test Name		Test Date				
		1				

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:31 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48858 | Department: CFSAN | RCT No.: RCT-1024069 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

	Low Test Range		High Test Range			
	More Information Available?					
Ad	ditional Comments					
Se	ction B - Product Availability					
	Do you still have the product in case we need to evaluate it? Do you have a picture of the	Yes				
	roduct? (check yes if you are ncluding a picture)					
Se	ction C - About the Products			1 of 1		
	Suspect	Yes				
	Primary?	Yes				
	Туре	Drug/Biologi				
	This report is about	Food/Medical food				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Crumbles - French Lentil &	Crumbles - French Lentil & Leek			
	Name of the company that makes (or compounds) the roduct	Daily Harvest				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	Compounded by a Pharmacy or an Outsourcing Facility Generi			
	Strength		If Other			
	NDC number					
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply				
Dru	ug Therapy			1 of 1		
	Expiration date					
	Lot number					
	Dosage Form		1			
	Quantity		If Other			
	Frequency		If Other			
	How was it taken or used		If Other			
	Date the person first started aking or using the product	31-May-2022				

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:31 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48858 | Department: CFSAN | RCT No.: RCT-1024069 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

	Date the person stopped taking or using the product	31-May-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
Wł	ny was the person using the pr	oduct? (such as what con	ndition was it supposed to treat)	1 of 1	
	The product was food, not a medi	cal product.			
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot		e model, catalog, lot, seria	al, or UDI number, and the expira	tion date, if you can	
loc	cate them)	<i>,</i>			
	Model Number				
	Catalog Number	_			
	Lot Number				
	Serial Number	-			
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast_mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ction E - About the Person Wh				
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)	55 Year(s)			
	Date of Birth				
	Weight	60.75 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati			
1		Native Hawaiian or Other Pacifi	ic islander		

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:31 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48858 | Department: CFSAN | RCT No.: RCT-1024069 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

		Asian White Black or African American				
Lis	t known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)				
	Mild gastric reflux					
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)				
		e to bell peppers, hay fever (various pollens)				
Lis		on about the person (such as moking, pregnancy, alcohol use, etc.)				
	Very healthy, doesn't smoke, and					
Lis	t all current prescription medic	cations and medical devices b ng used.				
	None					
Lis	t all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.				
	Multi-vitamin, iron supplement, and Vitamin D supplement					
Se	ction F - About the Person Fill	ing Out This Form 1 of 1				
	Primary?	Yes				
	Reporter is Patient?					
	Title					
	Last name	(b) (6)				
	Middle Name					
	First name	(b) (6)				
	Number/Street	(b) (6)				
	City	(b) (6)				
	State/Province	(6) (6)				
	Country	UNITED STATES				
	ZIP or Postal code	(b) (6)				
	Telephone number	(b) (6)				
1	Email address	(b) (6)				

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:31 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48858 | Department: CFSAN | RCT No.: RCT-1024069 | CTU Triage Date: 21-Jun-2022 | Total Pages: 7

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	21-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:31 Page 5 of 5

Compost Me

ERAL SESSIONER

Preparing Grumbles:

- O Heat a lightly oiled skillet or non-stick pan over medium-high heat
 - Add the desired amount of frozen Crumbles to the pan, breaking up any large clusters.
- Stirring frequently, sauté until nicely browned and thoroughly cooked to an internal to an internal temperature of 165°F, about 5-6 minutes.

(a) Let stand for 1-2 minutes. Enjoy on their own or add to your favorite dish PERIOHABLE, STORE FROZEN. Do not thaw or refreeze. Cook thoroughly warry.

Louis Hable. STORE FROZEN. Do not thaw or refreeze. Cour wary vary. Whitehal temperature of 165°F. Fill level and cook time may vary. Cook in the serving sodium.

ARY, ALSO PROCESSES INC. NY 10013

CTU No.: FDA-CDER-CTU-2022-46859 | Department: CFSAN | RCT No.: RCT-1024071 | DTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200 100 100 10	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	21-Jun-2022	CTU Received Date	21-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	14-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

My wife and I have been worked up for a mystery hepatitis. I work at nypcornell Presbyterian and am being followed closely by a hepatologist here as I was not feeling well and peeing bright orange which was bilirubin. I have had a whole work up done and my LFTs were dangerously high along with a prolonged PT (prothrombin time) I have been ruled out for hepatitis a-e. One of my coworkers showed me the daily harvest Reddit page where others are having similar stories, and the timeline matches up as my wife and I were both eating their meals then got acutely sick.

Relevant Test/Laborator	y Data		1 of 1
Test Name	LIVER PANEL	Test Date	15-Jun-2022
Test Result		Test Unit	

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:41 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48859 | Department: CFSAN | RCT No.: RCT-1024071 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

	Low Test Range		High Test Range		
	More Information Available?				
Ad	ditional Comments				
	Bilirubin total 2.0 direct 1.3 all pho	s 269 aspartate 740 alanine a	a 1,403 pt 13.8		
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French lentil and leek crumb	oles		
	Name of the company that makes (or compounds) the roduct	Daily harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Yes			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form		1-2		
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started	18-May-2022			

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:41 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48859 | Department: CFSAN | RCT No.: RCT-1024071 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	Date the person stopped taking or using the product	13-Jun-2022	
	Date the person reduced dose of he product		
	Give best estimate of duration		
	Is therapy still on-going?		
WI	ny was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
	For healthy living		
			<u> </u>
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that		
Ot	makes the medical device her identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	cate them)		
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the		
	medical device when the problem oc urred?		
Fo	r implanted medical devices O	DNLY (such as pacemakers, breast mplants, etc.)	
	ate the implant was put in	Date the implant was taken out (If	
		relevant)	
Se	ection E - About the Person Wh	no Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)	49 Year(s)	
	Date of Birth		
	Weight	69.75 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:41 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48859 | Department: CFSAN | RCT No.: RCT-1024071 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

		Asian White Black or African American	
Lis	st known medical conditions (S	such as diabetes, high blood pre ure, cancer, heart disease, or others)	
	Glaucoma		
Pl	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	None		
Lis		ion about the person (such as moking, pregnancy, alcohol use, etc.)	
	None		
Lis	st all current prescription medic	cations and medical devices b ng used.	
	Latanaprost eye drops		
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
	None		
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
ı	Email address	(b) (6)	1

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:41 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-48859 | Department: CFSAN | RCT No.: RCT-1024071 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	21-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 21-Jun-2022 11:16:41 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-49087 | Department: GFSAN | RCT No.: RCT-1024709 | DTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	A 12 A 12	220000000000000000000000000000000000000	12.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	
FDA Received Date	21-Jun-2022	CTU Received Date	21-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	16	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	-	777 70 7	A 1 1 1 1	
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem			
	ind of problem was it?	Were hurt or had a bad side	effect (including new or worsening sympto	ms)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	01-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

We have recently consumed Daily Harvest's French Lentils and Leek Crumbles, and my wife has had severe issues. We believe we had the product on Wednesday, June 1. Since that time, my wife has experienced diarrhea, nausea, severe itchy skin, elevated liver enzymes, dark urine, extreme fatigue. She's been to see a doctor and has had an ultrasound and a battery of tests, and is due to return for a second blood test and MRI as follow up. I have also had liver-related symptoms, though not as severe as my wife.

evant Test/Laboratory	Data		1 of 2
Test Name	METABOLIC PANEL AND CBC	Test Date	13-Jun-2022
Test Result	Elevated liver enzymes	Test Unit	
Low Test Range		High Test Range	4

Generated by: SYSTEM Generated on: 21-Jun-2022 22:16:23 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-49087 | Department: CFSAN | RCT No.: RCT-1024360 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

	More Information Available?						
Re	levant Test/Laboratory Data			2 of 2			
	Test Name	LIVER SONOGRAM	Test Date	13-Jun-2022			
	Test Result	Liver inflammation indicate d	Test Unit				
	Low Test Range		High Test Range				
	More Information Available?						
Ad	ditional Comments						
	CBC A-monos % 8.30; CBC A-RBC 5.11 millions/mcL; ALP(P) 204 U/L; ALT (P) 213 U/L; AST (P) 94.0 U/L; tbili(P) 3.5 mg/dL						
Se	ction B - Product Availability						
	Do you still have the product in case we need to evaluate it?	Yes					
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No					
Se	ction C - About the Products			1 of 1			
	Suspect	Yes					
	Primary?	Yes					
	Туре	Drug/Biologi Prug/Biologi					
	This report is about	Food/Medical food					
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil & Leek Crumbles					
	Name of the company that makes (or compounds) the roduct	Daily Harvest					
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar					
	Strength		If Other				
	NDC number	L5-A 12:48					
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No					
	Did the problem return if the rson started taking or using the roduct again?	No					
Dr	ug Therapy			1 of 1			
	Expiration date	27-Sep-2022					
	Lot number	L5-A 12:48					

Generated by: SYSTEM Generated on: 21-Jun-2022 22:16:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49087 | Department: CFSAN | RCT No.: RCT-1024360 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

	Dosage Form					
	Quantity		If Other			
	Frequency		If Other			
	How was it taken or used	Oral	If Other			
	Date the person first started aking or using the product	01-Jun-2022				
	Date the person stopped taking or using the product	03-Jun-2022				
	Date the person reduced dose of he product					
	Give best estimate of duration					
	Is therapy still on-going?	Yes				
Wł	ny was the person using the pr	oduct? (such as what c	ondition was it supp	osed to treat) 1 of 1		
	Eating food					
	Returned to Manufacturer On					
Se	ction D - About the Medical De	evice				
	Name of medical device					
	Name of the company that makes the medical device					
Ot	Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can ocate them)					
loc	ate them)					
	Model Number					
	Catalog Number					
	Lot Number					
	Serial Number					
	UDDI Number					
	Expiration date					
	Was someone operating the medical device when the problem oc urred?					
Fo	r implanted medical devices O	NLY (such as pacemak	ers, breast mplants	, etc.)		
Da	ate the implant was put in		Date the implant warelevant)	s taken out (If		
Se	ction E - About the Person Wh					
	Person's Initials	(b) (6)				
	Sex	Male				
	Gender	Cisgender man/boy				
	Please Specify Other Gender		·			

Generated by: SYSTEM Generated on: 21-Jun-2022 22:16:23 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49087 | Department: CFSAN | RCT No.: RCT-1024360 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	Age (specify unit of time for age)		
	Date of Birth	16-Jul-1970	
	Weight	99 kg	
	Ethnicity (Choose only one)	Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	N/A		
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	N/A		
Lis	st any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
	N/A		
Lis	st all current prescription medic	cations and medical devices b ng used.	
	N/A		
Lis	st all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
	N/A		
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6) ,	

Generated by: SYSTEM Generated on: 21-Jun-2022 22:16:23 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49087 | Department: CFSAN | RCT No.: RCT-1024360 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	21-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 21-Jun-2022 22:16:23 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-48886 | Department: CFSAN | RCT No.: RCT-1024104 | CTU Triage Date: 21-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	ayed in the report are in EST(G	ivi i -05.00) time zone				
Basic Deta						
Company l		CDER-CTU		nating Ac ount	FAERS	
Source Me	dium	MWO (Drug)	Sour	ce Form Type	E2B XML 3500B	
Priority		Routine				
Override A	uto Calculation Rule	No				
FDA Recei	ved Date	21-Jun-2022	СТО	Received Date	21-Jun-2022	
CTU Triage	e Date		СТИ	Data Entry Date		
Report Typ	е	Spontaneous	Repo	rt Classification	Drug	
Assign To		User	•			
User/Group)					
Forward to	Department					
Case Priori	ity	Direct				
Contact						
Case	First Name	Last Name	<u> </u>	Email Address	Phone	
Reporter	I list Name	Last Name	7	Lillali Addiess	1 Hone	
	(b) (6)	(b) (6)		(b) (6)		
Section A	- About the Problem				'	
	nd of problem was it? all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)				
(Onlook	an triat apply)	Used a product incorrectly which could have or led to a problem				
		Noticed a problem with the quality of the product				
Had problems after switching from one product maker to another maker					ker	
Date the problem oc urred 30-May-2022						
Serious		Yes				
	of the following happen?	Hospitalization - admitted or stayed longer				
(Check	all that apply)	Required help to prevent permanent harm				
		Disability or health problem				
		Birth defect				
		Life-threatening				
		Death				
			nportant medical incide	nt(Please Describe Below)		
4.Tell us w	hat happened and ho		•	· , , , , , , , , , , , , , , , , , , ,	FDA may reach out to you for	
any addition	onal documents if nece	essary)		- 0.0 0.0 p 0 0 0.0.0	. = 1	
High live	er enzymes 1600 when sh	ould be 35 Jaund	ice Liver pain F ve	r Orange urine X 2 hos	oital admissions -both times are	
he daily	y harvest lentils the day be	efore				
Palayant T	Foot/Laboratory Data				1 of 1	
	Test/Laboratory Data					
Test Na	ime	AST	Test	Date	01-Jun-2022	
Test Re	esult	1600	Test	Unit	UNKNOWN	
Low Tes	st Range		Hiah	Test Range		
Low Tes	st Range		High	Test Range		
More In	formation Available?					

Generated by: SYSTEM Generated on: 21-Jun-2022 12:16:29 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-48886 | Department: CFSAN | RCT No.: RCT-1024104 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Ad	ditional Comments			
	if it didn't reduce . Also tested pos	hepatic function being off he charts - x 2 doctors said I would have needed a liver trans lant tive for Q fever. My wife also ate this product and her liver scores soared also I still have what they should be and Teo hospitalizations including NY Cornell Might be longer term s !!! Please help us as consumer		
Se	ction B - Product Availability			
	Do you still have the product in case we need to evaluate it?	No		
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Se	ction C - About the Products	1 of 1		
	Suspect	Yes		
	Primary?	Yes	_	
	Туре	Drug/Biologi	_	
	This report is about	Food/Medical food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily harvest French lentil and leek crumbles		
	Name of the company that makes (or compounds) the roduct Product Type(check all that apply)	Daily harvest Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar		
	Strength	If Other		
	NDC number			
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?			
	Did the problem return if the rson started taking or using the roduct again?			
Dr	ug Therapy	1 of 1		
	Expiration date			
	Lot number			
	Dosage Form			
	Quantity	If Other		
	Frequency	If Other		
	How was it taken or used	If Other		
	Date the person first started aking or using the product	16-May-2022		
	Date the person stopped taking or using the product Date the person reduced dose of he product			

Generated by: SYSTEM Generated on: 21-Jun-2022 12:16:29 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-48886 | Department: CFSAN | RCT No.: RCT-1024104 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

	Give best estimate of duration			
	Is therapy still on-going?	Yes		
WI	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat)	1 of 1
	Food			
	Returned to Manufacturer On			
0		via		
Se	ction D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expiration date	, if you can
100	cate them)			
	Model Number			
	Catalog Number		-	
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the			
	medical device when the problem			
	oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
			relevant)	
Se	ction E - About the Person Wh	no Had the Problem		
	Person's Initials			
	Sex	Female		
	Gender	Cisgender woman/girl		
	Please Specify Other Gender	47.7//-)		
	Age (specify unit of time for age)	47 Year(s)		
	Date of Birth	00 1		
	Weight	63 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati	ve	
		Native Hawaiian or Other Pacif	ic Islander	
		☐ Asian White		
		Black or African American		

Generated by: SYSTEM Generated on: 21-Jun-2022 12:16:29 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-48886 | Department: CFSAN | RCT No.: RCT-1024104 | CTU Triage Date: 21-Jun-2022 | Total Pag es: 5

LIS	· · · · · · · · · · · · · · · · · · ·	such as diabetes, high blood pre ure, cancer, heart disease, or others)	T				
	None						
IPI	ease list all allergies (such as t	to drugs, foods, pollen or o hers)					
	Penicillin		T				
L							
Lis		ion about the person (such as moking, pregnancy, alcohol use, etc.)					
	None						
Lis	st all current prescription medic	cations and medical devices b ng used.					
	None						
1							
ll ic	et all over-the-counter medicati	ions and any vitamins, mineral, supplements, and herbal remedies being used					
Lis		ions and any vitamins, mineral, supplements, and herbal remedies being used.	T				
Lis	st all over-the-counter medicati None	ions and any vitamins, mineral , supplements, and herbal remedies being used.					
Lis		ions and any vitamins, mineral, supplements, and herbal remedies being used.					
Lis		ions and any vitamins, mineral , supplements, and herbal remedies being used.					
Lis		ions and any vitamins, mineral , supplements, and herbal remedies being used.					
	None						
	None ection F - About the Person Fill						
	None ection F - About the Person Fill Primary?	ling Out This Form 1 of 1					
	None ection F - About the Person Fill Primary? Reporter is Patient?	ling Out This Form 1 of 1					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title	ing Out This Form 1 of 1 Yes					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title Last name	ling Out This Form 1 of 1					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name	ing Out This Form 1 of 1 Yes (b) (6)					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name	ing Out This Form 1 of 1 Yes (b) (6)					
	None ction F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	ing Out This Form 1 of 1 Yes (b) (6) (b) (6)					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	ing Out This Form 1 of 1 Yes (b) (6)					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province	ing Out This Form 1 of 1 Yes (b) (6) (b) (6) (b) (6) (b) (6)					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	ing Out This Form 1 of 1 Yes (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) UNITED STATES					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country ZIP or Postal code	ing Out This Form 1 of 1 Yes (b) (6) (b) (6) (b) (6) (b) (6)					
	None ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City State/Province Country	ing Out This Form 1 of 1 Yes (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) UNITED STATES					

Generated by: SYSTEM Generated on: 21-Jun-2022 12:16:29 Page 4 of 5

Fax

Reporter Organization

CTU No.: FDA-CDER-CTU-2022-48886 | Department: CFSAN | RCT No.: RCT-1024104 | CTU Triage Date: 21-Jun-2022 | Total Pages: 5

Department		
Reporter Speciality		
Today's date	21-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 21-Jun-2022 12:16:29 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-49189 | Department: CFSAN | RCT No.: RCT-1024372 | CTU Triage Date: 22-Jun-2022 | Total Pag as: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details					
Company Unit	CDER-CTU	Originating Ac ount	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	22-Jun-2022	CTU Received Date	22-Jun-2022		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User				
User/Group					
Forward to Department					
Case Priority	Direct				

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)	

Se	Section A - About the Problem				
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker			
	Date the problem oc urred	04-Jun-2022			
	Serious	Yes			
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)			
	Other serious/important medical ncident(Please Describe Below)				

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

This is concerning the Daily Harvest Lentil + Leek Crumbles tha have caused serious GI and liver related issues. I have been a customer of Daily Harvest for close to a year. I ate the Lent I + Leek Crumbles somewhere between May 20 - May 31 2022. On May 26th / 27th 2022 I developed symptoms of nausea, stomach pain, fever, whole-body itching, loss of appetite, fatigue . With continued symptoms and a fever of close to 103, I was forced to go to the ER on June 4th 2022. Doctors were unable o figure out the cause. My blood work showed extremely elevated liver function levels in addition to other concerns. I was referred to my GP who has referred me to a GI specialist. I am an otherwise healthy person. These physical health issues have caused me to miss more than a week of work in addition to he impact to my mental health resulting from being unable to take prescribed medications that potentially affect liver functions and not being able to exercise which I rely on to treat depression/anxiety. Sadly, but perhaps the most unsurprising as of this situation has been the company's callous lack of empathy to the outcry from affected customers. I have documented this situation. I currently still have one opened but sealed bag and one unopened bag of Lentil + Leek Crumbles (Batch - L5-A). Thank You Ryan Isbell

Relevant Test/Laboratory Data

1 of 4

Generated by: SYSTEM Generated on: 22-Jun-2022 02:16:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-49189 | Department: CFSAN | RCT No.: RCT-1024372 | CTU Triage Date: 22-Jun-2022 | Total Pages: 7

Test Name	ALKALINE PHOSPHATAS	Test Date	01-Jun-2022
Test Result	185	Test Unit	INTERNATIONAL UNITS
Low Test Range	40	High Test Range	PER LITRE
	10	Trigit rest range	100
More Information Available? elevant Test/Laboratory Data	<u> </u>		2 of 4
Test Name	BILIRUBIN TOTAL	To at Data	
rest Name	BILIRUBIN TOTAL	Test Date	01-Jun-2022
Test Result	2.80	Test Unit	MILLIGRAMS PER DECI
Low Test Range	0.10	High Test Range	1.10
More Information Available?			
elevant Test/Laboratory Data	3		3 of 4
Test Name	AST	Test Date	01-Jun-2022
Test Result	54	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	8	High Test Range	48
More Information Available?			
elevant Test/Laboratory Data			4 of 4
Test Name	ALT	Test Date	01-Jun-2022
Test Result	279	Test Unit	INTERNATIONAL UNITS
Low Test Range	7	High Test Range	PER LITRE
More Information Available?		1.1.9.1.1.00.1.1.0.1.90	
iviore information Available?			
dditional Comments			
This is only four. There are mo	re flagged tests results which I c	an produce.	
ection B - Product Availability	/		
Do you still have the product in case we need to evaluate it?	Yes		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes		
ection C - About the Products			1 of 1
Collon O Tibout line i Touluct	>		
Suspect	Yes		
Suspect	Yes		
Suspect Primary?	Yes Yes		

Generated by: SYSTEM Generated on: 22-Jun-2022 02:16:25 Page 2 of 5

appears on the box, bottle,

CTU No.: FDA-CDER-CTU-2022-49189 | Department: CFSAN | RCT No.: RCT-1024372 | CTU Triage Date: 22-Jun-2022 | Total Pages: 7

or package (Include as many names as you see)				
Name of the company that makes (or compounds) the roduct	Daily Harvest			
Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generi Biosimilar	or an Outsourcing Facility		
Strength		If Other		
NDC number				
Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Drug Therapy			1 of 1	
Expiration date	28-Sep-2022			
Lot number	L5-A			
Dosage Form				
Quantity		If Other		
Frequency	As needed	If Other		
How was it taken or used	Oral	If Other		
Date the person first started aking or using the product	26-May-2022			
Date the person stopped taking or using the product	01-Jun-2022			
Date the person reduced dose o he product	f			
Give best estimate of duration				
Is therapy still on-going?	Yes			
Why was the person using the p	roduct? (such as what co	ondition was it supposed to t	reat) 1 of 1	
Daily Harvest is a plant based m	eal delivery service.			
Returned to Manufacturer On				_
Section D - About the Medical D)evice			
Name of medical device				
Name of the company that makes the medical device				
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can ocate them)				

Generated by: SYSTEM Generated on: 22-Jun-2022 02:16:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49189 | Department: CFSAN | RCT No.: RCT-1024372 | CTU Triage Date: 22-Jun-2022 | Total Pag es: 7

	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast mplants, etc.)	
	ate the implant was put in		Date the implant was taken out (If	
			relevant)	
Se	ction E - About the Person Wh	o Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Male		
	Gender	Cisgender man/boy		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth	(b) (6)		
	Weight	72 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati	ve	
		Native Hawaiian or Other Pacif	ic Islander	
		Asian		
		White		
		Black or African American		
l is	t known medical conditions (S	uch as diabetes, high blo	od pre ure, cancer, heart disease, or others)	
LIO	none	don de diabetee, mgn bies	ou pro ure, carreer, meart disease, or extension	
Ple	ease list all allergies (such as t	o drugs foods pollon or	hers)	
FIE	none	o drugs, loods, poller or c	niers)	
	HOH			
			h as moking pregnancy alcohol use etc.)	

Generated by: SYSTEM Generated on: 22-Jun-2022 02:16:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49189 | Department: CFSAN | RCT No.: RCT-1024372 | CTU Triage Date: 22-Jun-2022 | Total Pages: 7

	does not drink alcohol. does not smoke. exercises regularly and eats healthy.	
Lis	st all current prescription medications and medical devices b ng used.	
	adderall for adhd	
Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
	vitamin D, biotin, multi-vitamin, fish oil supplement	
		<u> </u>

tion F - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	22-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Generated by: SYSTEM Generated on: 22-Jun-2022 02:16:25 Page 5 of 5

CTU No.: FDA-CDER-CTU- 22-49189 | Department: CFSAN | RCT No.: RCT-1024372 | CTU Triage Date: 22-Jun-2022 | Total Pag

SAUDS SEED AN IN THE RESERVE TO THE PARTY OF THE PARTY

rumble

CTU No.: FDA-CDER-CTU-2022-49244 | Department: CFSAN | RCT No.: RCT-1024427 | CTU Triage Date: 22-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details					
Company Unit	CDER-CTU	Originating Ac ount	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	22-Jun-2022	CTU Received Date	22-Jun-2022		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User	1			
User/Group					
Forward to Department					
Case Priority	Direct				

Contact	Contact					
Case	First Name	Last Name	Email Address	Phone		
Reporter						
	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
Section A - About the Problem						

5	Section A - About the Problem	
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product
		Had problems after switching from one product maker to another maker
	Date the problem oc urred	07-Jun-2022
	Serious	Yes
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

My experience seems to be related to the consumption of cooked Daily Harvest French Lentil and Leek Crumbles, which have recently been recalled. You may be aware that there are reports of people being hospitalized with liver problems after eating the product, and this happened to me. I received the crumbles in a delivery on 5/20, and kept them frozen until I prepared a pasta dish using them on the evening of 6/6/2022. I cooked th m thoroughly on high in an Instant Pot. The next day I experienced nausea and vomiting (initially dry heaving but as the day progressed was able to vomit some liquid). My urine color was a good bit darker than normal. Around 6pm I felt so nauseated that I decided to go to urgent care. They suggested I go to the ER. While at the ER I developed cognitive issues. (I struggled to explain why I was visiting the ER--I could utter a few words then I would give up.) My memory from this point is fuzzy. I also presented with yellowing skin. A metabolic panel was requested which revealed extremely low sodium levels and high liver-related levels. A head CT, abdomen CT, chest xray, and abdomen ultrasound were also ordered and all were normal. I spent about 24 hours in the ER, where I was given fluids and sodium. I was then admitted to the hospital for moni oring for an additional day. With treatment, my sodium levels returned to normal. My liver-related levels improved but remain d somewhat elevated at the time of my discharge. A week later at an appointment with my PCP my liver-related levels wer still elevated (AST, ALT and GGT). At the hospital doctor's recommendation and my PCP's I had an Upper Endoscopy performed 6/17/2022 which did not show any abnormalities other han relatively normal signs of acid reflux. While I was hospitalized, my doctors identified that my issues were all related to liver problems and low sodium, but they were unable to explain what might have caused those issues (through testing they

Generated by: SYSTEM Generated on: 22-Jun-2022 10:46:26 Page 1 of 6

 $CTU\ No.:\ FDA-CDER-CTU-2022-49244\ |\ Department:\ CFSAN\ |\ RCT\ No.:\ RCT-1024427\ |\ CTU\ Triage\ Date:\ 22-Jun-2022\ |\ Total\ Pag$

es: 6

liminated the most likely culprits, like hepatitis, gallstones, tick or parasite related illnesses, etc). They did mention that food poisoning might be a possibility. When I saw the reports today of the liver issues others experienced after eating the product, it med like this was a likely explanation for the issues I experienced. I do still have the crumbles on hand; please let me know f there's any other information I can provide. I have pictures of the product but am having difficulty uploading/saving the them.

R	elevant Test/Laboratory Data			1 of 5
	Test Name	BILIRUBIN	Test Date	07-Jun-2022
	Test Result	4.3	Test Unit	MILLIGRAMS PER DECIL ITRE
	Low Test Range	.2	High Test Range	1
	More Information Available?			
Re	elevant Test/Laboratory Data			2 of 5
	Test Name	ASPARTATE AMINO TRA NSF (AST/SGOT)	Test Date	07-Jun-2022
	Test Result	161	Test Unit	
	Low Test Range	13	High Test Range	39
	More Information Available?			
Re	elevant Test/Laboratory Data			3 of 5
	Test Name	ALANINE AMINOTRANSF ERASE (ALT/SGPT)	Test Date	07-Jun-2022
	Test Result	354	Test Unit	
	Low Test Range	7	High Test Range	52
	More Information Available?			
R	elevant Test/Laboratory Data			4 of 5
	Test Name	GAMMA GLUTAMYL TRA NSPEPTIDASE (GGT)	Test Date	09-Jun-2022
	Test Result	122	Test Unit	
	Low Test Range	9	High Test Range	64
	More Information Available?			
Re	elevant Test/Laboratory Data			5 of 5
	Test Name	SODIUM	Test Date	07-Jun-2022
	Test Result	116	Test Unit	MILLIMOLES PER LITRE
	Low Test Range	135	High Test Range	145
	More Information Available?			

Additional Comments

GGT, ALT, and AST test units were U/L

Section B - Product Availability

Generated by: SYSTEM Generated on: 22-Jun-2022 10:46:26 Page 2 of 6

CTU No.: FDA-CDER-CTU-2022-49244 | Department: CFSAN | RCT No.: RCT-1024427 | CTU Triage Date: 22-Jun-2022 | Total Pages: 6

	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes		,	
	Primary?	Yes			
	Туре	Drug/Biologi		_	
	This report is about	Food/Medical food		_	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Crumbles: French Lentil + L	eek		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date	10-Oct-2022		_	
	Lot number	L02-VEGBN			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
Wł	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to t	reat) 1 of 1	

Generated by: SYSTEM Generated on: 22-Jun-2022 10:46:26 Page 3 of 6

CTU No.: FDA-CDER-CTU-2022-49244 | Department: CFSAN | RCT No.: RCT-1024427 | CTU Triage Date: 22-Jun-2022 | Total Pages: 6

Returned to Manufacturer On								
Section D - About the Medical De	evice							
Name of medical device								
Name of the company that makes the medical device								
Other identifying information (The	ther identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can							
locate them)								
Model Number		_						
Catalog Number								
Lot Number								
Serial Number								
UDDI Number								
Expiration date								
Was someone operating the medical device when the problem oc urred?								
For implanted medical devices C	DNLY (such as pacemakers, breast mplants, etc.)							
Date the implant was put in	Date the implant was taken out (If							
	relevant)							
Section E - About the Person Wh								
Person's Initials	(b) (6)							
Sex	Male							
Gender	Cisgender man/boy							
Please Specify Other Gender								
Age (specify unit of time for age)								
Date of Birth	(b) (6)							
Weight	58.95 kg							
Ethnicity (Choose only one)	Not Hispanic/Latino							
Race (Check all that apply)	American Indian or Alaska Native							
	Native Hawaiian or Other Pacific Islander							
	Asian							
	White							
	☐ Black or African American	=						
List known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)							
Please list all allernies (such as t	to drugs, foods, pollen or o hers)							

Generated by: SYSTEM Generated on: 22-Jun-2022 10:46:26 Page 4 of 6

CTU No.: FDA-CDER-CTU-2022-49244 | Department: CFSAN | RCT No.: RCT-1024427 | CTU Triage Date: 22-Jun-2022 | Total Pages: 6

	Alpha gal (mammalian meat)	
Lis	st any other important information about the person (such as moking, pregnancy, alcohol use, etc.)	
	Nonsmoker Social alcohol consumption - 1-2 drinks per 1-2 weeks No drug use	
Lis	st all current prescription medications and medical devices b ng used.	
	Pantoprazole (prescribed during my hospitalization) EPINEPHrine 0.3 MG/0.3ML Injection Solution Auto-injector (for Alpha gal allergy)	
Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
	Daily vitamin (Vegan)	

tion F - About the Person Filli Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	22-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the	No

Generated by: SYSTEM Generated on: 22-Jun-2022 10:46:26 Page 5 of 6

CTU No.: FDA-CDER-CTU-2022-49244 | Department: CFSAN | RCT No.: RCT-1024427 | CTU Triage Date: 22-Jun-2022 | Total Pages: 6

manufacturer, please mark this box (Confidentiality Requested):

Generated by: SYSTEM Generated on: 22-Jun-2022 10:46:26 Page 6 of 6

CTU No.: FDA-CDER-CTU-2022-49419 | Department: GPSAN | RCT No. | RCT-1024597 | DTU Trage Date: 22-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	-2.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	22-Jun-2022	CTU Received Date	22-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	10	
User/Group			
Forward to Department			
Case Priority	Direct		

Case Reporter	First Name	Last Name	Email Address	Phone	
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)	
Section A	- About the Problem				
	nd of problem was it? all that apply)	Used a product incorrectly w	effect (including new or worsening sympto which could have or led to a problem quality of the product g from one product maker to another make		
Date th	e problem occurred	02-Jun-2022			
Serious		Yes			
(Check	of the following happen? all that apply)	and the same and t	rmanent harm dical incident(Please Describe Below)		
	hat happened and how onal documents if neces		as many details as possible F	DA may reach out to you for	
intense	Constitution of the contract o	R, liver labs high and lesion	n on liver on ultrasound. received es had problems.	email from daily harvest	

elevant Test/Laboratory Data			1 of 4
Test Name	AST	Test Date	02-Jun-2022
Test Result	245	Test Unit	
Low Test Range	8	High Test Range	34
More Information Available?			

Generated by: SYSTEM Generated on: 22-Jun-2022 14:46:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-49419 | Department: CFSAN | RCT No.: RCT-1024597 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

Relevant Test/Laboratory Data				2 of 4		
	Test Name	ALT	Test Date	02-Jun-2022		
	Test Result	263	Test Unit			
	Low Test Range	10	High Test Range	49		
	More Information Available?					
Re	elevant Test/Laboratory Data			3 of 4		
	Test Name	BILI TOTAL	Test Date	02-Jun-2022		
	Test Result	2.1	Test Unit			
	Low Test Range	.3	High Test Range	1.2		
	More Information Available?					
Re	elevant Test/Laboratory Data			4 of 4		
	Test Name	WHITE BLOOD CELL	Test Date	02-Jun-2022		
	Test Result	12.7	Test Unit			
	Low Test Range	4.5	High Test Range	11		
	More Information Available?					
Ad	lditional Comments					
Se	ection B - Product Availability					
	Do you still have the product in case we need to evaluate it?	No				
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No				
Se	ection C - About the Products			1 of 1		
00	Suspect	Yes		1 01 1		
	Primary?	Yes				
	Туре	Drug/Biologi				
	This report is about	Food/Medical food				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil & Leek Crumbles				
	Name of the company that makes (or compounds) the roduct	Daily Harvest				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility			

Generated by: SYSTEM Generated on: 22-Jun-2022 14:46:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49419 | Department: CFSAN | RCT No.: RCT-1024597 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	21-May-2022			
	Date the person stopped taking or using the product	02-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
W	hy was the person using the pr	oduct? (such as what cor	ndition was it supposed to t	reat) 1 of 1	
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that		-		_
	makes the medical device				_
Ot loc	her identifying information (The cate them)	e model, catalog, lot, seri	al, or UDI number, and the	expiration date, if you can	
	Model Number				_
	Catalog Number				
	Lot Number				
	Serial Number				_
	UDDI Number				
	Expiration date				
	l				_

Generated by: SYSTEM Generated on: 22-Jun-2022 14:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49419 | Department: CFSAN | RCT No.: RCT-1024597 | CTU Triage Date: 22-Jun-2022 | Total Pag es: 5

Was someone operating the medical device when the problem oc urred?			
For implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)	
Date the implant was put in		Date the implant was taken out (If relevant)	
Section E - About the Person Wh	no Had the Problem		
Person's Initials	(b) (6)		
Sex	Female		
Gender	Cisgender woman/girl		
Please Specify Other Gender			
Age (specify unit of time for age)	25 Year(s)		
Date of Birth			
Weight	60.75 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska Nat	ive	
	Native Hawaiian or Other Pacit	fic Islander	
	Asian		
	White		
	Black or African American		
List known medical conditions (S	uch as diabetes, high blo	od nre ure cancer heart disease	or others)
none	deri de diabetes, riigii bio	od pre dre, carreer, ricart disease	2, or ources)
Please list all allergies (such as t	o drugs, foods, pollen or (o hers)	
none			
List any other important informati	on about the person (suc	h as moking, pregnancy, alcohol	use, etc.)
nothing			
List all current prescription medic	cations and medical devic	es b ng used.	
Mirena IUD, acne topicals on face	e, omeprazole ER 20mg daily		
List all over-the-counter medication	ons and any vitamins, mi	neral , supplements, and herbal re	emedies being used.

Generated by: SYSTEM Generated on: 22-Jun-2022 14:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49419 | Department: CFSAN | RCT No.: RCT-1024597 | CTU Triage Date: 22-Jun-2022 | Total Pag es: 5

multivitamin gummies, align probiotics, fish oil supplement	

tion F - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	22-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 22-Jun-2022 14:46:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-49557 | Department: ISFSAN | RCT No.: RCT-1024726 | DTU Triage Date: 23-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Contact

Other serious/important medical incident(Please Describe Below)

Basic Details		200 (200 200 40	-2.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	22-Jun-2022	CTU Received Date	22-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Case Reporter	First Name	Last Name	Email Address	Phone	
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)	
Section A	- About the Problem	1	_		
	nd of problem was it? all that apply)	Used a product incorrectly v	effect (including new or worsening sympton which could have or led to a problem quality of the product g from one product maker to another maker		
Date the	e problem occurred	15-Jun-2022			
Serious	0	Yes			
	ан шас арргуу	Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Life-threatening Death			

4 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I ate a new product from Daily Harvest, called Crumbles - French Lentil & Leek, on June 15th and 16th, 2022. I cooked them according to instructions, and likely longer, I like things crispy. I ate a little more on the 16th than on the 15th. I didn't eat anything else with them on the 16th. After I ate them, on both nights, within 15 ? 30 min. I experienced a strange discomfort below the sternum and a little to my right. The pain was much worse on the 2nd night. I eat Daily Harvest bowl meals about 4 ? 6 times a week, for about 6 months. On June 17th, after getting up the pain became very uncomfortable. Finally I applied arnica pain cream to stop the pain. Around noon on the 17th I started not feeling well, like I was getting a fever. This feeling continued until I called the Dr. and went directly over to see him around 4:15 pm. He checked me over, but wasn't sure what could be causing my upper abdominal pain I had earlier, and my overall not feeling well. I went home and went to bed as I quickly started feeling worse. I had fever and chills, headache and backache. We have two doctors ? a husband & wife team. They ended up coming over to check on me. I tried to get up but hyperventilated, vomited, and broke a sweat, which broke the fever by the time the doctors arrived. They decided I needed to go to ER to get an ultrasound to check if I had a blockage or gallbladder issue. They did test me for Covid before I left, it was negative. While waiting in emergency waiting room, I again began to feel feverish, chilled, and my head and back hurt, worst pain I've ever had. And there we sat 5 hours before getting

Generated by: SYSTEM Generated on: 22-Jun-2022 23:46:36 Page 1 of 6

CTU No.: FDA-CDER-CTU-2022-49557 | Department: CFSAN | RCT No.: RCT-1024728 | CTU Triage Date: 23-Jun-2022 | Total Pag es: 6

a room. Once in ER, they ran lots of tests. The ER doctor said my liver enzymes are elevated. He did run tests for hepatitis A, B. & C. they were all negative. My urine sample was dark, but no infection. I finally got out of there around 7:45 am. The ER doctor just said take Tylenol for pain. I text my doctors that I'm home, and the results, and that ER doctor wants me to follow up with tests for my gallbladder and liver blood test. Around 3:00 pm I have another headache and elevated temperature. I ake 2 Tylenol and go to bed. I wake 2-1/2 hours later. My urin was still really dark...looks like someone dumped iodine into it! Went to bed around 11:00 pm but woke up at 3:00 am in pain all over, headache, probably a fever, and my back hurts. I ook two more Tylenol. Sunday June 19th I'm looking over my ema Is around 2:00 pm, and I see and email from Daily Harvest. They say they have consumer complaints of gastrointestinal pain from eating this product? Crumbles, French Lentil & Leek. It says throw them out and DO NOT EAT. This is exactly what I a I wonder if the complaints are same as mine? So I write to Daily Harvest and tell them I was ill. I call my doctors and tell them. I also reported to her, that I still am having headach ? seems like every 12 hours, and that I don't want to take Tylenol anymore, which she agreed. So I decided if I get anymore headaches I'd take aspirin. Sunday evening around 9:00 pm, I ge another headache. Monday June 20th? No appetite, urine is still dark and I get a headache again around 9:00 pm. Tuesday June 21st ? around 2:00 pm, I start to feel very itchy around my scalp and neck. That evening I the soles of my feet b gan to itch. And then my palms of hands started itching. Wednesday ? I wake up and my palms and feet are itching. Wednesday afternoon my torso starts itching, front and back. I text my doctor about the itching, she says elevated liver enzymes might be the cause. There is no apparent rash anywhere, but my kin gets red immediately after scratching. By evening my body hes everywhere, and I feel the heat and inflammation where I've scratched. Will contact the doctor again in the morning about the itching.

Relevant Test/Laboratory Data			1 of 5
Test Name	TOTAL BILIRUBIN	Test Date	17-Jun-2022
Test Result	1.6	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	.2	High Test Range	1.3
More Information Available?			
Relevant Test/Laboratory Data			2 of 5
Test Name	ASPARTATE AMINO	Test Date	17-Jun-2022
Test Result	400	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	16	High Test Range	43
More Information Available?			
Relevant Test/Laboratory Data			3 of 5
Test Name	ALANINE AMINOTRANSF ERASE (ALT/SGPT)	Test Date	17-Jun-2022
Test Result	499	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	35	High Test Range	
More Information Available?			
Relevant Test/Laboratory Data			4 of 5
Test Name	ALKALINE PHOSPHATAS E	Test Date	17-Jun-2022
Test Result	154	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	38	High Test Range	126
More Information Available?			
Relevant Test/Laboratory Data			5 of 5
Test Name	URINE UROBILINOGEN	Test Date	17-Jun-2022
Test Result	1.0	Test Unit	MILLIGRAMS PER DECIL ITRE

Generated by: SYSTEM Generated on: 22-Jun-2022 23:46:36 Page 2 of 6

CTU No.: FDA-CDER-CTU-2022-49557 | Department: CFSAN | RCT No.: RCT-1024728 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

	Low Test Range	.2	High Test Range	1.0	
	More Information Available?				
Ad	ditional Comments				
	There were other Urine tests that	were at the high level. Urine l	Ketones 2+ H; s/b negative Urine	Acetest 2+ H; s/b negative.	
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are	Yes No			
	ncluding a picture)				
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Crumbles French Lentil & L	eek		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	23-Oct-2022			
	Lot number	L5-A 08:18			
	Dosage Form				
	Quantity	Other	If Other	4 Ounce(s)	
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	15-Jun-2022	,		

Generated by: SYSTEM Generated on: 22-Jun-2022 23:46:36 Page 3 of 6

CTU No.: FDA-CDER-CTU-2022-49557 | Department: CFSAN | RCT No.: RCT-1024728 | CTU Triage Date: 23-Jun-2022 | Total Pag es: 6

	Date the person stopped taking or using the product	16-Jun-2022		
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?	Yes		
W	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to treat) 1 of 1
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot	her identifying information (The	e model, catalog, lot, seri	al, or UDI number, and the expi	iration date, if you can
IOC	cate them)			
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Not selected		
	Please Specify Other Gender			
	Age (specify unit of time for age)	62 Year(s)		
	Date of Birth			
	Weight	85.5 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nat		

Generated by: SYSTEM Generated on: 22-Jun-2022 23:46:36 Page 4 of 6

CTU No.: FDA-CDER-CTU-2022-49557 | Department: CFSAN | RCT No.: RCT-1024728 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

		Asian White Black or African American	
Lis	t known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	none		
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	Tylenol & Codiene #3; and sulfa o		
Lis	t any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
	none		
Lis	t all current prescription medic	cations and medical devices b ng used.	
	none		
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
	Vitamin D3, Slippery Elm Bark, O	mega 3, zinc.	
Se	ction F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	

Generated by: SYSTEM Generated on: 22-Jun-2022 23:46:36 Page 5 of 6

CTU No.: FDA-CDER-CTU-2022-49557 | Department: CFSAN | RCT No.: RCT-1024728 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	22-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 22-Jun-2022 23:46:36 Page 6 of 6

CTU No.: FDA-CDER-CTU-2022-49471 | Department: CFSAN | RCT No.: RCT-10747 II/ 10TH Triage Date: 22-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200 (200 200 10	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	22-Jun-2022	CTU Received Date	22-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem			
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker		
Date the problem occurred	17-Jun-2022		
Serious	Yes		
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I ate French Lentil & Leek Crumbles from the company Daily Harvest a couple times between 6/6 and 6/6. On 6/17, started feeling itchy all over my body without any sign of rash, noticed dark urine, nausea and fatigue. Went to urgent care on 6/20. Urinalysis, blood work, and abdomen ultrasound were performed that day. There were high levels of billirubin in my blood and the diagnosis was Transaminitis. I was told that I need to get Hepatitis and Liver Panel tests from my primary care doctor. On 6/22, I had a primary care doctor visit and completed more blood tests, including hepatitis testing. Waiting for my results to come back, but I am still experiencing itchiness, dark urine, and fatigue.

elevant Test/Laboratory	Data		1 of 3
Test Name	TOTAL BILLIRUBIN	Test Date	20-Jun-2022
Test Result	3.2	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	0.3	High Test Range	1.2

Generated by: SYSTEM Generated on: 22-Jun-2022 21:16:29 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-49471 | Department: CFSAN | RCT No.: RCT-1024716 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

					_
	More Information Available?				
Re	elevant Test/Laboratory Data			2 of 3	
	Test Name	ALT (SGPT)	Test Date	20-Jun-2022	
	Test Result	224.0 U/L	Test Unit	UNKNOWN	
	Low Test Range	5.0 U/L	High Test Range	30.0 U/L	
	More Information Available?				
Re	elevant Test/Laboratory Data			3 of 3	
	Test Name	AST (SGOT)	Test Date	20-Jun-2022	
	Test Result	73.0	Test Unit	UNKNOWN	
	Low Test Range	7.0 U/L	High Test Range	31.0 U/L	
	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil and Leek Crui	mbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			

Generated by: SYSTEM Generated on: 22-Jun-2022 21:16:29 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49471 | Department: CFSAN | RCT No.: RCT-1024716 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

Did the problem return if the	Doesn't Apply				
rson started taking or using the roduct again?					
Drug Therapy			1 of 1		
Expiration date					
Lot number					
Dosage Form					
Quantity		If Other			
Frequency		If Other			
How was it taken or used	Oral	If Other			
Date the person first started aking or using the product	06-Jun-2022				
Date the person stopped taking or using the product	16-Jun-2022				
Date the person reduced dose o he product	f				
Give best estimate of duration					
Is therapy still on-going?					
Why was the person using the p	product? (such as what	condition was it suppos	ed to treat) 1 of 1		
Returned to Manufacturer On					
Section D - About the Medical D)evice				
Name of medical device					
Name of the company that makes the medical device					
Other identifying information (The locate them)	ne model, catalog, lot, s	serial, or UDI number, ar	nd the expiration date, if you can		
Model Number					
Catalog Number					
Lot Number					
Serial Number					
UDDI Number					
Expiration date					
Was someone operating the medical device when the probler oc urred?					
or implanted medical devices ONLY (such as pacemakers, breast mplants, etc.)					
For implanted medical devices		akers, breast mplants, e	tc.)		

Generated by: SYSTEM Generated on: 22-Jun-2022 21:16:29 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49471 | Department: CFSAN | RCT No.: RCT-1024716 | CTU Triage Date: 22-Jun-2022 | Total Pag es: 5

Se	ction E - About the Person Wh	o Had the Problem	
	Person's Initials	NA	Т
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)	36 Year(s)	T
	Date of Birth		
	Weight	61.2 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	t any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	t all current prescription medic	cations and medical devices b ng used.	
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
Se	ction F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	T
	Reporter is Patient?		T

Generated by: SYSTEM Generated on: 22-Jun-2022 21:16:29 Page 4 of 5

FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-49471 | Department: CFSAN | RCT No.: RCT-1024716 | CTU Triage Date: 22-Jun-2022 | Total Pag es: 5

Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	22-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 22-Jun-2022 21:16:29 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-49183 | Department: GPSAN | RCT No.: RCT-1024367 | DTU Trage Date: 22-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		2.00	12.22		
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine	- 1			
Override Auto Calculation Rule	No				
FDA Received Date	22-Jun-2022	CTU Received Date	22-Jun-2022		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User	16			
User/Group					
Forward to Department					
Case Priority	Direct	14-304			

Contact	20 L 2	2011	-	
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem			
What kind of problem was it? (Check all that apply) Date the problem occurred Serious		Used a product incorrectly v	effect (including new or worsening sympto which could have or led to a problem quality of the product g from one product maker to another make	_
		23-May-2022		
		Yes		
	y of the following happen?	Hospitalization - admitted or	stayed longer	

Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)		

4 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Liver disfunction following consumption of Daily Harvest product/s

levant Test/Laborato	ry Data		1 of 1
Test Name	HEPATIC FUNCTION PAN	Test Date	01-Jun-2022
Test Result	142 U/L	Test Unit	

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-49183 | Department: CFSAN | RCT No.: RCT-1024367 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

	Low Test Range	10	High Test Range	49	
	More Information Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it? Do you have a picture of the	Yes			
	roduct? (check yes if you are ncluding a picture)				
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek			
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date	23-Oct-2022			
	Lot number	L5-A			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started				

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49183 | Department: CFSAN | RCT No.: RCT-1024367 | CTU Triage Date: 22-Jun-2022 | Total Pag es: 5

	Date the person stopped taking or using the product				
	Date the person reduced dose of he product	_			
	Give best estimate of duration				
	Is therapy still on-going?				
W	hy was the person using the pr	oduct? (such as what cond	lition was it supposed to trea	t) 1 of 1	
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				_
	Name of the company that makes the medical device	_			
	her identifying information (The	e model, catalog, lot, serial	, or UDI number, and the exp	iration date, if you can	
loc	cate them)				
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemakers	, breast mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection E - About the Person Wh	o Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Not selected			
	Please Specify Other Gender				
	Age (specify unit of time for age)	_			
	Date of Birth				
	Weight				
	Ethnicity (Choose only one)				
	Race (Check all that apply)	American Indian or Alaska Native			

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49183 | Department: CFSAN | RCT No.: RCT-1024367 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

		Asian	
		White	
		Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	st any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
	, , , , , , , , , , , , , , , , , , ,		T
Lis	st all current prescription medic	ations and medical devices b ng used.	
			T
Lis	st all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
Se	ection F - About the Person Fill		<u> </u>
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street		
	City	(b) (6)	
	State/Province	(6) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49183 | Department: CFSAN | RCT No.: RCT-1024367 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	22-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-49182 | Department: GFSAN | RCT No.: RCT-1024366 | DTU Trage Date: 22-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details				
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine	Routine		
Override Auto Calculation Rule	No			
FDA Received Date	22-Jun-2022	CTU Received Date	22-Jun-2022	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department				
Case Priority	Direct			

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem			
	nd of problem was it? all that apply)	Used a product incorrectly w	effect (including new or worsening sympto hich could have or led to a problem quality of the product g from one product maker to another make	
Date th	e problem occurred	23-May-2022		
Serious		Yes		
(Check	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important med		
	erious/important medical (Please Describe Below)			
4.Tell us v any additi	vhat happened and how onal documents if neces	rit happened (Include ક sary)	as many details as possible F	DA may reach out to you for
Liver fu	nction decline following Dai	ly Harvest consumption		

elevant Test/Laborato	ry Data		1 of 1
Test Name	HEPATIC FUNCTION PAN	Test Date	01-Jun-2022
Test Result	142 U/L	Test Unit	1,

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-49182 | Department: CFSAN | RCT No.: RCT-1024366 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

	Low Test Range	10	High Test Range	49	
	More Information Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it? Do you have a picture of the	Yes No			
	roduct? (check yes if you are ncluding a picture)				
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek			
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Doesn © Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	23-Oct-2022			
	Lot number	L5-A			
	Dosage Form		[
	' uantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started				

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49182 | Department: CFSAN | RCT No.: RCT-1024366 | CTU Triage Date: 22-Jun-2022 | Total Pag es: 5

	Date the person stopped taking or using the product			
	Date the person reduced dose of he product			
	Give best estimate of duration	3 Month		
	Is therapy still on-going?			
WI	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to treat	t) 1 of 1
	Food			
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that			
Ot	makes the medical device	a model catalog let seri	al, or UDI number, and the exp	iration data, if you can
loc	cate them)	e moder, catalog, lot, sem	ai, or obt number, and the exp	iralion date, ir you can
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the			
	medical device when the problem oc urred?			
Fο	r implanted medical devices O	NI V (such as nacemake	rs hreast mnlants etc \	
	ate the implant was put in	14ET (Suoit as pasemake	Date the implant was taken out (If	:
			relevant)	
Se	ection E - About the Person Wh	o Had the Problem		
	Person@ Initials	Unspecified		
	Sex	Female		
	Gender	Not selected		
	Please Specify Other Gender			
	Age (specify unit of time for age)	41 Year(s)		
	Date of Birth			
	Weight			
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nat	tive	
		Native Hawaiian or Other Paci		

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49182 | Department: CFSAN | RCT No.: RCT-1024366 | CTU Triage Date: 22-Jun-2022 | Total Pages: 5

		Asian	
		White	
		Black or African American	=
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	st any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	ations and medical devices b ng used.	
Lis	st all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
Ca	otion F. About the Daveen Filli	na Out This Forms	
SE	ction F - About the Person Filli Primary?	ng Out This Form 1 of 1 Yes	
	Reporter is Patient?	165	
	Title		_
	Last name	(b) (6)	_
	Middle Name		
	First name	(b) (6)	_
	Number/Street		_
	City State/Province	(b) (6)	_
			_
	Country	UNITED STATES (b) (6)	
	ZIP or Postal code		_
	Telephone number	(b) (6)	_
	Email address	(b) (6)	

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49182 | Department: CFSAN | RCT No.: RCT-1024366 | CTU Triage Date: 22-Jun-2022 | Total Pag es: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today@ date	22-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 22-Jun-2022 00:46:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-49675 | Department: CFSAN | RCT No.: RCT-1024851 | CTU Triage Date: 23-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Company Unit CDER-CTU Originating Ac ount FAERS Source Medium MWO (Drug) Source Form Type E2B XML 35 Priority Routine Override Auto Calculation Rule No	00B
Priority Routine	00B
Override Auto Calculation Rule No	
FDA Received Date 23-Jun-2022 CTU Received Date 23-Jun-2022	
CTU Triage Date CTU Data Entry Date	
Report Type Spontaneous Report Classification Drug	
Assign To User	
User/Group	
Forward to Department	
Case Priority Direct	
Contact	
Case First Name Last Name Email Address Phone Reporter	
(b) (6) (b) (6)	
Section A - About the Problem	
What kind of problem was it? (Check all that apply) Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker Date the problem oc urred 19-Jun-2022 Serious Pes Did any of the following happen? (Check all that apply) Hospitalization - admitted or stayed longer (Check all that apply) Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below) 4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out any additional documents if necessary) Severe right upper quadrant abdominal pain Suspected adverse reaction to daily harvest French lentil crumble	to you for
Relevant Test/Laboratory Data	1 of 4
Test Name CT SCAN Test Date 19-Jun-2022	
Test Result Negative Test Unit	
Low Test Range High Test Range	

Generated by: SYSTEM Generated on: 23-Jun-2022 11:16:26 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-49675 | Department: CFSAN | RCT No.: RCT-1024851 | CTU Triage Date: 23-Jun-2022 | Total Pages: 5

Rε	elevant Test/Laboratory Data			2 of 4
	Test Name	ULTRASOUND	Test Date	19-Jun-2022
	Test Result	Negative	Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			
Re	elevant Test/Laboratory Data			3 of 4
	Test Name	METABOLIC PANEL	Test Date	19-Jun-2022
	Test Result	Normal	Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			
Re	elevant Test/Laboratory Data			4 of 4
	Test Name	CBC	Test Date	19-Jun-2022
	Test Result	Normal	Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			
Αc	Iditional Comments			
Se	ection B - Product Availability			
	Do you still have the product in case we need to evaluate it?	No		
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Se	ection C - About the Products			1 of 1
	Suspect	Yes		1011
	Primary?	Yes		
	Туре	Drug/Biologi		
	This report is about	Food/Medical food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French lentil and leek crum	ble	
	Name of the company that makes (or compounds) the roduct	Daily harvest		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility	

Generated by: SYSTEM Generated on: 23-Jun-2022 11:16:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49675 | Department: CFSAN | RCT No.: RCT-1024851 | CTU Triage Date: 23-Jun-2022 | Total Pages: 5

Strength NDC number Did the problem stop after the rson reduced the dose or opped taking or using the roduct? Did the problem return if the rson started taking or using the roduct again? Drug Therapy Expiration date Lot number Dosage Form Quantity If Other Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat)	1 of 1
Did the problem stop after the rson reduced the dose or opped taking or using the roduct? Did the problem return if the rson started taking or using the roduct again? Drug Therapy Expiration date Lot number Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	1 of 1
rson started taking or using the roduct again? Drug Therapy Expiration date Lot number Dosage Form Quantity If Other Frequency How was it taken or used Date the person first started aking or using the product Date the person reduced dose of he product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	1 of 1
Expiration date Lot number Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	1 of 1
Lot number Dosage Form Quantity If Other Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	
Dosage Form Quantity If Other Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	
Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	
Frequency How was it taken or used If Other Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	
How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	
Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	
aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	
or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	
he product Give best estimate of duration Is therapy still on-going?	
Is therapy still on-going?	
Why was the person using the product? (such as what condition was it supposed to treat)	
	to treat) 1 of 1
Returned to Manufacturer On	
Section D - About the Medical Device Name of medical device	
Name of the company that makes the medical device	
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration locate them)	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration locate them)	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration locate them) Model Number	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration locate them) Model Number Catalog Number	he expiration date, if you can
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expirate locate them) Model Number Catalog Number Lot Number	the expiration date, if you can

Generated by: SYSTEM Generated on: 23-Jun-2022 11:16:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49675 | Department: CFSAN | RCT No.: RCT-1024851 | CTU Triage Date: 23-Jun-2022 | Total Pages: 5

Was someone operating the medical device when the problem oc urred?			
For implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)	
Date the implant was put in		Date the implant was taken out (If relevant)	
Section E - About the Person Wh	no Had the Problem		
Person's Initials	(b) (6)		
Sex	Male		
Gender	Cisgender man/boy		
Please Specify Other Gender			
Age (specify unit of time for age)	57 Year(s)		
Date of Birth			
Weight	85.5 kg		
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska Nat	ive	
	Native Hawaiian or Other Pacit	fic Islander	
	Asian		
	White		
	Black or African American		
List known medical conditions (S	uch as diabotos, bigh blo	ad pro ura capcar boart discass	or others)
List Kilowii Medical conditions (o	dell as diabetes, flight blo	od pre dre, caricer, neart disease	s, or others)
Please list all allergies (such as t	o drugs, foods, pollen or o	o hers)	
Lactose intolerance			
List any other important informati	on about the person (suc	h as moking, pregnancy, alcohol	use, etc.)
List all current prescription medic	ations and medical devic	es b ng used.	
List all over-the-counter medication	ons and any vitamins, mi	neral , supplements, and herbal re	emedies being used.

Generated by: SYSTEM Generated on: 23-Jun-2022 11:16:26 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49675 | Department: CFSAN | RCT No.: RCT-1024851 | CTU Triage Date: 23-Jun-2022 | Total Pag es: 5

	$\overline{}$
	=

tion F - About the Person Filli	
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(5) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	23-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 23-Jun-2022 11:16:26 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-49817 | Department: CFSAN | RCT No.: RCT-1025083 | CTU Triage Date: 23-Jun-2022 | Total Pag

Low Test Range

	isic Detai	red in the report are in EST(G	VI I -05.	.00) time zone			
	ompany U		CDF	ER-CTU	Origi	nating Ac ount	FAERS
-	ource Med			O (Drug)		ce Form Type	E2B XML 3500B
-	riority	idili	Rou	, -,	Oodi	oc i dilli i ype	LEB ANIL GOOD
-	-	to Calculation Rule	No				
	DA Receiv			Jun-2022	CTU	Received Date	23-Jun-2022
-	TU Triage			7411 2022		Data Entry Date	20 0411 2022
-	eport Type		Sno	ntaneous		rt Classification	Drug
	ssign To	,	Use		, topo	Tr Gladomoditori	Diag
-	ser/Group			-			
		Department	\square				
	ase Priorit	·	Dire				
	430 1 110110	y	Dire				
Cc	ntact						
=	ase	First Name		Last Name		Email Address	Phone
Re	eporter	a > (2)		(1.) (2.)		a > (2)	(1) (2)
∇	3	(b) (6)		(b) (6)		(b) (6)	(b) (6)
Se	ction A -	About the Problem					
		d of problem was it?	۷	Vere hurt or had a bad side eff	fect (incl	uding new or worsening symptoms)	
	(Check a	ill that apply)		Jsed a product incorrectly which			
				Noticed a problem with the qua	lity of th	e product	
				Had problems after switching fr	rom one	product maker to another maker	
	Date the	problem oc urred	24-J	Jan-2021			
	Serious		Yes				
	_	of the following happen?		Hospitalization - admitted or sta	ayed lon	ger	
	(Check a	ıll that apply)		Required help to prevent perma	anent ha	rm	
				Disability or health problem			
				Birth defect			
			片	ife-threatening			
				Death			
	Other se	rious/important medical	MT (Other serious/important medica	al incider	nt(Please Describe Below)	
		Please Describe Below)					
4.∃ an	Fell us wl y additio	nat happened and how nal documents if nece	v it h ssar	appened (Include as y)	many	de ails as possible FDA	may reach out to you for
						til Topping. I ordered two deliv	
						penterologist and had an ultra oping but had a few other of tl	
		e had a gallbladder attac					
Re	elevant T	est/Laboratory Data					1 of 1
	Test Nar	ne			Test	Date	
	Test Res	-			Test		
_							

Generated by: SYSTEM Generated on: 23-Jun-2022 17:46:34 Page 1 of 5

High Test Range

CTU No.: FDA-CDER-CTU-2022-49817 | Department: CFSAN | RCT No.: RCT-1025083 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest			
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength	Biosimilai	If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number	_			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	09-Jan-2021			
	Date the person stopped taking or using the product	22-Jan-2021			

Generated by: SYSTEM Generated on: 23-Jun-2022 17:46:34 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49817 | Department: CFSAN | RCT No.: RCT-1025083 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

	Date the person reduced dose of he product				
_	Give best estimate of duration				
	Is therapy still on-going?				
W		l oduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
	Food item	(
_					_
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that				
	makes the medical device				
Ot	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expira	tion date, if you can	
100	cate them)	<u> </u>			
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem				
	oc urred?				
Fc	r implanted medical devices O	NI Y (such as nacemake	rs breast molants etc.)		
_	ate the implant was put in	1121 (Suoit as pacemake	Date the implant was taken out (If		
			relevant)		
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Male			
	Gender	Cisgender man/boy			
	Please Specify Other Gender				
_	Age (specify unit of time for age)	45 Year(s)			
	Date of Birth				
	Weight	102.6 kg			_
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)				
	(One on that apply)	American Indian or Alaska Nat			
		Native Hawaiian or Other Pacit	tic Islander		
l		│			

Generated by: SYSTEM Generated on: 23-Jun-2022 17:46:34 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49817 | Department: CFSAN | RCT No.: RCT-1025083 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

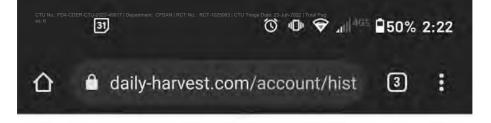
		White Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	High Blood Pressure (controlled)		
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	st any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	cations and medical devices b ng used.	
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
IC -	otion F. About the Domes Fill	in a Cout Thire Forms	
<u> </u>	ection F - About the Person Fill Primary?	ing Out This Form 1 of 1 Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	1

Generated by: SYSTEM Generated on: 23-Jun-2022 17:46:34 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49817 | Department: CFSAN | RCT No.: RCT-1025083 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	23-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 23-Jun-2022 17:46:34 Page 5 of 5





ORDER HISTORY

ORDER #S-52833924

DELIVERY DATE January 19th 2021

STATUS DATE Delivered

TOTAL \$97.88

MORE INFO Details

ORDER #S1-52503877

DELIVERY DATE January 13th 2021

STATUS DATE Delivered

TOTAL \$78.86

MORE INFO Details





CTU No.: FDA-CDER-CTU-2022-49823 | Department: CFSAN | RCT No.: RCT-1025105 | CTU Triage Date: 23-Jun-2022 | Total Pag

Basic Detai	ls			
Company U	nit	CDER-CTU	Originating Ac ount	FAERS
Source Med	ium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority		Routine	-	
Override Au	to Calculation Rule	No		
FDA Receiv	ed Date	23-Jun-2022	CTU Received Date	23-Jun-2022
CTU Triage	Date		CTU Data Entry Date	
Report Type	;	Spontaneous	Report Classification	Drug
Assign To		User		
User/Group				
Forward to [Department			
Case Priority	у	Direct		
Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Z	(b) (6)	(b) (6)	(b) (6)	(b) (6)
	T INFORMATION			
_	T INFORMATION dentifier (In Confidence)	(b) (6)		
	dentiner (in Confidence)	39 Year(s)		
Age Date of E	Rinth	39 Tear(s)		
Sex	סוונוו	Male		
Gender		Cisgender man/boy		
	Specify Other Gender	Cisgerider man/bog	<u> </u>	
Weight	bpecify Other Gender	75.6 kg		
_	(Check single best	_		
answer)	(Check single best	Not Hispanic/Latino	5	
Race (Cl	neck all that apply)	Asian		
		American Indian or	Alaska Native	
		Black or African Am	nerican	
		White		
		Native Hawaiian or	Other Pacific Islander	
. ADVERS	SE EVENT, PRODUC	T PROBLEM		
Type of F	Report (check all that	Adverse Event		
apply)		Product Use/Medica	ation Error	
			.g., defects/malfunctions)	
			ent Manufacturer of Same Medicine	
Serious		Yes		
Outcome	Attributed to Adverse	Death		
Event (C	heck all that apply)	Life Threatening		
			al ar aralangad\	
		Hospitalization (initi	al or prolonged)	
		Other Serious or Im	portant Medical Events	

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:30 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-49823 | Department: CFSAN | RCT No.: RCT-1025105 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

		Congenital Anomaly/Birth Defe	cts	
	D ((D ()	Required Intervention to Preve	nt Permanent Impairment/Damage	
	Date of Death	00 1 0000		
	Date of Event	03-Jun-2022		
	Date of this Report	23-Jun-2022		
De	escribe Event, Problem or Prod			
	Symptoms started several days por No fevers. Did have jaundice. Lab was 1.5. Rest of CMP was normal B and C. He did have rats remove experienced similar symptoms, but	rior to his appointment. Symp is showed elevated transamir I. CK was normal. CBC was r ad from her house recently, so it more severe. Her labs show tarvest French Leek and Lent	a acute hepatitis, that was initially dia tom consisted of mild epigastric pai hase with Alk phos at 245, AST at 8 hormal. Acute hepatitis panel was ne to a Hantavirus IgG/IgM was checked wed an acute hepatitis also but all ot iils, he did recall eating it recently. H lat this time.	n. No nausea. No diarrhea. 6 and ALT at 279. Biliruin egative for viral hepatitis A, I, which was negative. Wife her labs were normal. Once
Re	elevant Test/Laboratory Data			1 of 4
	Test Name	ALKALINE PHOSPHATAS E	Test Date	03-Jun-2022
	Test Result	245	Test Unit	UNITS
	Low Test Range	36	High Test Range	130
	More Information Available?			
Re	elevant Test/Laboratory Data			2 of 4
	Test Name	AST	Test Date	03-Jun-2022
	Test Result	86	Test Unit	UNITS
	Low Test Range	10	High Test Range	40
	More Information Available?			
Re	levant Test/Laboratory Data			3 of 4
	Test Name	ALT	Test Date	03-Jun-2022
	Test Result	279	Test Unit	UNITS
	Low Test Range	9	High Test Range	46
	More Information Available?			
Re	elevant Test/Laboratory Data			4 of 4
	Test Name	BILIRUBIN, TOTAL	Test Date	03-Jun-2022
	Test Result	1.5	Test Unit	MILLIGRAMS PER DECIL ITRE
	Low Test Range	0.2	High Test Range	1.2
	More Information Available?			
Ad	ditional Comments			

Other Relevant History, Including Preexisting Medical Condition

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:30 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49823 | Department: CFSAN | RCT No.: RCT-1025105 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

He does have a seizure disorder. medical issues or medications. Si			1 were normal. He has no other	
C. PRODUCT AVAILABILITY				
Product Available for Evaluation? (Do not send product to FDA)	Yes			
Returned to Manufacturer on				
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
D. PRODUCT(S)			1 of 1	
Suspect	Yes			
Primary?	Yes	_		
Туре	Drug/Biologi			
This report involves:	Food/Medical food		-	
Name,Strength,Manufacturer/Co	mpounder (from product	label)		
Product Name	French Leek and Lentils C	rumbles		
Strength		If Other		
Manufacturer/Compounder	Daily Harvest		,	
NDC# or Unique ID				
Product Type(check all that apply)	OTC Compounded Generi Biosimilar			
Event Abated After Use Stopped or Dose Reduced?	Yes			
Event Reappeared after Reintroduction ?	Doesn't Apply			
Drug Therapy			1 of 1	
Dose or Amount		If Other		
Frequency		If Other		
Route		If Other		
Dosage Form				
Start				
Stop		_		
Dose Reduced		_		
Therapy Duration		If Other		
Is therapy still on-going?			J	
Lot Number				
Expiration Date				
Diagnosis for Use (indication)			1 of 1	

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:30 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49823 | Department: CFSAN | RCT No.: RCT-1025105 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

F	SUSPECT MEDICAL DEVICE		
<u></u>	Brand Name		
	Common Device Name		
	Procode		
	Manufacturer Name		
	City		
	State		
	Model #		
	Lot #		_
	Catalog #		
	Expiration Date		
	Serial #		
	Unique Identifier (UDI)#		
	Operator of Device	Health Professional	
		Patient/Consumer	
		Other	
	Other		
	If Implanted, Give Date		
	If Explanted, Give Date		
	Is this a single-use device that was reprocessed and reused on a patient?		
	If Yes for the above field, Enter Name and Address of Reprocessor		
	Was this device serviced by a hird party?		
F.	OTHER (CONCOMITANT) ME	EDICAL PRODUCTS	
	CONCOMITANT MEDICAL PRODI		
G.	REPORTER	1 of 1	
<u> </u>	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last Name	(b) (6)	
	Middle Name		_
	First Name	(b) (6)	_

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:30 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49823 | Department: CFSAN | RCT No.: RCT-1025105 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

Address	(b) (6)			
City	(b) (6)			
State/Province/Region	(b) (6)			
Country	UNITED STATES	If Other		
ZIP/Postal Code	(b) (6)		,	
Phone	(b) (6)			
Email	(b) (6)			
Fax				
Reporter Organization				
Department				
Reporter Speciality				
Health Professional?	Yes			
Oc upation	Physician	If Other		
Also Reported to	Manufacturer/Comp	ounder	,	
	User Facility			
	Distributor/Importer			
If you do NOT want your identity disclosed to the manufacturer	No			

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:30 Page 5 of 5

CRUMBLES

Toss in a tortilla. Crumble on top of a Flatbread. Serve a lettuce wrap. Layer into lasagna. Upgrade you ppy Jops. Dare we say stuff into an empanar e French Bentil + Leek Crumbles truly work in an ang. Oh, don't forget to add into your ch Or even hepherd's pie. We could go on.

CTU No.: FDA-CDER-CTU-2022-49824 | Department: CFSAN | RCT No.: RCT-1025104 | CTU Triage Date: 23-Jun-2022 | Total Pag

	ails			
Company	Unit	CDER-CTU	Originating Ac ount	FAERS
Source Me	edium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority		Routine		
Override A	uto Calculation Rule	No		
FDA Rece	ived Date	23-Jun-2022	CTU Received Date	23-Jun-2022
CTU Triag	e Date		CTU Data Entry Date	
Report Typ	ре	Spontaneous	Report Classification	Drug
Assign To		User		
User/Grou	р			
Forward to	Department			
Case Prior	ity	Direct		
Contact				
Case	First Name	Last Name	Email Address	Phone
Reporter	(b) (6)	(b) (6)	(b) (6)	(b) (6)
✓			(8) (6)	(6) (6)
. PATIEI	NT INFORMATION			
Patient	Identifier (In Confidence)	(b) (6)		
Age		34 Year(s)		
Date of	Birth			
Sex		Female		
Gende	•	Cisgender woman/gir	I	_
Please	Specify Other Gender			
Weight		57.6 kg		
	y (Check single best	Not Hispanic/Latino		
Race (Check all that apply)	Asian		
		American Indian or Ala	ska Native	
		Black or African Americ	can	
		White		
		Native Hawaiian or Oth	er Pacific Islander	
. ADVE	RSE EVENT, PRODUC	T PROBLEM		
Type o	f Report (check all that	Adverse Event		
apply)		Product Use/Medication	n Error	
		Product Problem (e.g.,		
			Manufacturer of Same Medicine	
Serious	3	Yes		
	ne Attributed to Adverse	Death		
Event (Check all that apply)	Life Threatening		
		Hospitalization (initial o	r prolonged)	
		Other Serious or Impor		

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:22 Page 1 of 5

Disability or Permanent Damage

CTU No.: FDA-CDER-CTU-2022-49824 | Department: CFSAN | RCT No.: RCT-1025104 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

	Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage	
Date of Death		
Date of Event	23-May-2022	
Date of this Report	23-Jun-2022	

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: She suffered an acute hepatitis, that was initially diagnosed on 5/23/2022. Symptoms started 4 days prior to her appointment. Symptoms cons dof severe epigastric pain that radiated to her back. Had nausea but no vomiting. Had loose stools. No fevers. No jaundice. Had arthralgias. Labs showed elevated transaminases with Alk phos at 214, AST at 402 and ALT at 509. Rest of CMP wa normal. Lipase was normal. CBC was normal. Liver US didnlkshow any gallstones. Liver and gallbladder appeared normal. Followup labs a week later showed almost normal ransaminases. Acute hepatitis panel was negative for viral hepatitis A, B and C. Celiac panel is negative. CK is normal. Ceruloplasmin is normal. Alpha-1-Antitrypsin is normal. ANA is negative. Ferritin and iron panel is normal. TSH is normal. She did have rats removed from her house recently, so a Hantavirus IgG was checked, which was negative. She did go to the ER twice due to severe pain, on 6/1/2022 and 6/11/2022. Labs and abdominal CT were normal then. Husband experienced similar ymptoms, but also had jaundice. His labs showed an acute hepat also but all other labs were normal. Once she heard about a recall on Daily Harvest French Leek and Lentils, she did recall eating it the day before getting sick. Her husband also ate this product. Her children didnlkeat this product. She still has the product stored in her fre zer. She is much better, but still has intermittent pain. Her husband has recovered fully.

		·	
elevant Test/Laboratory Data			1 of 4
Test Name	AST	Test Date	23-May-2022
Test Result	402	Test Unit	UNITS
Low Test Range	10	High Test Range	30
More Information Available#			
levant Test/Laboratory Data			2 of 4
Test Name	ALT	Test Date	23-May-2022
Test Result	509	Test Unit	UNITS
Low Test Range	6	High Test Range	29
More Information Available#			
levant Test/Laboratory Data			3 of 4
Test Name	ALKALINE PHOSPHATAS E	Test Date	23-May-2022
Test Result	214	Test Unit	UNITS
Low Test Range	31	High Test Range	125
More Information Available#			
levant Test/Laboratory Data			4 of 4
Test Name	BILIRUBIN, TOTAL	Test Date	23-May-2022
Test Result	0.4	Test Unit	MILLIGRAMS PER DECI
Low Test Range	0.2	High Test Range	1.2
More Information Available#			_1
ditional Comments	<u> </u>		

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-49824 | Department: CFSAN | RCT No.: RCT-1025104 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

	T	·		,	1
Ot	her Relevant History, Including	Preexisting Medical Co	ndition		
	She is healthy overall. She doesn			ons. Liver labs in 2021 were all	
	normal.				
C.	PRODUCT AVAILABILITY				
	Product Available for Evaluation#	Yes			
	(Do not send product to FDA) Returned to Manufacturer on		_	_	
_	Do you have a picture of the	Yes	-		
	roduct# (check yes if you are	res			
	ncluding a picture)				
D.	PRODUCT(S)			1 of 1	
	Suspect	Yes			
	Primary#	Yes			
	Туре	Drug/Biologi			
	This report involves:	Food/Medical food			
Na	ame,Strength,Manufacturer/Co	· · · · ·	<u> </u>		
	Product Name	French Leek and Lentils C			
	Strength		If Other		
	Manufacturer/Compounder	Daily Harvest	_	_	
	NDC' or Unique ID			_	
	Product Type(check all that apply)	Отс			
	арріу)	Compounded			
		Generi			
	French Abertad After Hea Charmad	Biosimilar			
	Event Abated After Use Stopped or Dose Reduced#	Yes			
	Event Reappeared after Reintroduction #	Doesn k Apply			
Dr	rug Therapy			1 of 1	
	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start	19-May-2022			
	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going#				

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-49824 | Department: CFSAN | RCT No.: RCT-1025104 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

	Lot Number		
	Expiration Date		
Dia	agnosis for Use (indication)	1 of 1	
E.	SUSPECT MEDICAL DEVICE		
	Brand Name		Т
	Common Device Name		
	Procode		
	Manufacturer Name		
	City		
	State		
	Model '		
	Lot'		
	Catalog '		
	Expiration Date		
	Serial '		
	Unique Identifier (UDI)'		
	Operator of Device	Health Professional	
		Patient/Consumer	
		Other	L
	Other		<u> </u>
	If Implanted, Give Date		<u> </u>
	If Explanted, Give Date		$oxed{\bot}$
	Is this a single-use device that was reprocessed and reused on		
	a patient#		
	If Yes for the above field, Enter Name and Address of		
	Reprocessor		
	Was this device serviced by a		
	hird party#		<u></u>
F.	OTHER (CONCOMITANT) ME		
	CONCOMITANT MEDICAL PROD	UCT DESCRIPTION	
			<u></u>
G.	REPORTER	1 of 1	
	Primary#	Yes	_
	Reporter is Patient#		<u> </u>
	Title		

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-49824 | Department: CFSAN | RCT No.: RCT-1025104 | CTU Triage Date: 23-Jun-2022 | Total Pages: 6

Last Name	(b) (6)			
Middle Name				
First Name	(b) (6)			
Address	(b) (6)			
City	(b) (6)			
State/Province/Region	(b) (6)			
Country	UNITED STATES	If Other		
ZIP/Postal Code	(b) (6)		,	
Phone	(b) (6)			
Email	(b) (6)			
Fax				
Reporter Organization				
Department				
Reporter Speciality				
Health Professional#	Yes			
Oc upation	Physician	If Other		
Also Reported to	Manufacturer/Comp User Facility Distributor/Importer	ounder	,	
If you do NOT want your identity disclosed to the manufacturer	No			

Generated by: SYSTEM Generated on: 23-Jun-2022 19:16:22 Page 5 of 5

CRUMBLES

Toss in a tortilla. Crumble on top of a Flatbread. Serve a lettuce wrap. Layer into lasagna. Upgrade you opy Jops. Dare we say stuff into an empanar e French Bentil + Leek Crumbles truly work of an engang. Oh, don't forget to add into your chare even hepherd's pie. We could go on.

CTU No.: FDA-CDER-CTU-2022-50074 | Department: CFSAN | RCT No.: RCT-1025256 | CTU Triage Date: 24-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	eyed in the report are in EST(G	in -05.00) time zone				
Basic Deta	ails					
Company l	Jnit	CDER-CTU	Originating Ac ount	FAERS		
Source Me	dium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority		Routine				
Override A	uto Calculation Rule	No				
FDA Recei	ved Date	24-Jun-2022	CTU Received Date	24-Jun-2022		
CTU Triage	e Date		CTU Data Entry Date			
Report Typ	e	Spontaneous	Report Classification	Drug		
Assign To		User		1		
User/Group)					
Forward to	Department					
Case Priority		Direct				
	,					
Contact						
Case	First Name	Last Name	Email Address	Phone		
Reporter	- mot realing		Email / Nations	. nene		
\checkmark	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
Section A	- About the Problem					
	nd of problem was it?					
	all that apply)		d side effect (including new or worsening symp	toms)		
(Спеск ан (пасарру)		Used a product incorrectly which could have or led to a problem				
		Noticed a problem with	n the quality of the product			
			ritching from one product maker to another maker	кег		
Date the	e problem oc urred	15-Jun-2022				
Serious		Yes				
	of the following happen?	Hospitalization - admitt	ted or stayed longer			
Спеск	all that apply)	Required help to preve	ent permanent harm			
		Disability or health pro	blem			
		Birth defect				
		Life-threatening				
		Death				
		Other serious/importar	nt medical incident(Please Describe Below)			
	erious/important medical					
	(Please Describe Below)	wit begreged (led)	de as many de ails as possible			
any additio	onal documents if nece	w it nappened (incluessary)	de as many de alls as possible	FDA may reach out to you lot		
CFSAN	CAERS PHONE REPOR	T 6/24/2022- SHE EXF	PERIENCED MUSCLE ACHES, FEVI	ER. AND CHILLS ALL NIGHT.		
			HE IS CONCERNED ABOUT THE P			
AND HE	EARING ABOUT THE RE	CALL. THIS SHE GOT	FROM EATING DAILY HARVEST L	ENTIL.		
Dolovest	Fast/Laberatory Data					
	Test/Laboratory Data			1 of 1		
Test Na	ime		Test Date			
Test Re	esult		Test Unit			
Low Tes	st Range		High Test Range			

Generated by: SYSTEM Generated on: 24-Jun-2022 11:46:50 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50074 | Department: CFSAN | RCT No.: RCT-1025256 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	DAILY HARVEST			
	Name of the company that makes (or compounds) the roduct	Lentil Crumbles			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		_
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				

Generated by: SYSTEM Generated on: 24-Jun-2022 11:46:50 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50074 | Department: CFSAN | RCT No.: RCT-1025256 | CTU Triage Date: 24-Jun-2022 | Total Pag es: 5

	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
W	ny was the person using the pr	roduct? (such as what cor	ndition was it supposed to tr	reat) 1 of 1	
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the o	expiration date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast mplants, etc.)		
D	ate the implant was put in		Date the implant was taken ou relevant)	ıt (If	
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Not selected			
	Please Specify Other Gender				
	Age (specify unit of time for age)				
	Date of Birth				
	Weight				
	Ethnicity (Choose only one)				
	Race (Check all that apply)	American Indian or Alaska Nati			

Generated by: SYSTEM Generated on: 24-Jun-2022 11:46:50 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50074 | Department: CFSAN | RCT No.: RCT-1025256 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

		White Black or African American	
Lis	st known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	t any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis		cations and medical devices b ng used.	
	BUSPIRONE		
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
IC o	ction F - About the Person Fill	ing Out This Form	
JOE	Primary?	ing Out This Form 1 of 1 Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street		
	City		
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code		
	Telephone number	(b) (6)	
	Email address	(b) (6)	

Generated by: SYSTEM Generated on: 24-Jun-2022 11:46:50 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50074 | Department: CFSAN | RCT No.: RCT-1025256 | CTU Triage Date: 24-Jun-2022 | Total Pag es: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	24-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 24-Jun-2022 11:46:50 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50095 | Department: CFSAN | RCT No.: RCT-1025279 | CTU Triage Date: 24-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	ayed in the report are in EST(G	ivi1-05.00) time zone				
Basic Deta						
Company I		CDER-CTU	Originating Ac ount	FAERS		
Source Me	dium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority		Routine				
Override A	uto Calculation Rule	No				
FDA Recei	ved Date	24-Jun-2022	CTU Received Date	24-Jun-2022		
CTU Triage	e Date		CTU Data Entry Date			
Report Typ	е	Spontaneous	Report Classification	Drug		
Assign To		User	,	,		
User/Group)					
Forward to	Department					
Case Priority		Direct				
Contact						
Case	First Name	Last Name	Email Address	Phone		
Reporter						
\square	(b) (6)	(b) (6)		(b) (6)		
Section A	- About the Problem	·				
	nd of problem was it?					
	all that apply)		d side effect (including new or worsening sy	/mptoms)		
(Спеск ан тат арргу)		Used a product incorrectly which could have or led to a problem				
		Noticed a problem wit	h the quality of the product			
		Had problems after sv	vitching from one product maker to another	maker		
	e problem oc urred					
Serious		Yes				
	of the following happen? all that apply)	Hospitalization - admi	tted or stayed longer			
(Oncor	an that apply)	Required help to prevent permanent harm				
		Disability or health pro	oblem			
		Birth defect				
		Life-threatening				
		Death				
011		Other serious/importa	nt medical incident(Please Describe Below)			
	erious/important medical (Please Describe Below)					
4.Tell us v	hat happened and ho	w it happened (Inclu	ude as many de ails as possib	le FDA may reach out to you for		
any addition	onal documents if nece	essary)				
			EATING THE DAILY HARVEST LI			
			SLADDER AND ABDOMINAL PAIN			
	BEEN RECALLED. SHE A			R FINDING OUT THE PRODUCT		
	DELIN NEOALLED. SHE A	LOO LINDLD OF IN TO	TE ER TWIGE.			
Relevant ⁻	Test/Laboratory Data			1 of 1		
	-		Test Date			
Test Na						
Test Re	esult		Test Unit			
Low Te	st Range		High Test Range			

Generated by: SYSTEM Generated on: 24-Jun-2022 12:46:23 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50095 | Department: CFSAN | RCT No.: RCT-1025279 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

	More Information Available?			
Ad	ditional Comments			
Se	ction B - Product Availability			
	Do you still have the product in case we need to evaluate it?	Yes		
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Se	ection C - About the Products		1 of 1	
	Suspect	Yes		
	Primary?	Yes		
	Туре	Drug/Biologi		
	This report is about	Food/Medical food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	DAILY HARVEST		
	Name of the company that makes (or compounds) the roduct	Lentil Crumbles		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar		
	Strength	If Other		
	NDC number			
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?			
	Did the problem return if the rson started taking or using the roduct again?			
Dr	ug Therapy		1 of 1	
	Expiration date			
	Lot number			
	Dosage Form			
	Quantity	If Other		
	Frequency	If Other		
	How was it taken or used	If Other		
	Date the person first started aking or using the product		,	
	Date the person stopped taking or using the product			

Generated by: SYSTEM Generated on: 24-Jun-2022 12:46:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50095 | Department: CFSAN | RCT No.: RCT-1025279 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

	Date the person reduced dose of he product					
_	Give best estimate of duration					
	Is therapy still on-going?					
W		roduct? (such as what cor	ndition was it supposed to treat)	1 of 1		
		·				
	Returned to Manufacturer On				_	
Se	Section D - About the Medical Device					
	Name of medical device				_	
	Name of the company that makes the medical device					
Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)						
	Model Number					
	Catalog Number					
	Lot Number					
	Serial Number					
	UDDI Number					
	Expiration date					
	Was someone operating the medical device when the problem oc urred?					
For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.)						
D	ate the implant was put in		Date the implant was taken out (If relevant)			
Se	Section E - About the Person Who Had the Problem					
	Person's Initials	(b) (6)				
	Sex	Female				
	Gender	Not selected				
	Please Specify Other Gender					
	Age (specify unit of time for age)					
	Date of Birth					
	Weight					
	Ethnicity (Choose only one)					
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif				

Generated by: SYSTEM Generated on: 24-Jun-2022 12:46:23 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50095 | Department: CFSAN | RCT No.: RCT-1025279 | CTU Triage Date: 24-Jun-2022 | Total Pag

		White Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	st any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	ations and medical devices b ng used.	
Lis	t all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
<u>ا</u>	ection F - About the Person Fill	ing Out This Form 1 of 1	
JOC	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street		
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code		
_	Telephone number	(b) (6)	
	Email address		

Generated by: SYSTEM Generated on: 24-Jun-2022 12:46:23 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50095 | Department: CFSAN | RCT No.: RCT-1025279 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	24-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 24-Jun-2022 12:46:23 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50116 | Department: CFSAN | RCT No.: RCT-1025294 | CTU Triage Date: 24-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	ayed in the report are in EST(G	ivi i -05:00) time zone					
Basic Deta							
Company l	Jnit	CDER-CTU	Origi	nating Ac ount	FAERS		
Source Medium		MWO (Drug)	Sour	ce Form Type	E2B XML 3500B		
Priority		Routine					
Override A	uto Calculation Rule	No	No				
FDA Recei	ved Date	24-Jun-2022	СТИ	Received Date	24-Jun-2022		
CTU Triage	e Date		CTU	Data Entry Date			
Report Typ	е	Spontaneous	Repo	rt Classification	Drug		
Assign To		User	,				
User/Group							
Forward to Department Case Priority							
Case Priori	ity	Direct					
	<u> </u>						
Contact							
Case	First Name	Last Name		Email Address	Phone		
Reporter	1 iist ivaine	East Name		Email / Address	THORIC		
\square	(b) (6)	(b) (6)			(b) (6)		
ISaction A	- About the Problem						
				<u> </u>			
What kind of problem was it? (Check all that apply)		Were hurt or had a bad side effect (including new or worsening symptoms)					
		Used a product incorrectly which could have or led to a problem					
		Noticed a problem with the quality of the product					
		Had problems after switching from one product maker to another maker					
Date the	e problem oc urred	11-May-2022					
Serious		Yes					
	of the following happen?	Hospitalization - admitted or stayed longer					
(Check all that apply)		Required help to prevent permanent harm					
		Disability or health problem					
		Birth defect					
		Life-threatening					
		Death					
		Other serious/impo	ortant medical incide	nt(Please Describe Below)			
	erious/important medical						
	(Please Describe Below)	it bannanad /lm		de eile ee reseible FDA	may reach out to you for		
any additio	onal documents if nece	w it nappened (in essary)	iciude as many	de alis as possible FDA	may reach out to you for		
		 	HUSBAND AFTE	R EATING THE DAILY HAR	VEST, EXPERIENCED		
				SIPTAL TWICE AND JARDIA			
Palayant	Fest/Laboratory Data				1 of 1		
	•						
Test Na	ime		Test	Date			
Test Re	esult		Test	Unit			
Low Te	st Range		High	Test Range			

Generated by: SYSTEM Generated on: 24-Jun-2022 13:16:32 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50116 | Department: CFSAN | RCT No.: RCT-1025294 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi		_	
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	DAILY HARVEST			
	Name of the company that makes (or compounds) the roduct	DAILY HARVEST			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number		ı		
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				

Generated by: SYSTEM Generated on: 24-Jun-2022 13:16:32 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50116 | Department: CFSAN | RCT No.: RCT-1025294 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
W		roduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
		·			
	Returned to Manufacturer On				_
Se	ection D - About the Medical De	evice			
	Name of medical device				_
	Name of the company that makes the medical device				
Ot loc	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the expira	tion date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fc	or implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)		
D	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Not selected			
	Please Specify Other Gender				
	Age (specify unit of time for age)				
	Date of Birth				
	Weight				
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif			

Generated by: SYSTEM Generated on: 24-Jun-2022 13:16:32 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50116 | Department: CFSAN | RCT No.: RCT-1025294 | CTU Triage Date: 24-Jun-2022 | Total Pag

		White Black or African American	
lLis	st known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	st any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	cations and medical devices b ng used.	
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
0	(;		
56	ection F - About the Person Fill		
_	Primary? Reporter is Patient?	Yes	
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street		
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code		
	Telephone number	(b) (6)	
	Email address		

Generated by: SYSTEM Generated on: 24-Jun-2022 13:16:32 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50116 | Department: CFSAN | RCT No.: RCT-1025294 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	24-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 24-Jun-2022 13:16:32 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50120 | Department: CFSAN | RCT No.: RCT-1025298 | CTU Triage Date: 24-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Low Test Range

	yed in the report are in EST(G	W I -US	.00) time zone					
Basic Deta		CDI	ER-CTU	Origi	acting A a quet	FAERS		
Company U		_			nating Ac ount			
	ulum	Rou	O (Drug)	Sour	ce Form Type	EZD AIV	ИL 3500B	
Priority	sta Calasslatian Dula		itine					
	uto Calculation Rule	No	L 0000	OTU	December of Dete	04 1	0000	
FDA Recei		24-0	Jun-2022		Received Date	24-Jun-		
CTU Triage					Data Entry Date			
Report Typ	e 		ntaneous	Керс	rt Classification	Drug		
Assign To		Use	er 					
User/Group			7					
	Department							
Case Priori	ty	Dire	ect					
Contact			T					
Case Reporter	First Name		Last Name		Email Address	Phone	е	
	(b) (6)		(b) (6)		(b) (6)	(b) (6	6)	
	- A7out the Pro7lem							
	nd of pro7lem was itb all that apply)				uding new or worsening symptoms)			
	(Chec1 all that apply)		Used a product incorrectly which could have or led to a pro7lem					
			Noticed a pro7lem with the kua	•	·			
Data the	e pro7lem oc urred		? ad pro7lems after switching f Jun-2022	rom one	product ma1er to another ma1 r			
Serious	e promem oc uneu		Jul 1-2022					
	of the following happenb	qe		-				
	all that apply)		ospitalization - admitted or st	,				
			Rekuired help to prevent perm	anent ha	ırm			
			Disa7ility or health pro7lem					
			Birth defect					
			Life-threatening Death					
			Other serious/important medic	al incide	nt(Please Descri7e Below)			
	erious/important medical		Saler Serieus/Important medie	<u> </u>	ii(i loado Docolii o Dolow)			
	(Please Descri7e Below)	wit b	annoned (Include as	man	/ de ails as possi7le FDA	may raga	a out to you for	
any addition	onal documents if nece	ssar	appened (include as y)	illally	r de alis as possirie i DA	may reaci	i out to you for	
					IVER PROBLEM AFTER EA			
					LLS, FATIGUE, DARK URINE D WORK AND ?URT KIDNE			
110.4.	7.2.110. 17 0 . 9 7 11 12 17 2.		71.2300101101	BLOO	3 1101111711112	,0,110.2		
Dalamata							0 -10	
	est/La7oratory Data						6 of 6	
Test Na	me			Test	Date			
Test Re	sult			Test	Unit			

Generated 7y: SqSTEM G nerated on: 24-Jun-2022 63:66:45 Page 6 of 5

? gh Test Range

CTU No.: FDA-CDER-CTU-2022-50120 | Department: CFSAN | RCT No.: RCT-1025298 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

	More Information Availa7leb				
Ad	ditional Comments				
Se	ction B - Product Availa7ility				
	Do you still have the product in case we need to evaluate itb	qe			
	Do you have a picture of the productb (chec1 yes if you are ncluding a picture)	No			
Se	ction C - A7out the Products			6 of 6	
	Suspect	qe			
	Primaryb	qe			
	Туре	Drug/Biologi			
	This report is a7out				
	Name of the product as it appears on the 7oZ, 7ottle, or pac1age (Include as many names as you see)	DAILq ?ARVEST			
	Name of the company that ma1 (or compounds) the roduct	FRENC? LENTIL AND LEE	EKS		
	Product Type(chec1 all that apply)	Over-the-Counter Compounded 7y a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC num7er				
	Did the pro7lem stop after the rson reduced the dose or opped ta1 ng or using the roductb	qe			
	Did the pro7lem return if the rson started ta1 ng or using the roduct againb	Doesnx Apply			
Dr	ug Therapy			6 of 6	
	EZ ration date				
	Lot num7er				
	Dosage Form				
	Quantity		If Other		
	Frekuency		If Other		
	? ow was it ta1 n or used		If Other		
	Date the person first started a1 ng or using the product				
	Date the person stopped ta1 ng or using the product				

Generated 7y: SqSTEM G nerated on: 24-Jun-2022 63:66:45 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50120 | Department: CFSAN | RCT No.: RCT-1025298 | CTU Triage Date: 24-Jun-2022 | Total Pag es: 5

	Date the person reduced dose of he product			
	Give 7est estimate of duration			
	Is therapy still on-goingb			
WI		oductb (such as what condition was it sup	posed to treat) 6 of 6	
	Returned to Manufacturer On			_
Se	ection D - A7out the Medical De	evice		
	Name of medical device			
	Name of the company that ma1 the medical device			
Ot	her identifying information (The cate them)	e model, catalog, lot, serial, or UDI num7e	r, and the eZ ration date, if you can	
	Model Num7er			
	Catalog Num7er			
	Lot Num7er			
	Serial Num7er			
	UDDI Num7er			
	EZ ration date			
	Was someone operating the medical device when the pro7lem oc urredb			
Fo	r implanted medical devices O	NLq (such as pacema1 rs, 7reast mplant	s, etc.)	
Di	ate the implant was put in	Date the implant v relevant)	vas ta1 n out (If	
Se	ction E - A7out the Person Wh	o ? ad the Pro7lem		
	Personx Initials	(b) (6)		
	SeZ	Female		
	Gender	Not selected		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth			
	Weight			
	Ethnicity (Choose only one)	Not ? anic/Latino		
	Race (Chec1 all that apply)	American Indian or Alas1a Native Native ? awaiian or Other Pacific Islander Asian		

Generated 7y: SqSTEM G nerated on: 24-Jun-2022 63:66:45 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50120 | Department: CFSAN | RCT No.: RCT-1025298 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

		White Blac1 or African American	
Lis	st 1nown medical conditions (S	Such as dia7etes, high 7lood pre ure, cancer, heart disease, or others)	
PΙε	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	DUST		
Lis	st any other important informati	ion a7out the person (such as mo1 ng, pregnancy, alcohol use, etc.)	
Lis	t all current prescription medic	cations and medical devices 7 ng used.	
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and her7al remedies 7eing used.	
<u>د</u> د	ection F Azout the Derson Fill	ing Out This Form	
J C	ection F - A7out the Person Fill Primaryb	ing Out This Form 6 of 6	
-	Reporter is Patientb		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Num7er/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	' IP or Postal code	(b) (6)	
	Telephone num7er	(b) (6)	
	Email address	(b) (6)	İ

Generated 7y: SqSTEM G nerated on: 24-Jun-2022 63:66:45 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50120 | Department: CFSAN | RCT No.: RCT-1025298 | CTU Triage Date: 24-Jun-2022 | Total Pag es: 5

FaZ		
Reporter Organization		
Department		
Reporter Speciality		
Todayx date	24-Jun-2022	
Did you report this pro7lem to the company that ma1 the product (the manufacturer/compounder)b		
If you do NOT want your dentity disclosed to the manufacturer, please mar1 this 7oZ (Confidentiality Rekuested):	No	

Generated 7y: SqSTEM G nerated on: 24-Jun-2022 63:66:45 Page 5 of 5

ĈTU No.: FDA-CDER-CTU-2022-50132 | Department: ©FSAN | RCT No.: RCT-1025-101 | DTU Trage Date: 24-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	
FDA Received Date	24-Jun-2022	CTU Received Date	24-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact			All residents and the	
Case Reporter	First Name	Last Name	Email Address	Phone
Z	(b) (6)	(b) (6)	(b) (6)	(b) (6)
ection A	- About the Problem			
(Check	nd of problem was it? all that apply)	Used a product incorrectly w Noticed a problem with the q Had problems after switching	effect (including new or worsening sympto hich could have or led to a problem uality of the product g from one product maker to another make	
Serious	e problem occurred	23-May-2022 Yes		
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important med		
	erious/important medical (Please Describe Below)			
Tell us w	hat happened and how onal documents if neces	rit happened (Include a sary)	as many details as possible F	DA may reach out to you for
	LADDER PROBLEMS, TH		NG THE DAILY HARVEST CRUM DER OUT AND STOMACH PAIN.	

elevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	

Generated by: SYSTEM Generated on: 24-Jun-2022 13:46:29 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50132 | Department: CFSAN | RCT No.: RCT-1025310 | CTU Triage Date: 24-Jun-2022 | Total Pages: 5

	Low Test Range		9 gh Test Range		
	More Hiformation Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	le			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			Z of Z	
	Suspect	le			
	Primary?	le			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the boK/bottleV or package (Hiclude as many names as you see)	DAHLI 9ARYEST			
	Name of the company that makes (or compounds) the roduct	CRUMBLES			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		HI Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	le			
	Did the problem return if the rson started taking or using the roduct again?	Doesnx Apply			
Dr	ug Therapy			Z of Z	
	EK ration date	Z0-Oct-2022			
	Lot number	L5-A			
	Dosage Form		1		
	' uantity		HI Other		
	Frequency		HI Other		
	9 ow was it taken or used		HI Other		
	Date the person first started aking or using the product				

Generated by: SI STEM G nerated on: 24-Jun-2022 Z3:41:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50132 | Department: CFSAN | RCT No.: RCT-1025310 | CTU Triage Date: 24-Jun-2022 | Total Pag es: 5

	Date the person stopped taking or using the product			
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
WI	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to treat	z) Z of Z
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot	her identifying information (The	e modelVcatalogVlotVseri	alVor UDHnumberVand the eKp	iration dateVif you can
IOC	cate them)			
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDHNumber			
	EK ration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLI (such as pacemake	rsVbreast implantsVetc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	no 9 ad the Problem		
	Personx Hnitials	(b) (6)		
	SeK	Female		
	Gender	Not selected		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth			
	Weight			
	Ethnicity (Choose only one)			
	Race (Check all that apply)	American Indian or Alaska Nat		

Generated by: SI STEM G nerated on: 24-Jun-2022 Z3:41:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50132 | Department: CFSAN | RCT No.: RCT-1025310 | CTU Triage Date: 24-Jun-2022 | Total Pag

		Asian White Black or African American	
Lis	st known medical conditions (S	uch as diabetesVhigh blood pressureVcancerVheart diseaseVor others)	
		Э г г г г г г г г г г г г г г г г г г г	
PΙ	ease list all allergies (such as t	o drugsVfoodsVpollen or others)	
Lis	t any other important informat	ion about the person (such as mokingV pregnancyValcohol useVetc.)	
Lis	t all current prescription medic	cations and medical devices b ng used.	
	ESCI€ALOPRAM Z0 MILL		
Lis	t all over-the-counter medicati	ons and any vitamins Vminerals Vsupplements Vand herbal remedies being used.	
Se	ction F - About the Person Fill	ing Out This Form Z of Z	
	Primary?	le	\top
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	\perp
	Country	UNIFIED STATES	\perp
	QHP or Postal code	(b) (6)	\perp
	Telephone number	(b) (6)	_
	Email address	(b) (6)	

Generated by: SI STEM G nerated on: 24-Jun-2022 Z3:41:26 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50132 | Department: CFSAN | RCT No.: RCT-1025310 | CTU Triage Date: 24-Jun-2022 | Total Pag es: 5

FaK		
Reporter Organization		
Department		
Reporter Speciality		
Todayx date	24-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your dentity disclosed to the manufacturerVplease mark this boK(Confidentiality Requested):	No	

Generated by: SI STEM G nerated on: 24-Jun-2022 Z3:41:26 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50136 | Department: GPSAN | RCT No.: RCT-1025323 | DTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	2000	200 000 000 00	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	
FDA Received Date	24-Jun-2022	CTU Received Date	24-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	16	
User/Group			
Forward to Department			
Case Priority	Direct		

Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (G)	(b) (6)	(b) (6)	(b) (6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	21-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

My wife and I are Daily Harvest subscribers and ate the Lentil + Leek Crumbles that have since been recalled on Tuesday. Following consumption, we both experienced indigestion, diarrhea, back pains, bloating, and headaches. Neither serious to go to hospital, but we read about the recall about 2 hours after we ate and grew very concerned. My wife found an email from Daily Harvest buried in her spam email from the Sunday before, but we had the bag of Crumbles for weeks by that point and could have consumed earlier. We are absolutely horrified to read about the hospitalization, liver damage, gallbladder removal, and other reactions and experiences from other consumers. We still have one unopened bag in case it needs to be submitted and tested.

levant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50136 | Department: CFSAN | RCT No.: RCT-1025323 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			_
	This report is about	Food/Medical food			_
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	+ Leek Crumble		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number		I		
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	23-Oct-2022			
	Lot number	L02-VEGBN L5-A			
	Dosage Form				
	Quantity		If Other		
	Frequency	As needed	If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	21-Jun-2022			
	Date the person stopped taking or using the product	21-Jun-2022			

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50136 | Department: CFSAN | RCT No.: RCT-1025323 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 6

	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
W	ny was the person using the pr	roduct? (such as what cor	ndition was it supposed to treat) 1 of 1	
	Hunger	· ·		
	Returned to Manufacturer On			
Se	ction D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if you can	
100	eate them)			
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number		-	
	UDDI Number			
	Expiration date			
	Was someone operating the			
	medical device when the problem oc urred?			
Га		MIV (auch ac macaraly)	o broost mulante ata \	_
	r implanted medical devices Oate the implant was put in	INLY (such as pacemake)	Date the implant was taken out (If	
D	ate the implant was put in		relevant)	
Se	ction E - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Male		
	Gender	Cisgender man/boy		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth	(b) (6)		
	Weight			
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati	ve	
		Native Hawaiian or Other Pacif		
		Asian		

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50136 | Department: CFSAN | RCT No.: RCT-1025323 | CTU Triage Date: 27-Jun-2022 | Total Pag

		White Black or African American	
Lis	st known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
		pro en	
PΙ	ease list all allergies (such as t	to drugs, foods, pollen or o hers)	
Lis	t any other important informat	tion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	cations and medical devices b ng used.	
Lis	t all over-the-counter medicati	ions and any vitamins, mineral, supplements, and herbal remedies being used.	
100	ection F - About the Person Fill	ling Out This Form 1 of 1	
36	Primary?	Yes	
	Reporter is Patient?		-
	Title		+
	Last name	(b) (6)	+
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
1	Email address	(b) (6)	

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50136 | Department: CFSAN | RCT No.: RCT-1025323 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	24-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:22 Page 5 of 5

LOZ-VERBN BEST BY 10/23/2022 LS-A 12:10 LENTIL **BUTTERNUT SQUASH** HEMP SEED QUINOA **CREMINI** TARA

Preparing Crumbles:

- Heat a lightly oiled skillet or non-stick pan over medium-high heat.
- ② Add the desired amount of frozen Crumbles to the pan, breaking up any large clusters.
- Stirring frequently, sauté until nicely browned and thoroughly cooked to an internal temperature of 165°F, about 5-6 minutes.
- Let stand for 1-2 minutes. Enjoy on their own or add to your favorite dish.

PERISHABLE. STORE FROZEN Do not thaw or refreeze Cook thorsusal

DAILY HARVEST

LOZ-VEGEN BEST BY 10/23/2022 L5-A 12:10

BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI IRA

Preparing Crumbles:

- O had a lightly oiled skillet or non-stick pan over medium-high heat
- Add the desired amount of frozen Crumbles to the pan, breaking up
- Sing frequently, sauté until nicely browned and thoroughly cooked

CTU No.: FDA-CDER-CTU-2022-50214 | Department: CFSAN | RCT No.: RCT-1025500 | CTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		1
Override Auto Calculation Rule	No		
FDA Received Date	25-Jun-2022	CTU Received Date	25-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		'
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

S	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
	Date the problem oc urred	05-Jun-2022	
	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
	Other serious/important medical ncident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

We received the Daily Harvest Lentil crumbles on 05/26 and ate hem prepared as directed on 06/03. On 06/05 my partner starting experiencing fatigue symptoms. On 06/10 he began to have yellowing of eyes and itching skin. On 06/11 it was worse so he went to the ER and was admitted to the hospital with high liver enzymes. They tested for Covid, Flu, Hepatitis (ABC), Epstein Barr, and autoimmune conditions and all were negative. After a few days in the hospital he came home, though still suffered from extreme fatigue and levels rose slightly. He saw a GI specialist and MRI was clear. It is now 06/25 and he has missed 2 weeks of work and still suffers from extreme fatigue. On 06/22 he had bloodwork done again and bilirubin levels declined for the first time since 06/11. The GI doctor says it may be weeks / months of recovery from this liver injury. Daily Harvest issued a recall in early June after we had already eaten. At first they reported it was GI, now latest reports and cla ms of consumers list liver damage.

R	Relevant Test/Laboratory Data				
	Test Name	LIVER ENZYME PANEL - BILIRUBIN	Test Date	11-Jun-2022	

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:22 Page 1 of 5

 $CTU\ No.:\ FDA-CDER-CTU-2022-50214\ |\ Department:\ CFSAN\ |\ RCT\ No.:\ RCT-1025500\ |\ CTU\ Triage\ Date:\ 27-Jun-2022\ |\ Total\ Pag$

es: 5

Test Result	7.8	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	.3	High Test Range	1.2
More Information Available?			
Relevant Test/Laboratory Data			2 of 5
Test Name	LIVER ENZYME PANEL - BILIRUBIN	Test Date	11-Jun-2022
Test Result	8.8	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	.3	High Test Range	1.2
More Information Available?			
Relevant Test/Laboratory Data			3 of 5
Test Name	AST	Test Date	11-Jun-2022
Test Result	103	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	10	High Test Range	40
More Information Available?			
Relevant Test/Laboratory Data			4 of 5
Test Name	ALT	Test Date	11-Jun-2022
Test Result	262	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	7	High Test Range	56
More Information Available?			
Relevant Test/Laboratory Data			5 of 5
Test Name	ALKALINE PHOSPHATAS E	Test Date	11-Jun-2022
Test Result	149	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	44	High Test Range	147
More Information Available?			
Additional Comments			
Levles continued to rise until 06/2	22.		
Section B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
On the On About the Donale to	I.		

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:22 Page 2 of 5

1 of 1

Section C - About the Products

CTU No.: FDA-CDER-CTU-2022-50214 | Department: CFSAN | RCT No.: RCT-1025500 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Suspect	Yes			
	Primary?	Yes		-	
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	+ Leek Crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form			,	
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	03-Jun-2022			
	Date the person stopped taking or using the product	03-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?	Yes			
W	hy was the person using the pr	oduct? (such as what cor	ndition was it supposed to t	reat) 1 of 1	
	It was a food				
	Returned to Manufacturer On				
_					
Se	ection D - About the Medical De	evice			
Se	ection D - About the Medical De Name of medical device	evice			

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50214 | Department: CFSAN | RCT No.: RCT-1025500 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

	Name of the company that makes the medical device			
Ot loc	her identifying information (Theate them)	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if you can	
	·			
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices C	NLY (such as pacemake	rs, breast mplants, etc.)	
	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Male		
	Gender	Cisgender man/boy		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth	(b) (6)		
	Weight	81 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati	ive	
		Native Hawaiian or Other Pacif		
		Asian		
		White		
		Black or African American		
lLis	at known medical conditions (S	Such as diabetes, high blo	od pre ure, cancer, heart disease, or others)	
	None	<u>,</u>		
Ple	ease list all allergies (such as t	to drugs, foods, pollen or	o hers)	
-10	None	o arago, roodo, policir oi c		
	- -			

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50214 | Department: CFSAN | RCT No.: RCT-1025500 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Lis	t any other important information about the person (such as moking, pregnancy, alcohol use, etc.)	
	Nonsmoker, minimal alcohol use	
Lis	t all current prescription medications and medical devices b ng used.	
	None	П
Lis	t all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
	Athletic Greens (discontinued 06/15)	Т

tion F - About the Person Filli	ing Out This Form 1 of	1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(b) (6)	_
Country	UNITED STATES	_
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	_
Email address	(b) (6)	
Fax		
Reporter Organization		_
Department		_
Reporter Speciality		
Today's date	25-Jun-2022	_
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50153 | Department: GPSAN | RCT No.: RCT-1025889 | DTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		2.00	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	P	
Override Auto Calculation Rule	No		
FDA Received Date	24-Jun-2022	CTU Received Date	24-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	-6	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

S	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
	What kind of problem was it? (Check all that apply) Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product		
	Serious	Yes	
		Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

6/2/2022: Ate Daily Harvest French Lentil and Leek Crumbles for lunch. I cooked them thoroughly as directed until they were crispy all the way through on the verge of being burnt. That night I had severe bloating & stomach descension, trouble sleeping, tightness in the chest. 6/3/2022 - 6/5/2022: Felt pressure and tightness in chest/abdomen, and starting feeling achy all over and flu-like symptoms. Felt very ill all weekend and wasn't able to eat or have a BM. Urine was very dark colored 6/6/2022: Went to urgent care at (b) (6) Pee looked tea colored. (b) (6) ordered blood work and referred to have ultrasound next day. During physical exam, pushed on upper right abdomen and felt sharp pain. Was thinking potentially gallstones (b) (6) called in the afternoon as labs were coming back elevated (3.3 Bilirubin, high liver tests, etc.) told me to go to (b) (6) for Ultrasound and probable MRI. Went to (b) (6) and had a clear ultrasound and abdominal MRI. They didn't know what was wrong with me so we left at 3am after a 9 hour stay with directions to follow up with GI and PCP. 6/7/2022: Extremely itchy body, hands and feet burning and itching and had lost ~6 pounds from not eating. Not sleeping because itching driving me crazy. Follow up call with(b) (6) who prescribed hydrOXYzine hydrochloride for itching but said may not work since itching was related to liver/blood issue. 6/8/2022: Follow up with my new PCP, (b) (6) . She ordered more labs/tests. Did H. Pylori breath test as well. Started being able to eat again, extreme itching on palms and feet. She prescribed cholestyramine powder for the itching. 6/13/2022: Endoscopy with (b)(6). He said all looked good from the GI perspective, took 2 biopsies. 6/15/2022: (b) (6) called.

Generated by: SYSTEM Generated on: 24-Jun-2022 15:46:25 Page 1 of 6

CTU No.: FDA-CDER-CTU-2022-50153 | Department: CFSAN | RCT No.: RCT-1025389 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

Bloodwork was starting to look better than it was prior week so he didn't recommend liver biopsy. He said positive biopsy for H. Pylori and he would prescribe antibiotics but that wasn't what was causing my symptoms. 6/16/2022: (b) (6) called and said to wait on the antibiotics because lots of people have H. Pylori and that's not causing my symptoms. Cholestasis from bile was the cause for itchy so now that itch is gone, I should discontinue both meds. Low fat, healthy diet. If liver enzymes don't normalize can see a liver specialist (Hepatologist), whi h is subspecialty of GI. Not primary biliary cirrhosis, could s II be gallstone. 6/20/2022: Figured out the cause of my current medical issues. Discovered that a food product I had consumed for lunch on 6/2 had been recalled: Daily Harvest French Lentil and Leek Crumbles. There is a Reddit page with hundreds of customers who were severely sick from eating the product. Their stories. Labs and symptoms were exactly like mine, some even more severe involving surgeries and gallbladder removal. Nothing has been released about what toxin/contaminant was in the product. Current symptoms still extreme fatigue, spl ng headaches that come and go, cramping in upper right abdomen, itchy arms, loss of appetite and bloating when I eat. Tried to go back to work today but am still feeling too sick. 6/22/2022 Began an unpaid medical leave to give me the time to get better and go to all these doctors appointments and tests.

Re	levant Test/Laboratory Data			1 of 8
	Test Name	TOTAL BILIRUBIN	Test Date	06-Jun-2022
	Test Result	3.3	Test Unit	MILLIGRAMS PER DECIL ITRE
	Low Test Range	0.2 mg/dL	High Test Range	1.0 mg/dL
	More Information Available?			
Re	levant Test/Laboratory Data			2 of 8
	Test Name	AST	Test Date	08-Jun-2022
	Test Result	78	Test Unit	
	Low Test Range		High Test Range	<39 U/L
	More Information Available?			
Re	levant Test/Laboratory Data			3 of 8
	Test Name	ALK PHOS	Test Date	08-Jun-2022
	Test Result	228	Test Unit	
	Low Test Range	37 U/L	High Test Range	128 U/L
	More Information Available?			
Re	levant Test/Laboratory Data			4 of 8
	Test Name	ALT	Test Date	08-Jun-2022
	Test Result	154	Test Unit	
	Low Test Range		High Test Range	<56 U/L
	More Information Available?			
Re	levant Test/Laboratory Data			5 of 8
	Test Name	BLOOD UREA NITROGEN (BUN)	Test Date	06-Jun-2022
	Test Result	2 mg/dL	Test Unit	MILLIGRAMS PER DECIL ITRE
	Low Test Range	7 mg/dL	High Test Range	24 mg/dL
	More Information Available?			
Re	levant Test/Laboratory Data			6 of 8
	Test Name	MAN SEGS	Test Date	08-Jun-2022
	Test Result	33%	Test Unit	

Generated by: SYSTEM Generated on: 24-Jun-2022 15:46:25 Page 2 of 6

CTU No.: FDA-CDER-CTU-2022-50153 | Department: CFSAN | RCT No.: RCT-1025389 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

	Low Test Range	40%	High Test Range	64%	_
	More Information Available?				
Rε	elevant Test/Laboratory Data			7 of 8	
	Test Name	MAN LYMPHS	Test Date	08-Jun-2022	
	Test Result	57%	Test Unit		
	Low Test Range	16%	High Test Range	46%	
	More Information Available?				
Re	elevant Test/Laboratory Data			8 of 8	
	Test Name	GGT	Test Date	08-Jun-2022	
	Test Result	181 Units/L	Test Unit		
	Low Test Range	9 Units/L	High Test Range	36 Units/L	
	More Information Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			_
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest Crumbles Fre	nch Lentil + Leek		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or	No			

Generated by: SYSTEM Generated on: 24-Jun-2022 15:46:25 Page 3 of 6

CTU No.: FDA-CDER-CTU-2022-50153 | Department: CFSAN | RCT No.: RCT-1025389 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

	opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy				1 of 1
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	02-Jun-2022			
	Date the person stopped taking or using the product				
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?	Yes			
WI	ny was the person using the pr	oduct? (such as what	condition was it suppose	ed to treat)	1 of 1
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot loc	her identifying information (The cate them)	e model, catalog, lot, s	erial, or UDI number, an	nd the expiration date, if y	ou can
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				

For implanted medical devices ONLY (such as pacemakers, breast mplants, etc.)

Generated by: SYSTEM Generated on: 24-Jun-2022 15:46:25 Page 4 of 6

CTU No.: FDA-CDER-CTU-2022-50153 | Department: CFSAN | RCT No.: RCT-1025389 | CTU Triage Date: 27-Jun-2022 | Total Pag

	ate the implant was put in		Date the implant was taken out (If relevant)	
180	ction E - About the Person Wh	o Had the Problem		
00	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Not selected		
	Please Specify Other Gender	Not selected		
	Age (specify unit of time for age)	35 Year(s)		
	Date of Birth	33 Tear(s)		
		70 75 kg		
	Weight The picity (Chance only one)	78.75 kg		
	Ethnicity (Choose only one)			
	Race (Check all that apply)	American Indian or Alaska Nat	ive	
		Native Hawaiian or Other Paci	fic Islander	
		Asian		
		White		
		Black or African American		
Lis	t known medical conditions (S	Such as diabetes, high blo	od pre ure, cancer, heart disease	e, or others)
	none			
DI	saa list all alleraine (auch as t	ra druga faada nallan ar	a haral	
I I I E	ease list all allergies (such as t	o drugs, loods, polleri or	o ners)	
	none			
	none			
	none			
	Tione			
Lis		ion about the person (suc	ch as moking, pregnancy, alcoho	l use, etc.)
Lis		ion about the person (suc	ch as moking, pregnancy, alcoho	l use, etc.)
Lis	t any other important informat	ion about the person (suc	ch as moking, pregnancy, alcoho	I use, etc.)
Lis	t any other important informat	ion about the person (suc	ch as moking, pregnancy, alcoho	l use, etc.)
Lis	t any other important informat	ion about the person (suc	ch as moking, pregnancy, alcoho	l use, etc.)
	t any other important informat none- healthy 35 year old			l use, etc.)
	t any other important informat none- healthy 35 year old t all current prescription medic			l use, etc.)
	t any other important informat none- healthy 35 year old			l use, etc.)
	t any other important informat none- healthy 35 year old t all current prescription medic			l use, etc.)
	t any other important informat none- healthy 35 year old t all current prescription medic			I use, etc.)
Lis	t any other important informat none- healthy 35 year old t all current prescription medic none	cations and medical devic	es b ng used.	
Lis	t any other important informat none- healthy 35 year old t all current prescription medic none	cations and medical devic		
Lis	t any other important informat none- healthy 35 year old t all current prescription medic none	cations and medical devic	es b ng used.	
Lis	t any other important informat none- healthy 35 year old t all current prescription medic none	cations and medical devic	es b ng used.	
Lis	t any other important informat none- healthy 35 year old t all current prescription medic none	cations and medical devic	es b ng used.	
Lis	t any other important informat none- healthy 35 year old t all current prescription medic none	cations and medical devic	es b ng used.	

Section F - About the Person Filling Out This Form

1 of 1

CTU No.: FDA-CDER-CTU-2022-50153 | Department: CFSAN | RCT No.: RCT-1025389 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(5) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	24-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 24-Jun-2022 15:46:25 Page 6 of 6

CTU No.: FDA-CDER-CTU-2022-50138 | Department: CFSAN | RCT No.: RCT-1025325 | CTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details					
Company Unit	CDER-CTU	Originating Ac ount	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine	Routine			
Override Auto Calculation Rule	No				
FDA Received Date	24-Jun-2022	CTU Received Date	24-Jun-2022		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User				
User/Group					
Forward to Department					
Case Priority	Direct				

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

$ S\epsilon$	ection A - About the Problem	
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
	Date the problem oc urred	04-Jun-2022
	Serious	Yes
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

After consuming Lentils from Daily Harvest (an online food company) I experienced severe aches, chills, and convulsions, and hen my eyes and skin turned yellow. I was admitted to the hosp al for four nights while they ran a series of blood test and other diagnostics such as CT scan, HIDA scans, etc. to try and figure out what was wrong. After being discharged from the hospital I was informed by Daily Harvest that some of their cus omers were having abdominal issues as a result of eating their lentils. As I've looked more and more into this I see that many other consumers have reported the same symptoms that I had... Elevated liver enzymes, jaundice, body aches and chills, etc. Daily harvest is investigating the cause of these symptoms, but I want to report it here so that it's known that I experienced this as well. I'm working with a series of doctors to try to figure out exactly what happened, the long term effects, and the hospital bills are increasing. Many news outlets (WSJ, Post, NPR) have ues articles on this situation. Please reach out to me to di uss this if you would like additional details. I am happy to hare.

R	elevant Test/Laboratory Data			1 of 1	
	Test Name	A VARIETY OF TESTS	Test Date	04-Jun-2022	
	Test Result		Test Unit		

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:36 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50138 | Department: CFSAN | RCT No.: RCT-1025325 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Low Test Range		High Test Range			
	More Information Available?					
Ad	Additional Comments					
Section B - Product Availability						
	Do you still have the product in case we need to evaluate it?	No				
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No				
Section C - About the Products				1 of 1		
	Suspect	Yes				
	Primary?	Yes				
	Туре	Drug/Biologi				
	This report is about	Food/Medical food				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil and Leek Crumble				
	Name of the company that makes (or compounds) the roduct					
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar				
	Strength		If Other			
	NDC number					
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply				
Drug Therapy				1 of 1		
	Expiration date					
	Lot number					
	Dosage Form					
	Quantity		If Other			
	Frequency		If Other			
	How was it taken or used	Oral	If Other			
	Date the person first started	01-Jun-2022				

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:36 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50138 | Department: CFSAN | RCT No.: RCT-1025325 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

	Date the person stopped taking or using the product	01-Jun-2022		
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
WI	hy was the person using the pr	oduct? (such as what co	ndition was it supposed to treat	t) 1 of 1
	Food			
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that			
Ot	makes the medical device	madal catalog lat acri	al, or UDI number, and the exp	iration data if you can
loc	cate them)	e moder, catalog, lot, sen	ai, or obt number, and the exp	olialion date, il you can
	Model Number		-	
	Catalog Number		-	
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the			
	medical device when the problem oc urred?			
Fο	r implanted medical devices O	NI Y (such as nacemake	rs hreast mnlants etc.)	
	ate the implant was put in	TTET (Such as passimans	Date the implant was taken out (If	:
			relevant)	
Se	ection E - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Cisgender woman/girl		
	Please Specify Other Gender			
	Age (specify unit of time for age)	41 Year(s)		
	Date of Birth			
	Weight	53.1 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nat	tive	
		Native Hawaiian or Other Paci		

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:36 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50138 | Department: CFSAN | RCT No.: RCT-1025325 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

		Asian White Black or African American						
Lis	ist known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)							
	None prior to this event		П					
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)						
	None							
Lis	st any other important informat	on about the person (such as moking, pregnancy, alcohol use, etc.)						
	None							
Lis	st all current prescription medic	cations and medical devices b ng used.						
	None							
Lis	st all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.						
Se	ection F - About the Person Fill	ing Out This Form 1 of 1						
	Primary?	Yes						
	Reporter is Patient?		\vdash					
	Title		\vdash					
	Last name	(b) (6)						
	Middle Name							
	First name	(b) (6)	\vdash					
	Number/Street	(b) (6)						
	City	(b) (6)	+					
	State/Province	(6) (6)	\vdash					
	Country	UNITED STATES	\vdash					
	ZIP or Postal code	(b) (6)	+					
	Telephone number	(b) (6)	\vdash					
	Email address	(b) (6)						

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:36 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50138 | Department: CFSAN | RCT No.: RCT-1025325 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	24-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 24-Jun-2022 14:16:36 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50160 | Department: CFSAN | RCT No.: RCT-1025403 | DTU Triage Date: 27-Jun-2022 | Total Pagec 8

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	-2.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	24-Jun-2022	CTU Received Date	24-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)	

Section A - About the Problem			
What kind of problem was it? (Check all that apply) Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker			
Date the problem occurred			
Serious	Yes		
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

On Thursday, May 26, 2022 I ate French Lentil + Leek Crumbles from Daily Harvest. The next day I experienced severe stomach pain that would not subside. I went to (b) (6) care on Saturday, May 28, 2022 after my symptoms did not improve for two days. I was prescribed medication at that visit. Over the course of the week, I continued to have stomach pain and digestive problems. I ate the French Lentil + Leek Crumbles again on Thursday, June 2, 2022. I woke up the next day with severe stomach pain that worsened as the day went on. That evening I went back tc(b) (6) . During my visit, they prescribed additional medications and advised if I did not get better to go to the ER. Within a few hours my symptoms continued to worsen and I started to run a fever with chills. I went to the (b) (6) and spent Friday, June 3, 2022- Sunday, June 5, 2022 in the ER and observation unit. I continued to have severe pain and fever in the ER with additional symptoms of Jaundice, diarrhea, body aches/weakness, headache, nausea and loss of appetite. During my stay, I had many tests run: CT Scan, MRI, Ultrasound, bloodwork, urine tests and stool tests. My ALT, AST and Bilirubin levels were very elevated, because of this I was moved from the ER to observation where I stay from Saturday, June 4th- Sunday, June 5th. My Bilirubin continued to raise and ALT/AST were still elevated, but levels were decreasing. In addition to my liver levels, there was E.coli found in my stool. After being released from the hospital, I continued to have weakness, stomach pain, loss of appetite, headache, jaundice and nausea. I continued to have a fever until June 7, 2022. I have since continued to have stomach pain and have been on a very limited diet. I have visited a specialist to continue to monitor my liver levels. My official diagnosis from the hospital was

Generated by: SYSTEM Generated on: 24-Jun-2022 16:16:30 Page 1 of 6

 $CTU\ No.:\ FDA-CDER-CTU-2022-50160\ |\ Department:\ CFSAN\ |\ RCT\ No.:\ RCT-1025403\ |\ CTU\ Triage\ Date:\ 27-Jun-2022\ |\ Total\ Pag$

es: 8

acute hepatitisx?ut AvBvC were not indicated on any tests6Daily 4 arvest has since advised not to eat the crum?les and to dispose o/ them6The ?atch I have is marqed as: Best By: k0vk0v2022 L5-A k2:256

Relevant Testwa?oratory Data			k o/ 8
Test Name	ALT	Test Date	03-f un-2022
Test Result	80J	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	4 gh Test Range	38
More In/ormation Availa?leH			
Relevant Testwa?oratory Data			2 o/ 8
Test Name	ALT	Test Date	0J-f un-2022
Test Result	585	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	4 gh Test Range	38
More In/ormation Availa?leH			
Relevant Testwa?oratory Data			3 o/ 8
Test Name	ALT	Test Date	05-f un-2022
Test Result	38k	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	4 gh Test Range	38
More In/ormation Availa?leH			
Relevant Testwa?oratory Data			J o/ 8
Test Name	AST	Test Date	03-f un-2022
Test Result	kx22k	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	5	4 gh Test Range	3J
More In/ormation Availa?leH			
Relevant Testwa?oratory Data			5 o/ 8
Test Name	AST	Test Date	0J-f un-2022
Test Result	Jb7	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	5	4 gh Test Range	3J
More In/ormation Availa?leH			
Relevant Testwa?oratory Data			b o/ 8
Test Name	AST	Test Date	05-f un-2022
Test Result	k75	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	5	4 gh Test Range	3J
More In/ormation Availa?leH	5	4 gh Test Range	
_	5	4 gh Test Range	8 o/ 8

Generated ?y: S1STEM Generated on: 2J-f un-2022 kb:kb:30 Page 2 o/ b

CTU No.: FDA-CDER-CTU-2022-50160 | Department: CFSAN | RCT No.: RCT-1025403 | CTU Triage Date: 27-Jun-2022 | Total Pages: 8

	Test Result	J6k	Test Unit	MILLIGRAMS PER DECIL
	Low Test Range	062	4 gh Test Range	k62
	More In/ormation Availa?leH			,
Re	elevant Testwa?oratory Data			8 o/ 8
	Test Name	BILIRUBIN TOTAL	Test Date	0J-f un-2022
	Test Result	562	Test Unit	MILLIGRAMS PER DECIL ITRE
	Low Test Range	062	4 gh Test Range	k62
	More In/ormation Availa?leH			
Ac	ditional Comments			
	detected	AGGREGATIKE E6COLI (E	AEC) and ENTEROPAT4 OGENIC	E6COLI (EPEC) were
Se	ection B - Product Availa?ility			
	Do you still have the product in case we need to evaluate itH	1e		
	Do you have a picture o/ the productH(checq yes i/ you are ncluding a picture)	1e		
_				<u>X</u>
Se	ection C - A?out the Products			k o/ k
Se	ection C - A?out the Products Suspect	1e		k o/ k
Se		1e 1e		k o/ k
Se	Suspect			k o/ k
Se	Suspect PrimaryH	1e		k o/ k
Se	Suspect PrimaryH Type	1e DrugvBiologi	Ples	k o/ k
Se	Suspect PrimaryH Type This report is a?out Name o/ the product as it appears on the ?oj x?ottlex or pacqage (Include as many	1e DrugvBiologi FoodvMedical /ood	Ples	k o/ k
Se	Suspect PrimaryH Type This report is a?out Name o/ the product as it appears on the ?oj x?ottlex or pacqage (Include as many names as you see) Name o/ the company that maq (or compounds) the	1e DrugvBiologi FoodvMedical /ood French Lentil , Leeq Crum?		k o/ k
Se	Suspect PrimaryH Type This report is a?out Name o/ the product as it appears on the ?oj x?ottlex or pacqage (Include as many names as you see) Name o/ the company that maq (or compounds) the roduct Product Type(checq all that	DrugvBiologi FoodvMedical /ood French Lentil , Leeq Crum? Daily 4 arvest Over-the-Counter Compounded ?y a Pharmacy of Generi		k o/ k
Se	Suspect PrimaryH Type This report is a?out Name o/ the product as it appears on the ?oj x?ottlex or pacqage (Include as many names as you see) Name o/ the company that maq (or compounds) the roduct Product Type(checq all that apply)	DrugvBiologi FoodvMedical /ood French Lentil , Leeq Crum? Daily 4 arvest Over-the-Counter Compounded ?y a Pharmacy of Generi	or an Outsourcing Facility	k o/ k
Se	Suspect PrimaryH Type This report is a?out Name o/ the product as it appears on the ?oj x?ottlex or pacqage (Include as many names as you see) Name o/ the company that maq (or compounds) the roduct Product Type(checq all that apply) Strength	DrugvBiologi FoodvMedical /ood French Lentil , Leeq Crum? Daily 4 arvest Over-the-Counter Compounded ?y a Pharmacy of Generi	or an Outsourcing Facility	k o/ k

Generated ?y: S1STEM Generated on: 2J-f un-2022 kb:kb:30 Page 3 o/ b

CTU No.: FDA-CDER-CTU-2022-50160 | Department: CFSAN | RCT No.: RCT-1025403 | CTU Triage Date: 27-Jun-2022 | Total Pages: 8

Dr	ug Therapy			k o/ k	
	Ej ration date	k0-Oct-2022			
	Lot num?er	L5-A k2:25			
	Dosage Form				
	9 uantity		I/ Other		
	FreYuency		I/ Other		
	4 ow was it taq n or used		I/ Other		
	Date the person /irst started aq ng or using the product				
	Date the person stopped taq ng or using the product				
	Date the person reduced dose o/ he product				
	Give ?est estimate o/ duration				
	Is therapy still on-goingH				
W	hy was the person using the pr	oductH(such as what cor	ndition was it supposed to tr	reat) k o/ k	
	Returned to Manu/acturer On				
Se	ection D - A?out the Medical De	evice			
	Name o/ medical device				
	Name o/ the company that mag the medical device				
Ot	her identi/ying in/ormation (The	e modelxcatalogxlotxseria	alxor UDI num?erxand the	ej piration datexi/ you can	
100	cate them)				
		T			
_	Model Num?er				
	Catalog Num?er				
	Lot Num?er				
	Serial Num?er				
	UDDI Num?er				
	Ej ration date				
	Was someone operating the medical device when the pro?lem oc urredH				
Fo	r implanted medical devices O	NL1 (such as pacemaqe	rsx?reast implantsxetc6		
D	ate the implant was put in		Date the implant was taq n out relevant)	t (I/	
Se	ection E - A?out the Person Wh	no 4 ad the Pro?lem			
	Person- Initials	(b) (6)			

Generated ?y: S1STEM G nerated on: 2J-f un-2022 kb:kb:30 Page J o/ b

CTU No.: FDA-CDER-CTU-2022-50160 | Department: CFSAN | RCT No.: RCT-1025403 | CTU Triage Date: 27-Jun-2022 | Total Pages: 8

	Sej	Female	
	Gender	Cisgender womanwgirl	
	Please Speci/y Other Gender		
	Age (speci/y unit o/ time /or age)	27 1 ar(s)	
	Date o/ Birth		
	Weight	bk@ qg	
	Ethnicity (Choose only one)	Not 4 anicwLatino	
Lis	Race (Checq all that apply) st qnown medical conditions (S	American Indian or Alasqa Native Native 4 awaiian or Other Paci/ic Islander Asian White Blacq or A/rican American uch as dia?etesxhigh ?lood pressurexcancerxheart diseasexor others)	
PI	<u> </u>	o drugsx/oodsx ollen or o hers)	
	PENICILLIN AND MINOC1 CLINE		
Lis	st any other important in/ormat	ion a?out the person (such as moq ingxpregnancyxalcohol usexetc6)	
Lis	st all current prescription medic	cations and medical devices? ng used6	
	LILETTA IUD		
Lis	st all over-the-counter medicati	ons and any vitaminsxmineralsxsupplementsxand her?al remedies ?eing used6	
Se	ection F - A?out the Person Fill	ing Out This Form	
Se	ection F - A?out the Person Fill	ing Out This Form k o/ k	
Se	ection F - A?out the Person Fill PrimaryH Reporter is PatientH		
Se	PrimaryH		

Generated ?y: S1STEM Generated on: 2J-f un-2022 kb:kb:30 Page 5 o/ b

CTU No.: FDA-CDER-CTU-2022-50160 | Department: CFSAN | RCT No.: RCT-1025403 | CTU Triage Date: 27-Jun-2022 | Total Pages: 8

Middle Name	
First name	(b) (6)
Num?erv6treet	(b) (6)
City	(b) (6)
StatewProvince	(b) (6)
Country	UNITED STATES
QIP or Postal code	(b) (6)
Telephone num?er	(b) (6)
Email address	(b) (6)
Faj	
Reporter Organization	
Department	
Reporter Speciality	
Today-s date	2J-f un-2022
Did you report this pro?lem to the company that maq the product (the manu/acturervcompounder)H	
I/ you do NOT want your dentity disclosed to the manu/acturerxplease marq this ?oj (Con/identiality ReYuested):	No

Generated ?y: S1STEM Generated on: 2J-f un-2022 kb:kb:30 Page b o/ b



The French Lentil + Leek Crumbles truly work with anthing. Oh, don't forget to add into your chili. Or eveninshepherd's pie. We could go on.

NET WT. 12oz (340g)
KEEP FROZEN, COOK THOROUGHLY

CTU No.: FDA-CDER-CTU-2022-50215 | Department: CFSAN | RCT No.: RCT-1025501 | CTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	·	
Override Auto Calculation Rule	No		
FDA Received Date	25-Jun-2022	CTU Received Date	25-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	•	
User/Group			
Forward to Department			
Case Priority	Direct		
<u>.</u>			

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Se	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
	Date the problem oc urred	13-Jun-2022	
	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

Monday June 13 in the evening I felt chills and got a 100°F fev r, headache, nausea, tiredness. I went to bed. I woke up with severe nausea, stomach ache and started vomiting. I continue to have nausea and bouts of vomiting all day. I couldn't eat. I had to stay in bed. I tested for Covid. All my tests were negative. It felt like a severe case of food poisoning. I lost 3 pounds in wo days. On Wednesday I started to feel better so I didn't con act my doctor. I stated looking for info about food recalls bu nothing I ate was recalled. I tossed some Driscoll's organic ra berries and local lettuce that I always buy from Fresh Direct , just in case, but those items were not recalled. On June 17 I r ved an e-mail from DH about the Lentil+Leek crumbles. I ate a serving of this food for dinner on Sunday June 12. It was a new bag from an order I received the previous week. The crumbles were stored in the freezer and I cooked them following the instructions. I ate them with some steamed broccoli and a bit of whole wheat pasta. I ate a bag of this food previously but it didn't caused noticeable symptoms. I don't drink and I eat a very healthy vegetarian diet so probably that's the rea on I didn't end in the ER as other people have reported. DH told customers to discard the product so I did. Unfortunately that was valuable evidence. They also asked me to fill out a form, which I did. I still have other DH products in my freezer which I don't plan to eat until we are sure there was not cros contamination.

Relevant Test/Laboratory Data

1 of 1

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50215 | Department: CFSAN | RCT No.: RCT-1025501 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Test Name		Test Date		
	Test Result		Test Unit		
	Low Test Range		High Test Range		
	More Information Available?			J	
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in	No			
	case we need to evaluate it?				
	Do you have a picture of the roduct? (check yes if you are	No			
	ncluding a picture)				_
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle,	French Lentil + Leek Crumb	les		
	or package (Include as many				
	names as you see) Name of the company that	Daily Harvest			
	makes (or compounds) the roduct				
	Product Type(check all that	Over-the-Counter			
	apply)	Compounded by a Pharmacy of	or an Outsourcing Facility		
		Generi			
		Biosimilar	,		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or				
	opped taking or using the roduct?				
	Did the problem return if the				
	rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50215 | Department: CFSAN | RCT No.: RCT-1025501 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	How was it taken or used		If Other		
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
W	ny was the person using the pr	oduct? (such as what cor	idition was it supposed to tr	eat) 1 of 1	
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot loc	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the e	expiration date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken ou relevant)	t (If	
Se	ction E - About the Person Wh	no Had the Problem			
	Person's Initials	Unspecified			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)	52 Year(s)			
	Date of Birth				
	Weight	43.2 kg			

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50215 | Department: CFSAN | RCT No.: RCT-1025501 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

	Ethnicity (Choose only one)	Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	
Lis	t known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	N/A		
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	N/A		
Lis	t any other important informat	on about the person (such as moking, pregnancy, alcohol use, etc.)	
	N/A		
Lis	t all current prescription medic	ations and medical devices b ng used.	
Lis	<u>-</u>	ations and medical devices bing used. les everyday, Estradiol 0.025mg patch twice wk.	
Lis	<u>-</u>		
Lis	<u>-</u>		
Lis	<u>-</u>		
	Progesterone Micro 100mg capsu		
	Progesterone Micro 100mg capsu	lles everyday, Estradiol 0.025mg patch twice wk.	
	Progesterone Micro 100mg capsu	lles everyday, Estradiol 0.025mg patch twice wk.	
	Progesterone Micro 100mg capsu	lles everyday, Estradiol 0.025mg patch twice wk.	
	Progesterone Micro 100mg capsu	lles everyday, Estradiol 0.025mg patch twice wk.	
Lis	Progesterone Micro 100mg capsust all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
Lis	Progesterone Micro 100mg capsust all over-the-counter medicati Multivitamin, Vitamin D	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1	
Lis	Progesterone Micro 100mg capsulate all over-the-counter medicati Multivitamin, Vitamin D ection F - About the Person Fill Primary?	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
Lis	Progesterone Micro 100mg capsust all over-the-counter medicati Multivitamin, Vitamin D ection F - About the Person Fill Primary? Reporter is Patient?	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1	
Lis	Progesterone Micro 100mg capsulated all over-the-counter medication Multivitamin, Vitamin Decition F - About the Person Fill Primary? Reporter is Patient? Title	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1 Yes	
Lis	Progesterone Micro 100mg capsust all over-the-counter medicati Multivitamin, Vitamin D ction F - About the Person Fill Primary? Reporter is Patient? Title Last name	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1	
Lis	Progesterone Micro 100mg capsulated all over-the-counter medication Multivitamin, Vitamin Dection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1 Yes (b) (6)	
Lis	Progesterone Micro 100mg capsulate all over-the-counter medicati Multivitamin, Vitamin D ection F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1 Yes (b) (6)	
Lis	Progesterone Micro 100mg capsulated all over-the-counter medication Multivitamin, Vitamin D Action F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1 Yes (b) (6) (b) (6) (b) (6)	
Lis	Progesterone Micro 100mg capsulate all over-the-counter medicati Multivitamin, Vitamin D Cotion F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street City	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1 Yes (b) (6) (b) (6) (b) (6) (b) (6)	
Lis	Progesterone Micro 100mg capsulated all over-the-counter medication Multivitamin, Vitamin D Action F - About the Person Fill Primary? Reporter is Patient? Title Last name Middle Name First name Number/Street	ons and any vitamins, mineral, supplements, and herbal remedies being used. Ing Out This Form 1 of 1 Yes (b) (6) (b) (6) (b) (6)	

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50215 | Department: CFSAN | RCT No.: RCT-1025501 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	25-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 25-Jun-2022 12:46:25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50257 | Department: CFSAN | RCT No.: RCT-1025549 | CTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details				
Company Unit	CDER-CTU	Originating Ac ount	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	26-Jun-2022	CTU Received Date	26-Jun-2022	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User			
User/Group				
Forward to Department				
Case Priority	Direct			

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the	Problem	
What kind of problet (Check all that apply	m was it?	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker
Date the problem or	urred 04-	Jun-2022
Serious	Yes	,
Did any of the follow (Check all that apply		Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)
Other serious/impor ncident(Please Des		

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

https://www.fda.gov/safety/recalls-market-withdraw als-safety-alerts/daily-harvest-issues-voluntary-r ecall-french-lentil-leek-crumbles-due-potential-he alth-risk My family and I consumed th recalled Daily Harvest french lentil and leek product on 6-4-2022 in chili and it was cooked at the recommended cooking me. We are all having labwork with elevated liver enzymes. For (SGPT) test: My brother in law was 300, my sister 140 (she d 21 prior to this test), my husband 124 and I was 111, I was 35 on this test 2 months earlier so a 76 point change! My SGOT test was 55 on the test on 6/24/22 and was 39 - 2 months arlier. My sister tested 81 on SGOT & was 25 in her last test rior. My son will be tested next week and I can send you that nformation. My sister is jaundiced with yellow whites of her eyes and yellowing skin. We had symptoms starting a week and half after eating the product, reflux, felt terrible, low fever, bloated, Nausea, upset stomach & felt like throwing up would make us feel better, fatigue, and weird deeper yellow colored urine. We have seen our doctors for this issue and done lab work for liver work up if you need more information and test results. Please let us know your findings so we can keep our doctor's nformed. This is extremely upsetting the handling of the notif ation to consumers by Daily Harvest and the damage they have caused to our bodies. I am 57 years old female consumer.

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:26 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50257 | Department: CFSAN | RCT No.: RCT-1025549 | CTU Triage Date: 27-Jun-2022 | Total Pag

Re	elevant Test/Laboratory Data			1 of 2
	Test Name	ALANINE AMINOTRANSF ERASE (SGPT)	Test Date	24-Jun-2022
	Test Result	111	Test Unit	
	Low Test Range	35	High Test Range	111
	More Information Available?			
Re	elevant Test/Laboratory Data			2 of 2
	Test Name	ASPARTATE AMINOTRN SFRASE (SGOT)	Test Date	24-Jun-2022
	Test Result	55	Test Unit	
	Low Test Range	29	High Test Range	55
	More Information Available?			
Ac	Iditional Comments			
Se	My sister subscribed to Daily Handmade on June 4, 2022. ection B - Product Availability	vest and had the French lentil	leek product. I believe we used the	entire bag in the chili we
	Do you still have the product in case we need to evaluate it?	No		
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Se	ection C - About the Products			1 of 1
	Suspect	Yes		
	Primary?	Yes		
	Туре	Drug/Biologi		
	This report is about	Food/Medical food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	& Leek crumbles	
	Name of the company that makes (or compounds) the roduct	Daily Harvest		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility	
	Strength		If Other	
	NDC number			
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No		

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50257 | Department: CFSAN | RCT No.: RCT-1025549 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Did the problem return if the	Doesn't Apply		
rson started taking or using the roduct again?	9		
Drug Therapy			1 of 1
Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started aking or using the product	04-Jun-2022		
Date the person stopped taking or using the product	04-Jun-2022		
Date the person reduced dose on the product	of		
Give best estimate of duration			
Is therapy still on-going?			
Why was the person using the p	oroduct? (such as what c	ondition was it supposed to tre	at) 1 of 1
Returned to Manufacturer On			
Section D - About the Medical D	Device		
Name of medical device			
Name of the company that makes the medical device			
Other identifying information (TI locate them)	he model, catalog, lot, se	rial, or UDI number, and the ex	xpiration date, if you can
Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating the medical device when the problem oc urred?	m		
For implanted medical devices	ONLY (such as pacemak	ers, breast mplants, etc.)	

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50257 | Department: CFSAN | RCT No.: RCT-1025549 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Section E - About the Person Wh	no Had the Problem	
Person's Initials	(b) (6)	
Sex	Female	
Gender	Cisgender woman/girl	
Please Specify Other Gender		
Age (specify unit of time for age)	57 Year(s)	
Date of Birth		
Weight	123.75 kg	
Ethnicity (Choose only one)	Not Hispanic/Latino	
Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
List known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	cer - thyroid & some lymph nod removed, PVC's, osteoarthritis, barrett's esophagus, hip onmental allergies, asthma (mild) and sleep apnea.	
Please list all allergies (such as t	o drugs, foods, pollen or o hers)	
ulfa drugs and cefdinir		
List any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
non smoker, limited alcohol use 1	drink a week	
List all current prescription medic	cations and medical devices b ng used.	
Levothyroxine, metoprolol XR, pra vitamin d, fish oil, baby aspirin, &	avastatin, xyzal (allergy OTC), flonase, alaway eye drops, sleep apnea machine, prilosec, CoQ10.	
List all over-the-counter medication	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
See above - vitamin d, C0Q10, fis	h oil, flonase, xyzal & prilos	
Section F - About the Person Filli	ing Out This Form 1 of 1	
Primary?	Yes	

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:26 Page 4 of 5

Reporter is Patient?

CTU No.: FDA-CDER-CTU-2022-50257 | Department: CFSAN | RCT No.: RCT-1025549 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	26-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:26 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50262 | Department: GFSAN | RCT No.: RCT-1025560 | DTU Trage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	A 1 1 1 1 1 1	220000000000000000000000000000000000000	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		No. down to the
FDA Received Date	26-Jun-2022	CTU Received Date	26-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	Ø		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product	
Date the problem occurred	Had problems after switching from one product maker to another maker 04-Jun-2022	
Serious	No	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

June 4, 2022 We used Daily Harvest Lentil and Leek crumbles in a Chili, with tomatoes, chili beans, onions and jalapeño, this product was simmered with a low boil for two hours or more then served immediately. We did not have immediate issues. About a week later I noticed darker urine and it seemed to continue to get darker till about June 16 where other symptoms were showing up my symptoms were dark urine, burping, bloodshot eyes, nausea, acid reflux, abdominal pain, itchiness, lethargy and no appetite (my husband almost brought me to hospital). June 20 I finally contacted my primary Dr and she sent me to immediate care, they gave me a urine test and it only showed ketones so she didn't think I needed bloodwork and sent me home, I followed up with my Dr and she got me in on June 21 for exam, Urine and bloodwork. Exam noted jaundiced skin and eyes, I explained I had grayish and yellow stools, she did Urine test, hepatitis test, three different blood panels, Urine test normal, blood showed all elevated liver enzyme's. My urine 6/25/2022 is finally looking a normal shade and I'm drinking an average of 90 oz a water per day. I'm still feeling lower energy, some burping, some nausea, mid to lower back aches and only wanting a blander diet and have lost 7 pounds since last week. We no longer have package because we used entire package in chili. We also threw out all remaining product by Daily Harvest Friday June 24. I have a picture of confirmation email too

Relevant Test/Laboratory Data

1 of 4

Generated by: SYSTEM Generated on: 26-Jun-2022 12:16:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50262 | Department: CFSAN | RCT No.: RCT-1025560 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	1	T	
Test Name	ALKALINE PHOSPHATE	Test Date	21-Jun-2022
Test Result	140	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	34	High Test Range	104
More Information Available?			
Relevant Test/Laboratory Data			2 of 4
Test Name	AST	Test Date	21-Jun-2022
Test Result	81	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	High Test Range	39
More Information Available?			
elevant Test/Laboratory Data			3 of 4
Test Name	BILIRUBIN	Test Date	21-Jun-2022
Test Result	2.3	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	0.0	High Test Range	1.1
More Information Available?			
elevant Test/Laboratory Data			4 of 4
Test Name	ALT	Test Date	21-Jun-2022
Test Result	140	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	High Test Range	52
More Information Available?			
dditional Comments			
ection B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Section C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologi		
This report is about	Food/Medical food		
Name of the product as it	Daily Harvest French lentil	and leek crumbles	
appears on the box, bottle,	I		

Generated by: SYSTEM Generated on: 26-Jun-2022 12:16:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50262 | Department: CFSAN | RCT No.: RCT-1025560 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

	or package (Include as many names as you see)				
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number		-		
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of he product				
	Give best estimate of duration	2 Day			
	Is therapy still on-going?				
W	hy was the person using the pr	oduct? (such as what co	ndition was it supposed to t	reat) 1 of 1	
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
	her identifying information (The	e model, catalog, lot, seri	al, or UDI number, and the	expiration date, if you can	

Generated by: SYSTEM Generated on: 26-Jun-2022 12:16:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50262 | Department: CFSAN | RCT No.: RCT-1025560 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Model Number			
Catalog Number			
Lot Number			
Serial Number			
UDDI Number			
Expiration date			
Was someone operating th medical device when the procurred?			
For implanted medical devi	ces ONLY (such as pacema	ikers, breast mplants, etc.)	
Date the implant was put in		Date the implant was taken out (If relevant)	
Section E - About the Perso	on Who Had the Problem		
Person's Initials	(b) (6)		
Sex	Female		
Gender	Cisgender woman/girl		
Please Specify Other Gend		<u></u>	
Age (specify unit of time for			
Date of Birth	290, 200000		
Weight	64.8 kg		
Ethnicity (Choose only one			
Race (Check all that apply)	•	N. C	
	Native Hawaiian or Other R		
	Asian	done islands	
	White		
	Black or African American		
List known medical condition	ns (Such as diabetes, high	blood pre ure, cancer, heart disease	e, or others)
Thyroid disease, seasonal	allergies		
Please list all allergies (suc	h as to drugs, foods, pollen	or o hers)	
Penicillin, pollen, mold			
List any other important info	ormation about the person (s	such as moking, pregnancy, alcohol	use, etc.)

Generated by: SYSTEM Generated on: 26-Jun-2022 12:16:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50262 | Department: CFSAN | RCT No.: RCT-1025560 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Not drinking alcohol at all currently, typically 3-5 drinks total per week normally	
Lis	st all current prescription medications and medical devices b ng used.	
	80mg er propranolol	
Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
	Flonase as needed, vitamin d once a week	

ction F - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	26-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 26-Jun-2022 12:16:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50258 | Department: CFSAN | RCT No.: RCT-1025550 | CTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Detai	ls				
Company U	nit	CDER-CTU	Origii	nating Ac ount	FAERS
Source Med	ium	MWO (Drug)	Sour	ce Form Type	E2B XML 3500B
Priority		Routine	1		
Override Au	to Calculation Rule	No			
FDA Receiv	ed Date	26-Jun-2022	CTU	Received Date	26-Jun-2022
CTU Triage	Date		CTU	Data Entry Date	
Report Type	•	Spontaneous	Repo	rt Classification	Drug
Assign To		User	1		
User/Group					
Forward to [orward to Department				
Case Priority					
Contact	E. W				D.
Case	First Name	Last Name		Email Address	Phone
Reporter	(b) (6)	(b) (6)			
Section A	About the Problem				
What kin	What kind of problem was it? (Check all that apply) Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker				
Date the	problem oc urred	04-Jun-2022			
Serious		No			
	of the following happen? ill that apply)	Hospitalization - admitted Required help to prever Disability or health pro	ent permanent ha	=	

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

Other serious/important medical incident(Please Describe Below)

Death

Made chili which included Daily Harvest french lentil and leek crumbles on 6/4/2022. On 6/13/22 started noticing dark yellow urine which lasted until 6/23. On 6/15 started to experience heartburn and upset stomach which lasted until about 6/22. On 6/17 started to feel fatigued/dizzy and slept almost all day on 6/19. Fatigue lasted until 6/21. On 6/19 started to have extreme itching from chest up to top of head until 6/23. Went to get bloodwork done on 6/23. Stool light yellow from 6/13 to 6/24.

R	elevant Test/Laboratory Data			1 of 4	
	Test Name	COMPREHENSIVE META BOLIC PANEL - ALT	Test Date	23-Jun-2022	
	Test Result	384	Test Unit	INTERNATIONAL UNITS PER LITRE	
	Low Test Range	0 u/L	High Test Range	52 u/L	

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:29 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50258 | Department: CFSAN | RCT No.: RCT-1025550 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

More Information Available?			
levant Test/Laboratory Data			2 of 4
Test Name	COMPREHENSIVE META BOLIC PANEL - ALKALIN E PHOSPHATE	Test Date	23-Jun-2022
Test Result	140	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	34 u/L	High Test Range	104 u/L
More Information Available?			
levant Test/Laboratory Data			3 of 4
Test Name	COMPREHENSIVE META BOLIC PANEL - AST	Test Date	23-Jun-2022
Test Result	194	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0 u/L	High Test Range	39 u/L
More Information Available?			
levant Test/Laboratory Data			4 of 4
Test Name	COMPREHENSIVE META BOLIC PANEL - TOTAL BI LIRUBIN	Test Date	23-Jun-2022
Test Result	1.8	Test Unit	MICROGRAMS PER DEC
Low Test Range	0.0 mg/dl	High Test Range	1.0 mg/dl
More Information Available?			
ditional Comments			
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
ction C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologi		
1 3 90	İ		-
This report is about	Food/Medical food		

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:29 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50258 | Department: CFSAN | RCT No.: RCT-1025550 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	Compounded by a Pharmacy or an Outsourcing Facility Generi		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				_
	Quantity		If Other		
	Frequency		If Other		_
	How was it taken or used		If Other		
	Date the person first started aking or using the product	04-Jun-2022	I		
	Date the person stopped taking or using the product	04-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
VVI	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to t	reat) 1 of 1	
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot loc	her identifying information (The cate them)	e model, catalog, lot, seri	al, or UDI number, and the	expiration date, if you can	
	Model Number				
		1			

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:29 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50258 | Department: CFSAN | RCT No.: RCT-1025550 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		
Fo	r implanted medical devices C	DNLY (such as pacemakers, breast mplants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	ho Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Male	
	Gender	Cisgender man/boy	
	Please Specify Other Gender		
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	
	Weight	82.8 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	
Lis	t known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
	none		
Ple	ease list all allergies (such as t	to drugs, foods, pollen or o hers)	
	none		
Lis	t any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
	none		
Lis	t all current prescription medic	cations and medical devices bing used.	

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:29 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50258 | Department: CFSAN | RCT No.: RCT-1025550 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

	none	
Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
	multivitamin	

ection F - About the Person Filli	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	
Email address	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	26-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 26-Jun-2022 11:16:29 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50296 | Department: CFSAN | RCT No.: RCT-1025604 | CTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	lyed in the report are in EST(G	wit-05.00) title zone					
Basic Deta							
Company L		CDER-CTU	Originating Ac ount	FAERS			
Source Med	dium	MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority		Routine					
Override Au	uto Calculation Rule	No					
FDA Receiv	ved Date	26-Jun-2022	CTU Received Date	26-Jun-2022			
CTU Triage	e Date		CTU Data Entry Date				
Report Typ	е	Spontaneous	Report Classification	Drug			
Assign To		User					
User/Group)						
Forward to	Department						
Case Priori	ty	Oirect					
Contact							
Case	First Name	Last Name	Email Address	Phone			
Reporter							
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)			
Section A	- About the Problem						
	nd of problem was it?						
	all that apply)		Were hurt or had a bad side effect (including new or worsening symptoms)				
		Used a product incorrectly which could have or led to a problem					
		Noticed a problem with the quality of the product					
		Had problems after switching from one product maker to another maker					
	e problem oc urred	18-May-2022					
Serious		Yes					
Did any of the following happen? (Check all that apply)		Hospitalization - admitted or stayed longer					
(Oncor.	an triat apply)	Required help to prevent permanent harm					
		Disability or health pr	Disability or health problem				
		Birth defect	Birth defect				
		Life-threatening					
		Death					
		Other serious/importa	ant medical incident(Please Describe Below)				
	erious/important medical (Please Describe Below)						
	•	w it happened (Incl	ude as many de ails as possible	e FDA may reach out to you for			
any additio	onal documents if nece	ssary)					
			es and had th following symptoms: h				
and lack of appetite for 4-5 days, dark urine for multiple days, pain in my abdomen, chills, fatighousehold member consumed the lentil crumbles in mid-June and roorted abdominal discomf							
nousend	ola member consumea ine	a lentii Crumbies in mi	u-June and r orted abdominal discol	mort.			
Relevant I	est/Laboratory Data			1 of 1			
Test Na	•		Test Date				
Test Re	sult		Test Unit				
Low Tes	st Range		High Test Range				

Generated by: SYSTEM Generated on: 26-Jun-2022 22:16:48 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50296 | Department: CFSAN | RCT No.: RCT-1025604 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	More Information Available?				
Ad	Iditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	+ Leek Crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number		I		
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	10-Oct-2022			
	Lot number	L5-A 12:10			
	Dosage Form				
	Quantity	Other	If Other	1 serving each time	
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	11-May-2022			
	Date the person stopped taking or using the product	25-May-2022			

Generated by: SYSTEM Generated on: 26-Jun-2022 22:16:48 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50296 | Department: CFSAN | RCT No.: RCT-1025604 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				_
W	ny was the person using the pr	oduct? (such as what con	dition was it supposed to tr	reat) 1 of 1	
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the o	expiration date, if you can	
	Model Number				_
	Catalog Number	_			
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast_mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken our elevant)	it (If	
Se	ction E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)	34 Year(s)			
	Date of Birth				
	Weight	90 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati	ve		
		Native Hawaiian or Other Pacifi	c Islander		
		Asian			

Generated by: SYSTEM Generated on: 26-Jun-2022 22:16:48 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50296 | Department: CFSAN | RCT No.: RCT-1025604 | CTU Triage Date: 27-Jun-2022 | Total Pag

		White Black or African American	
Lis	t known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as	to drugs, foods, pollen or o hers)	
Lis	t any other important informat	tion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	t all current prescription medic	cations and medical devices b ng used.	
	none		
Lis	t all over-the-counter medicat	ions and any vitamins, mineral, supplements, and herbal remedies being used.	
	none		
0 -	-t' E Abt tb D E''	4.54	
Se	ction F - About the Person Fill Primary?	ling Out This Form 1 of 1 Yes	
	Reporter is Patient?	Tes	-
	Title		+
	Last name	(b) (6)	+
	Middle Name		1
	First name	(b) (6)	
	Number/Street		
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	

Generated by: SYSTEM Generated on: 26-Jun-2022 22:16:48 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50296 | Department: CFSAN | RCT No.: RCT-1025604 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	26-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 26-Jun-2022 22:16:48 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50263 | Department: GPSAN | RCT No.: RCT-1025661 | DTU Trage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	F	
Override Auto Calculation Rule	No		The state of the
FDA Received Date	26-Jun-2022	CTU Received Date	26-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	- 6	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	V 0 0 0		17000	200.0
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem			
	ind of problem was it?	Were hurt or had a bad side	effect (including new or worsening sympto	ms)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	27-May-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I received two Daily Harvest orders containing their recalled product French Lentil + Leek Crumble -- on May 24 and also June 7, 2022. I consumed the first French Lentil + Leek Crumble pouch that was delivered in the May 24 order over several, spread out meals (I cooked the crumbles on a stove top correctly) and first experienced severe lower back pain on 5/27. I consulted with a doctor and had several days in bed. Since then I've experienced weeks of extreme nausea, lower back pain, abdominal pains, vomiting, severe body aches, dark urine, exhaustion, night sweats and many other bizarre symptoms. I have spent countless days in bed due to the nausea and pain. I ended up in an Urgent Care facility on the evening of 6/6 as was so nauseous I was vomiting up water and could barely stand. I then saw my primary care doctor al(b) (6) the next day on 6/7. They ran tests that showed extremely elevated Gamma GT, ALT(SGPT) and Alkaline Phosphate levels among many other things. My doctor thought I might have food borne Hep A or Mono. I am able to provide copies of all tests if needed. Reading back through the online summary report they noted: "Feels poisoned and has been this way for about 10 days on and off" I disposed of the second French Lentil + Leek Crumble pouch after reading the Daily Harvest recall email that was sent to consumers on 6/17 but have consumed other DH products on a daily basis. I am still unwell and very worried about the long term damage to my health. The Daily Harvest recall email was incredibly vague and I have only just put things together this morning after a friend sent me the related New York Times article and I have now read others experiences that are so closely

Generated by: SYSTEM Generated on: 26-Jun-2022 12:46:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50263 | Department: CFSAN | RCT No.: RCT-1025561 | CTU Triage Date: 27-Jun-2022 | Total Pag

related to mine. I have stopped my weekly Daily Harvest delivery as of this morning but still have the unconsumed products in my freezer (unfortunately I do not have the French Lentil + Leek Crumble pouch as disposed of it when asked to).

Relevant Test/Laboratory Data			1 of 3
Test Name	ALKALINE PHOSPHATE	Test Date	09-Jun-2022
Test Result	240	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	44	High Test Range	121
More Information Available?			
Relevant Test/Laboratory Data			2 of 3
Test Name	ALT(SGPT)	Test Date	09-Jun-2022
Test Result	312	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	High Test Range	32
More Information Available?			
Relevant Test/Laboratory Data			3 of 3
Test Name	GAMMA GT	Test Date	09-Jun-2022
Test Result	176	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	High Test Range	60
More Information Available?			
Additional Comments			
I was given many tests that show	ed unusual results - these are	e just three that stood out to me.	
Section B - Product Availability			
Do you still have the product in ase we need to evaluate it?	No		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Section C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologi		

Generated by: SYSTEM Generated on: 26-Jun-2022 12:46:22 Page 2 of 5

Food/Medical food

Daily Harvest

French Lentil + Leek Crumble

This report is about

names as you see)

roduct

Name of the product as it

appears on the box, bottle, or package (Include as many

Name of the company that

makes (or compounds) the

CTU No.: FDA-CDER-CTU-2022-50263 | Department: CFSAN | RCT No.: RCT-1025561 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generi	y or an Outsourcing Facility		
	Strength	Biosimilar	If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity	Other	If Other	3 servings	
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	24-May-2022			
	Date the person stopped taking or using the product	06-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
WI	ny was the person using the pr	oduct? (such as what co	ondition was it supposed	to treat) 1 of 1	
	Meal delivery service				
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot loc	her identifying information (The ate them)	e model, catalog, lot, se	rial, or UDI number, and	the expiration date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				

Generated by: SYSTEM Generated on: 26-Jun-2022 12:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50263 | Department: CFSAN | RCT No.: RCT-1025561 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fc	or implanted medical devices C	NLY (such as pacemake	rs, breast mplants, etc.)		
D	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl	-		
	Please Specify Other Gender				
	Age (specify unit of time for age)	47 Year(s)			
	Date of Birth				
	Weight	68.4 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif Asian White Black or African American			
LIS	st known medical conditions (S	such as diabetes, high bio	od pre ure, cancer, heart disease	e, or otners)	
	ease list all allergies (such as t	to drugge foods, pollon or a	a hara)		
Г	ease list all allergles (such as t	to drugs, 100ds, policit of t	J Hels)		
l i	st any other important informat	ion about the person (suc	h as moking, pregnancy, alcohol	use etc)	
	st arry other important imormat	- about the person (suc	Tras monning, prognancy, alcohol	430, Cto.)	
Lis	st all current prescription medic	cations and medical devic	es b ng used.		

Generated by: SYSTEM Generated on: 26-Jun-2022 12:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50263 | Department: CFSAN | RCT No.: RCT-1025561 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	

ction F - About the Person	Filling Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	26-Jun-2022
Did you report this problem to company that makes the prod (the manufacturer/compounded)	luct
If you do NOT want your dentity disclosed to the manufacturer, please mark the box (Confidentiality Requeste	

Generated by: SYSTEM Generated on: 26-Jun-2022 12:46:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50283 | Department: GPSAN | RCT No.: RCT-1025586 | DTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		No. do not not not not not not not not not no
FDA Received Date	26-Jun-2022	CTU Received Date	26-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	12-May-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Late daily harvest lentil crumbles on 5/11/22 after receiving it in a PR package. The next day my husband took me to the ER in the early morning hours for excruciating abdominal and gastro pains. The doctors performs multiples tests at (b) (6) in NYC but could not come up with a diagnosis but did state my liver enzymes were elevated and I had bacteria in my urine. They gave me 5 days of antibiotics. 5 days later after finishing the antibiotics, I again had pains worst than the first time around and went back to NYI Langones ER on 5/19/22. They admitted me as my liver enzyme levels were in the mid to high 400 range. They performed multiple types of blood tests, a chest X-ray, an ultrasound of my gallbladder and liver, a vaginal ultrasound, a cat scan of my liver and more. Multiple divisions from their doctors staff saw me as they simply couldn't figure out what the issue was. I was released after being monitored the next evening and was told to schedule a follow up blood test with my primary care doctor. I had that appointment and then followed up with the liver specialist for more blood tests. I am supposed to have an MRI in august to confirm I do not have any permanent liver damage.

Rele	vant Test/Laboratory Data		1 of 1
	est Name	Test Date	

Generated by: SYSTEM Generated on: 26-Jun-2022 19:46:23 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50283 | Department: CFSAN | RCT No.: RCT-1025588 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

	Test Result		Test Unit			
	Low Test Range		High Test Range			
	More Information Available?					
Ad	ditional Comments					
	I have all test results on my chart	and printed out. High liver en	zyme levels around 443.			
Se	ction B - Product Availability					
	Do you still have the product in case we need to evaluate it?	No				
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes				
Se	ction C - About the Products			1 of 1		
	Suspect	Yes				
	Primary?	Yes				
	Туре	Drug/Biologi				
	This report is about	Food/Medical food				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	Daily Harvest French Lentil + Leek Crumbles			
	Name of the company that makes (or compounds) the roduct	Daily Harvest				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility			
	Strength		If Other			
	NDC number		,			
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply				
Dru	ug Therapy			1 of 1		
	Expiration date					
	Lot number					
	Dosage Form					
	Quantity		If Other			
	Frequency		If Other			
	How was it taken or used		If Other			

Generated by: SYSTEM Generated on: 26-Jun-2022 19:46:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50283 | Department: CFSAN | RCT No.: RCT-1025588 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

	Date the person first started aking or using the product	11-May-2022		
	Date the person stopped taking or using the product	11-May-2022		
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
Wł	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat) 1 of 1	
	Eating as a meal			
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Otl	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if you can	
100	ate them)			
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
S-6	ection E - About the Person Wh	o Had the Problem		
00	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Cisgender woman/girl		
	Please Specify Other Gender	ologonadi iromanigin		
	Age (specify unit of time for age)			
	Date of Birth	(b) (6)		
	Weight	67.5 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		

Generated by: SYSTEM Generated on: 26-Jun-2022 19:46:23 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50283 | Department: CFSAN | RCT No.: RCT-1025588 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	Sulfa allergy		
Lis	st any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	cations and medical devices b ng used.	
	Adderall 20 mg XR		
Lis	at all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
			T
0 -	- San E. Alan Atlan Danis a Fill		
Se	ction F - About the Person Fill Primary?	ing Out This Form 1 of 1 Yes	_
	Reporter is Patient?	res	+
	Title		+
	Last name	(b) (6)	-
		(b) (6)	+-
	Middle Name	(b) (6)	+
	First name	(b) (6)	
	Number/Street	(b) (6)	_
	City	(b) (6)	_
	State/Province		_
	Country	UNITED STATES	_
	ZIP or Postal code	(b) (6)	

Generated by: SYSTEM Generated on: 26-Jun-2022 19:46:23 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50283 | Department: CFSAN | RCT No.: RCT-1025588 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	26-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 26-Jun-2022 19:46:23 Page 5 of 5

Toss in a tortilla. Crumble on top of a Flatbread n a lettuce wrap. Layer into lasagna. Upgrade sloppy Joes. Dare we say stuff into an empanad! These French Lentil + Lee Crumbles truly workw anything. Oh, don't forget to add into your chi even in shepherd's pie. We could go on

NET WT. 120 KEEP FROZEN, COOK IHOROUGHLY

ČTU No.: FDA-CDER-CTU-2022-50477 | Department | GFSAN | RCT No. | RCT-1025867 | DTU Trage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Contact

incident(Please Describe Below)

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	
FDA Received Date	27-Jun-2022	CTU Received Date	27-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	16	
User/Group			
Forward to Department			
Case Priority	Direct		

Case Reporter	First Name	Last Name	Email Address	Phone		
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
ection A	- About the Problem	!	- 1900			
	nd of problem was it? all that apply)	Used a product incorrectly v Noticed a problem with the	effect (including new or worsening symptor which could have or led to a problem quality of the product g from one product maker to another make			
Date th	e problem occurred	11-Jun-2022				
Serious	01	Yes				
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Life-threatening Death	rmanent harm			
Other s	erious/important medical	outer consularing transfer	and management reduce Describe Descript			

4 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

On June 11th I went to Prairie Ridge Urgent Care in Columbus, WI with a fever, severe stomach pain, fever, upper back pain, and overall aches and severe dizziness. I was given a Covid, Influenza, and Strep test and they all came back negative. I was given something for nausea and sent home. On June 16th I returned as symptoms continued and now my stool was clay-colored and my urine dark orange. They took bloodwork and I had an EKG, two ultrasounds, and a CT scan as they thought it was possibly my gall bladder. No blockage but I had bacteria in my urine and my Alkaline Phosphatase was above normal at 167, my ALT was 264 (normal range is 0-55) and my AST was 71 (normal range 5-34). They could not determine what was wrong and insisted I follow up with my regular doctor the next week and retake the blood tests. I did this and my levels were coming down but still high. In the meantime, I received an email from Daily Harvest on June June 17th stating that had purchased their French Lentil + Leek Crumbles and that they must be cooked thoroughly but to dispose of the order I received. I had already consumed them and had cooked them thoroughly - I had put them on top of one of their flatbreads and cooked them at 425 for 20 minutes. On June 19th I received an email to dispose of them and not to eat them. I did not eat any more of them but did not realize what the side effects were until yesterday when I saw updates on social media noting they could cause liver issues. I feel that there could possibly be a connection here. I have not consumed alcohol for over 11 years and I

Generated by: SYSTEM Generated on: 27-Jun-2022 09:46:22 Page 1 of 6

CTU No.: FDA-CDER-CTU-2022-50477 | Department: CFSAN | RCT No.: RCT-1025667 | CTU Triage Date: 27-Jun-2022 | Total Pag

es: 8

am at a normal / ght and normal BMI. I still have the crum6les in the Jeezer and / II not consume 6ut / ill not dispose oJun I his has resolved.

Re	elevant TestfLa6oratory Data			HoJ8
	Test Name	AL+ALINE Pq OSPq ATAS E	Test Date	H8-9un-2022
	Test Result	H81	Test Unit	LITRES
	Lo/ Test Range	40	q gh Test Range	H50
	More In brmation Availa6lek			
Re	elevant TestfLa6oratory Data			2 oJ8
	Test Name	ALT	Test Date	H8-9un-2022
	Test Result	284	Test Unit	LITRES
	Lo/ Test Range	0	q gh Test Range	55
	More Inbrmation Availa6lek			
Re	elevant TestfLa6oratory Data			3 oJ8
	Test Name	AST	Test Date	H8-9un-2022
	Test Result	1H	Test Unit	LITRES
	Lo/ Test Range	5	q gh Test Range	34
	More In.brmation Availa6lek			
Re	elevant TestfLa6oratory Data			4 oJ8
	Test Name	AL+ALINE Pq OSPq ATAS E	Test Date	2H-9un-2022
	Test Result	нзн	Test Unit	LITRES
	Lo/ Test Range	2H	q gh Test Range	H04
	More In brmation Availa6lek			
Re	elevant TestfLa6oratory Data			5 oJ8
	Test Name	ALT	Test Date	2H-9un-2022
	Test Result	10	Test Unit	LITRES
	Lo/ Test Range	5	q gh Test Range	27
	More In brmation Availa6lek			
Re	More In brmation Availa6lek elevant TestfLa6oratory Data			8 o J 8
Re		AST	Test Date	8 oJ8 2H-9un-2022
Re	elevant TestfLa6oratory Data	AST Hb	Test Date Test Unit	
Re	Plevant TestfLa6oratory Data Test Name			2H-9un-2022
Re	Test Result	Нь	Test Unit	2H9un-2022 LITRES

Additional Comments

Generated 6y: SYSTEM Generated on: 21-9un-2022 0b:48:22 Page 2 oJ8

CTU No.: FDA-CDER-CTU-2022-50477 | Department: CFSAN | RCT No.: RCT-1025667 | CTU Triage Date: 27-Jun-2022 | Total Pages: 8

	The Jrst set oJtests / as Jom my second urgent care visit on 8fH8f2022 and the second my Jollo/ up / ith GP on 8f2Hf2022					
Se	ction B - Product Availa6ility					
	Do you still have the product in	Yes				
	case / need to evaluate itk					
	Do you have a picture oJthe productk (chec. yes iJyou are ncluding a picture)	Yes				
Se	ction C - A6out the Products			НоЈН		
	Suspect	Yes				
	Primaryk	Yes				
	Туре	DrugfBiologi				
	This report is a6out	FoodfMedical bod				
	Name oJthe product as it appears on the 6o', 6ottle, or pac. age (Include as many names as you see)	Daily q arvest French Lentil + Lee. Crum6les				
	Name oJthe company that ma. (or compounds) the roduct	Daily q arvest				
	Product Type(chec. all that apply)	Over-the-Counter Compounded 6y a Pharmacy or an Outsourcing Facility Generi Biosimilar				
	Strength		IJOther			
	NDC num6er					
	Did the pro6lem stop aJ r the rson reduced the dose or opped ta. ng or using the roductk	No				
	Did the pro6lem return iJthe rson started ta. ng or using the roduct againk	Yes				
Dr	ug Therapy			НоЈН		
	E' ration date	H0-Oct-2022				
	Lot num6er	L5-A				
	Dosage Form					
	Vuantity		IJOther			
	Fre?uency		IJOther			
	qo/ / as it ta. n or used		IJOther			
	Date the person Jrst started a. ng or using the product	30-May-2022				
	Date the person stopped ta. ng or using the product	H0-9un-2022				
	Date the person reduced dose oJ he product					
	Give 6est estimate oJduration				ĺ	

Generated 6y: SYSTEM Generated on: 21-9un-2022 0b:48:22 Page 3 oJ8

CTU No.: FDA-CDER-CTU-2022-50477 | Department: CFSAN | RCT No.: RCT-1025667 | CTU Triage Date: 27-Jun-2022 | Total Pages: 8

	Is therapy still on-goingk	Yes			
Wł	ny / as the person using the pr	oductk (such as / hat cor	ndition / as it supposed to treat)	НоЈН	
	Returned to Manu acturer On				
	Returned to Manuacturer On				
Se	ction D - A6out the Medical De	evice			
	Name oJmedical device				
	Name oJthe company that ma. the medical device				
Ot loc	her identiJying inbrmation (The ate them)	e model, catalog, lot, seria	al, or UDI num6er, and the e' pira	tion date, iJyou can	
	Model Num6er				
	Catalog Num6er				
	Lot Num6er				
	Serial Num6er				
	UDDI Num6er				
	E' ration date				
	Was someone operating the medical device / hen the pro6lem oc urredk				
Fo	r implanted medical devices O	NLY (such as pacema. rs	s, 6reast mplants, etc.)		
Da	ate the implant / as put in		Date the implant / as ta. n out (IJ relevant)		
Se	ction E - A6out the Person Wh	o g ad the Profilem			
	Person%Initials	UnspeciJ d			
	Se'	Female			
	Gender	Cisgender / omanfgirl			
	Please SpeciJy Other Gender				
	Age (speciJy unit oJtime Jbr age)				
	Date oJBirth	(b) (6)			
	Weight	80.15 . g			
	Ethnicity (Choose only one)	Not q anicfLatino			
	Race (Chec. all that apply)	American Indian or Alas. a Nati	ive		
		Native q a/ aiian or Other Pacid	J Islander		
		Asian			
		White			
		Blac. or AJican American			

Generated 6y: SYSTEM Generated on: 21-9un-2022 0b:48:22 Page 4 oJ8

CTU No.: FDA-CDER-CTU-2022-50477 | Department: CFSAN | RCT No.: RCT-1025667 | CTU Triage Date: 27-Jun-2022 | Total Pages: 8

List . no/ n medical conditions (Such as dia6etes, high 6lood pre ure, cancer, heart disease, or others)	
Please list all allergies (such as	to drugs, bods, pollen or o hers)	
List any other important in໓rma	tion a6out the person (such as mo. ng, pregnancy, alcohol use, etc.)	
mo.		
List all current prescription medi	cations and medical devices 6 ng used.	
azelaic acid H5 x gel, tretinoin 0	.025 x cream, DULo' etine 80 MG capsule	
List all over-the-counter medical	tions and any vitamins, mineral , supplements, and her6al remedies 6eing used.	
Continue Continue Davidus Ci	ling Out This Form HoJH	
Section F - A6out the Person Fil		
Primaryk Reporter is Patientk	Yes	
Title		
Last name	(b) (6)	_
Middle Name		
First name	(b) (6)	
Num6erfStreet	(b) (6)	
City	(b) (6)	
StatefProvince	(b) (c)	
Statem Tovince		

Generated 6y: SYSTEM Generated on: 21-9un-2022 0b:48:22 Page 5 oJ8

(b) (6)

(b) (6)

(b) (6)

ZIP or Postal code

Telephone num6er

Reporter Organization

Email address

Department

Fa'

CTU No.: FDA-CDER-CTU-2022-50477 | Department: CFSAN | RCT No.: RCT-1025667 | CTU Triage Date: 27-Jun-2022 | Total Pages: 8

Reporter Speciality		
Today‰date	21-9un-2022	
Did you report this pro6lem to the company that ma. the product (the manu.acturerfcompounder)k		
IJyou do NOT / ant your dentity disclosed to the manuacturer, please mar. this 6o' (ConJdentiality Re?uested):	No	

Generated 6y: SYSTEM Generated on: 21-9un-2022 0b:48:22 Page 8 oJ8

CTU No.: FDA-CDER-CTU-2022-50727 | Department: GFSAN | RCT No. | RCT-1025937 | DTU Trage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	A 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	220000000000000000000000000000000000000	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	P.	
Override Auto Calculation Rule	No		
FDA Received Date	27-Jun-2022	CTU Received Date	27-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
	(b) (6)	(b) (6)	(b) (6)	(b) (6)	j	

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)	
	Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	27-May-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I have already documented with the company but wanted to make sure FDA had record as well. I ate Daily Harvest Lentil Crumbles on the evening of 5/26/22 and awoke the next morning with severe cramping, vomiting, fever, chills and aches. At the time I didn't think it was food related but rather that I had a bad stomach flu. Severe symptoms lasted for around 48hours and then I started to feel slightly better but still was having issues eating. On 6/1/22 I went to see the doctor as I was still having underlying issues - no appetite and starting to looking jaundice. The doctor took blood tests at that time and it was found my liver enzymes were highly elevated. A hepatitis panel was performed - came back negative. Another blood test was taken a week later, while enzymes were down, they were still elevated. An ultrasound of my liver was performed and has since come back with no major issues detected. Days after the ultrasound I received an email from Daily Harvest about the recall and realized that the product I had consumed may have been the catalyst for my issues. I am due for another blood test in 4 weeks and the Dr. is hoping my enzymes will be back to normal by then. I have let my Dr. know about the recall. I know you all are aware of this issue but wanted to make sure to write in so you can keep track of possible cases. Thank you!

Relevant Test/Laboratory Data

1 of 2

Generated by: SYSTEM Generated on: 27-Jun-2022 15:46:29 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50727 | Department: CFSAN | RCT No.: RCT-1025937 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Test Name	COMPREHENSIVE META BOLIC PANEL - GOT/AST	Test Date	01-Jun-2022
	Test Result	148	Test Unit	LITRES
	Low Test Range	0	High Test Range	37
	More Information Available?			
Re	elevant Test/Laboratory Data			2 of 2
	Test Name	COMPREHENSIVE META BOLIC PANEL - GOT/ALT	Test Date	01-Jun-2022
	Test Result	409	Test Unit	LITRES
	Low Test Range	0	High Test Range	64
	More Information Available?			
Ac	Iditional Comments			
	This was the result of the first bloc	od test. Taken about 6 days a	fter the initial ingestion of the food	in question.
Se	ection B - Product Availability			
	Do you still have the product in case we need to evaluate it?	No		
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Se	ection C - About the Products			1 of 1
	Suspect	Yes		
	Primary?	Yes		
	Туре	Drug/Biologi		
	This report is about	Food/Medical food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	& Leek Crumbles	
	Name of the company that makes (or compounds) the roduct	Daily Harvest		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility	
	Strength		If Other	
	NDC number	'		
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?			

Generated by: SYSTEM Generated on: 27-Jun-2022 15:46:29 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50727 | Department: CFSAN | RCT No.: RCT-1025937 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Did the problem return if the rson started taking or using the	Doesn't Apply		
	roduct again?			
Dr	ug Therapy			1 of 1
	Expiration date			
	Lot number			
	Dosage Form			
	Quantity		If Other	
	Frequency		If Other	
	How was it taken or used		If Other	
	Date the person first started aking or using the product	27-May-2022		
	Date the person stopped taking or using the product			
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
WI	ny was the person using the pr	roduct? (such as what co	ndition was it supposed to treat)	1 of 1
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot	her identifying information (The cate them)	e model, catalog, lot, seri	al, or UDI number, and the expir	ation date, if you can
	ato trom,			
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number		<u> </u>	
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices C	NLY (such as pacemake	ers, breast mplants, etc.)	
	ate the implant was put in		Date the implant was taken out (If relevant)	

Generated by: SYSTEM Generated on: 27-Jun-2022 15:46:29 Page 3 of 5

Section E - About the Person Who Had the Problem

CTU No.: FDA-CDER-CTU-2022-50727 | Department: CFSAN | RCT No.: RCT-1025937 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Person's Initials		
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	
	Weight	74.25 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	Hypothyrodism	, , , , , , , , , , , , , , , , , , , ,	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
		s and 35, 100 as, policin or o not 5/	
l is	st any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lic	t arry out or important imorrinati	on about the percent (each ac metally, programe), alcohol acc, etc.)	
l is	et all current prescription modic	cations and medical devices bing used.	
<u> </u>	Levothyroxin	ations and medical devices by hig used.	
	Lovolityioxiii		
Lic	et all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
LIS	Ritual Prenatal Vitamin	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
	Tritual i Teriatai Vitailiili		
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	I.		

Generated by: SYSTEM Generated on: 27-Jun-2022 15:46:29 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50727 | Department: CFSAN | RCT No.: RCT-1025937 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	27-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 27-Jun-2022 15:46:29 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50567 | Department: GPSAN | RCT No.: RCT-1025779 | DTU Trage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Contact

Relevant Test/Laboratory Data

Test Name

Test Result

Basic Details		200 (200) 200 (200)	12.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	
FDA Received Date	27-Jun-2022	CTU Received Date	27-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	16	
User/Group			
Forward to Department			
Case Priority	Direct		

Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem			
	nd of problem was it? all that apply)	Used a product incorrectly v Noticed a problem with the	effect (including new or worsening sympto which could have or led to a problem quality of the product g from one product maker to another make	
Date the	e problem occurred	27-May-2022		
Serious		/es		
]]]	Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Life-threatening Death Other serious/important med		
	erious/important medical (Please Describe Below)			
4.Tell us v anv additio	hat happened and how onal documents if necess	it happened (Include : sary)	as many details as possible F	DA may reach out to you for
After co	nsuming Daily Harvest Fren	ch Lentil + Leek crumble hills and body aches for a	s, I experienced excruciating ches approximately 48hrs post consump	

Generated by: SYSTEM Generated on: 27-Jun-2022 11:46:34 Page 1 of 5

Test Date

Test Unit

28-May-2022

COMPREHENSIVE META

ALT-863, AST-379, Bilirub

BOLIC PANEL

in-2.9

CTU No.: FDA-CDER-CTU-2022-50567 | Department: CFSAN | RCT No.: RCT-1025779 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

	Low Test Range		High Test Range	863	
	<u>-</u>		g., root rungo		
De	More Information Available? elevant Test/Laboratory Data			2 of 2	
1 76	Test Name	LIA DIDETICK VICUAL W/	Toot Date		
	rest Name	UA DIPSTICK VISUAL W/ O MICRO	Test Date	28-May-2022	
	Test Result	+ Protein & Bilirubin in urin	Test Unit		
	Low Test Range		High Test Range		
	More Information Available?				
Ac	ditional Comments				
Se	Abnormally elevated liver enzyme hosphatase- 174 and Bilirubin-2.9		e 6-29) and AST at 379 (,standard	range 0-10). Alkaline	
	Do you still have the product in	No			_
	case we need to evaluate it?	NO			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	+ Leek Crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				

Generated by: SYSTEM Generated on: 27-Jun-2022 11:46:34 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50567 | Department: CFSAN | RCT No.: RCT-1025779 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	27-May-2022		-	
	Date the person stopped taking or using the product	28-May-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
W	ny was the person using the pr	oduct? (such as what c	ondition was it supposed to t	treat) 1 of 1	
	Hoping for healthier meal options				
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device		_		
Ot	her identifying information (The	e model, catalog, lot, se	rial, or UDI number, and the	expiration date, if you can	
loc	cate them)				
	Model Number				
	Catalog Number				
				_	
	Lot Number				
		I .			
	Serial Number				
	UDDI Number				
	UDDI Number Expiration date				
	UDDI Number				
Fo	UDDI Number Expiration date Was someone operating the medical device when the problem		ers, breast mplants, etc.)		
	UDDI Number Expiration date Was someone operating the medical device when the problem oc urred?		ers, breast mplants, etc.) Date the implant was taken o relevant)	ut (If	
Da	UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? r implanted medical devices O	NLY (such as pacemak	Date the implant was taken o	ut (If	
Da	UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? It implanted medical devices Of the implant was put in	NLY (such as pacemak	Date the implant was taken o	ut (If	
Da	UDDI Number Expiration date Was someone operating the medical device when the problem oc urred? In implanted medical devices Of the implant was put in ection E - About the Person When the implant was put in the implant was put in ection E - About the Person When it is a some of the implant was put in the implant was	NLY (such as pacemak	Date the implant was taken o	ut (If	

Generated by: SYSTEM Generated on: 27-Jun-2022 11:46:34 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50567 | Department: CFSAN | RCT No.: RCT-1025779 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

$\overline{}$			-
	Please Specify Other Gender		
	Age (specify unit of time for age)		
	Date of Birth	26-Jan-1988	
	Weight	58.05 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White	
		Black or African American	
			=
Lis		uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	N/A		
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	Pollen, mold, ragweed, juniper, pe	et dander, & mountain cedar.	
Lis	t any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
	N/A		
Lis	st all current prescription medic	ations and medical devices b ng used.	
	N/A		
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
	Vitamin D		
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	-		_
	Reporter is Patient?	(b) (6)	_
	Reporter is Patient? Title	(b) (6)	

Generated by: SYSTEM Generated on: 27-Jun-2022 11:46:34 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50567 | Department: CFSAN | RCT No.: RCT-1025779 | CTU Triage Date: 27-Jun-2022 | Total Pages: 6

Number/Street	(b) (6)
City	(b) (6)
State/Province	(5) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	27-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 27-Jun-2022 11:46:34 Page 5 of 5



CTU No.: FDA-CDER-CTU-2022-50753 | Department: GFSAN | RCT No.: RCT-1026019 | DTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	-	
Override Auto Calculation Rule	No	4	
FDA Received Date	27-Jun-2022	CTU Received Date	27-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	16	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

What kind of problem was it?		
(Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product	
	Had problems after switching from one product maker to another maker	
Date the problem occurred	08-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I ate the Daily Harvest Lentil crumbles for dinner on Thurs, June 7 and again on June 8. The first night, I woke up in a sweat with a headache and mild abdominal pain/gas. Couldn't sleep the rest of the night and didn't feel well the next day, but I attributed it to the lack of sleep. The second night, I again woke up in a sweat, with full body aches, especially in my arms and the center of my back, headache, abdominal pain/gas, all of which got worse over the next several hours. My temperature peaked at 101.8OC, and I took some Aleve. I then became extremely weak and light-headed to the point where all I could do was lay in bed for the rest of that day and the next. I took a home Covid test, which was negative, but I still thought it must be Covid, since I felt so badly. On the second or third day, I realized that my urine was a dark color. After the second day I slowly started feeling better, but spent most of the next two days in bed. Also went for a PCR Covid test, which came back negative. I continued to get better each day, with the exception of 2 separate days during which I felt worse than the day before - mentioning this because I ate the Portabello & Pesto flatbread at some point during that week - it was my last remaining Daily Harvest meal. But I don't remember which day I ate (all of) it. By June 18, I was feeling pretty good overall and had the crumbles again for dinner. That night - same story as before - I woke up at 3:30am feeling sick - fever, headache, abdominal pain, etc. Was laying in bed on June 19 reading my email when I saw the email from Daily Harvest. My daughter drove me to urgent care that night, where they did a bunch of blood tests and an ultrasound. Everything was normal, except for my liver tests. Enzyme levels were over 10x normal and bilirubin and alkaline phosphatase were abnormally high. They gave

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:34 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50753 | Department: CFSAN | RCT No.: RCT-1026019 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

me fluids and anti-nausea meds there, and sent me home with a couple of prescriptions and an emergency referral to a GI, lus instructions to follow up with my PCP and repeat blood tes in a couple days. Over the next few days, I developed a new ymptom - my hands and feet started itching. Blood tests on Jun 22 showed my enzyme levels had come down to about 3-4x normal, and bilirubin and alkaline phosphatase were down but st II above normal. Today (June 27), I feel as if I have mostly recovered, except I still have nausea and a lack of energy. Get ng blood tests again tomorrow. Note: I ate most of the bag of crumbles, but I dug the bag out of the trash and saved it. I have a photo of the lot number, but am having technical issues right now and can't upload it. The marking on the bag is "Best by: 10/10/2022 L5-A 13:23"

Relevant Test/Laboratory Data			1 of 4
Test Name	ALKALINE PHOSPHATAS E	Test Date	19-Jun-2022
Test Result	210 Units/L	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	38	High Test Range	126
More Information Available?			
Relevant Test/Laboratory Data			2 of 4
Test Name	AST	Test Date	19-Jun-2022
Test Result	194 Units/L	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	14	High Test Range	36
More Information Available?			
Relevant Test/Laboratory Data			3 of 4
Test Name	ALT	Test Date	19-Jun-2022
Test Result	327 Units/L	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	hould be below 34	High Test Range	
More Information Available?			
Relevant Test/Laboratory Data			4 of 4
Test Name	BILIRUBIN, TOTAL	Test Date	19-Jun-2022
Test Result	3.3 mg/dL	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	0.2	High Test Range	1.3
More Information Available?			
Additional Comments			
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Section C - About the Products			1 of 1

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:34 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50753 | Department: CFSAN | RCT No.: RCT-1026019 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Primary? Yes Drug/Biologi This report is about Food/Medical food Food/Medical food Prench Lentil + Leek Crumbles Food/Medical food Prench Lentil + Leek Crumbles Prench Le		Suspect	Yes			
This report is about FoodMedical food French Lentil + Leek Crumbles appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the roduct Product Type(check all that apply) Daily Harvest makes (or compounds) the roduct Product Type(check all that apply)		Primary?	Yes		-	
Name of the product as it appears on the box, bottle, or package (include as many names as you see) Name of the company that makes (or compounds) the roduct Product Type(check all that apply) Strength NDC number Did the problem stop after the rson reduced the dose or opped taking or using the roduct? Did the problem return if the rson started taking or using the roduct again? Drug Therapy 1 of 1 Expiration date Lot number Los A 13:23 Dosage Form Quantity How was it taken or used Date the person first started aking or using the roduct again; or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Date the person reduced dose of he product Section D - About the Medical Device		Туре	Drug/Biologi			
appears on the box, bottle, or package (include as many names as you see) Name of the company that makes (or compounds) the roduct Product Type(check all that apply) Strength Strength NDC number Did the problem stop after the rson reduced the dose or opped taking or using the roduct dagain? Did the problem return if the rson sended taking or using the roduct dagain? Did the problem return if the rson sended taking or using the roduct dagain? Did the problem return if the rson sended taking or using the roduct dagain? Drug Therapy Expiration date 10-Oct-2022 Lot number L5-A 13:23 Dosage Form Quantity Frequency How was it taken or used Oral Date the person first started aking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Date the person stopped taking or using the product Date the person using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person stopped taking or using the product Date the person using the product? (such as what condition was it supposed to treat) Frequency Returned to Manufacturer On Section D - About the Medical Device		This report is about	Food/Medical food			
makes (or compounds) the roduct roduct roduct apply) Product Type(check all that apply) Strength NDC number Did the problem stop after the roduct? Did the problem stop after the roduct? Did the problem return if the reson reduced the dose or opped taking or using the roduct again? Drug Therapy L5-A 13:23 Dosage Form Quantity Frequency If Other Date the person first started aking or using the product Date the person stoped taking or using the roduct again? Date the person stoped taking or using the roduct as the person stoped taking or using the product Date the person stoped taking or using the product Date the person stoped taking or using the product Date the person reduced dose of he product Between the product of the produc		appears on the box, bottle, or package (Include as many	French Lentil + Leek Crumb	oles		
apply) Compounded by a Pharmacy or an Outsourcing Facility Generi		makes (or compounds) the	Daily Harvest			
NDC number Did the problem stop after the rson reduced the dose or opped taking or using the roduct? Did the problem return if the rson started taking or using the roduct again? Drug Therapy L5-A 13:23 Dosage Form Quantity Frequency If Other Frequency If Other Date the person first started aking or using the roduct again? Date the person reduced dose of he product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) Returned to Manufacturer On Returned to Manufacturer On Section D - About the Medical Device			Compounded by a Pharmacy of Generi	or an Outsourcing Facility		
Did the problem stop after the rson reduced the dose or opped taking or using the roduct? Did the problem return if the rson started taking or using the roduct again? Drug Therapy Expiration date Lot number Quantity If Other Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) Returned to Manufacturer On Section D - About the Medical Device		Strength		If Other		
rson reduced the dose or opped taking or using the roduct? Did the problem return if the rson started taking or using the roduct again? Programmer Indicates Indicat		NDC number				
rson started taking or using the roduct again? Drug Therapy 1 of 1 Expiration date 10-Oct-2022 Lot number L5-A 13:23 Dosage Form Quantity If Other Frequency How was it taken or used Oral Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) Returned to Manufacturer On Section D - About the Medical Device		rson reduced the dose or opped taking or using the	Yes			
Expiration date 10-Oct-2022 Lot number L5-A 13:23 Dosage Form Quantity If Other Frequency If Other How was it taken or used Oral If Other Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) Returned to Manufacturer On Section D - About the Medical Device		rson started taking or using the	Yes			
Lot number Lot nu	Dr	ug Therapy			1 of 1	
Dosage Form Quantity If Other		Expiration date	10-Oct-2022			
Quantity If Other		Lot number	L5-A 13:23			
Frequency How was it taken or used Oral If Other Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) I of 1 Peturned to Manufacturer On Section D - About the Medical Device		Dosage Form				
How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 Patental Condition was it supposed to treat) Returned to Manufacturer On Section D - About the Medical Device		Quantity		If Other		
Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 just food for dinner Returned to Manufacturer On Section D - About the Medical Device		Frequency		If Other		
aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 just food for dinner Returned to Manufacturer On Section D - About the Medical Device		How was it taken or used	Oral	If Other		
or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 just food for dinner Returned to Manufacturer On Section D - About the Medical Device			07-Jun-2022			
he product Give best estimate of duration Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) just food for dinner Returned to Manufacturer On Section D - About the Medical Device			18-Jun-2022			
Is therapy still on-going? Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 just food for dinner						
Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1 just food for dinner		Give best estimate of duration				
just food for dinner Returned to Manufacturer On Section D - About the Medical Device						
Returned to Manufacturer On Section D - About the Medical Device	W	hy was the person using the pr	oduct? (such as what co	ndition was it supposed to t	reat) 1 of 1	
Section D - About the Medical Device		just food for dinner				
		Returned to Manufacturer On				
	=					
i i	Se		evice			

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:34 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50753 | Department: CFSAN | RCT No.: RCT-1026019 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

	Name of the company that makes the medical device				
Ot	her identifying information (The cate them)	e model, catalog, lot, seria	I, or UDI number, and the expiration date, if you can		
				\top	
				4	
	Model Number				
	Catalog Number			_	
	Lot Number			_	
	Serial Number				
	UDDI Number			_	
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices C	NLY (such as pacemaker	s, breast mplants, etc.)		
Date the implant was put in			Date the implant was taken out (If relevant)		
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)		$\overline{}$	
	Sex	Female		+	
	Gender	Cisgender woman/girl		+	
	Please Specify Other Gender			+	
	Age (specify unit of time for age)			+	
	Date of Birth	(b) (6)			
	Weight	65.7 kg		\top	
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Native			
		Native Hawaiian or Other Pacifi			
		Asian			
		White			
		Black or African American			
Lis	st known medical conditions (S	Such as diabetes, high bloc	od pre ure, cancer, heart disease, or others)		
	none			T	
Ple	ease list all allergies (such as t	to drugs, foods, pollen or c	hers)		
	fiberglass		,		
	-				

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:34 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50753 | Department: CFSAN | RCT No.: RCT-1026019 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Lis	t any other important information about the person (such as moking, pregnancy, alcohol use, etc.)	
	very healthy, non-smoker, essentially non-drinker	
Lis	t all current prescription medications and medical devices b ng used.	
	none	
Lis	t all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
	Multivitamins w/ iron, Niacinamide	

tion F - About the Person Filli Primary?	ing Out This Form 1 of 1 Yes
-	Tes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	27-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:34 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50752 | Department: CFSAN | RCT No.: RCT-1026018 | CTU Triage Date: 27-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Ва	sic Deta	ils		•					
Company Unit		CDER-CTU		Originating Ac ount		FAERS			
S	ource Med	ium	MW	O (Drug)	Sour	ce Form Type	E2B XML 3500B		
Pı	riority		Rou	ıtine					
0	verride Au	to Calculation Rule	No						
FI	DA Receiv	ed Date	27-	Jun-2022	CTU	Received Date	27-Jun-2022		
C	TU Triage	Date			CTU	Data Entry Date			
R	eport Type)	Spo	ontaneous	Report Classification		Drug		
A	ssign To		Use	Jser					
U:	ser/Group								
Fo	orward to I	Department	abla]					
C	ase Priorit	у	Dire	ect					
Co	ontact								
-	ase eporter	First Name		Last Name		Email Address	Phone		
\overline{V}	3	(b) (6)		(b) (6)		(b) (6)	(b) (6)		
Se	ection A -	About the Problem							
	r	d of problem was it?	П.						
(Check all that apply)									
	Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product								
	Had problems after switching from one product maker to another maker								
	Date the problem oc urred 27-Jun-2022								
	Serious		No						
Did any of the following happen?			Hospitalization - admitted or sta	ayed lon	ger				
(Check all that apply)			Required help to prevent permanent harm						
				Disability or health problem					
			\Box	Birth defect					
				Life-threatening					
			Death Other serious/important medical incident(Please Describe Below)						
4.	Tell us wi	nat happened and how	v it h	appened (Include as		de ails as possible FDA n	hay reach out to you for		
an	ř.	nal documents if nece		· · · · · · · · · · · · · · · · · · ·			U 1 6 U		
	and inve	stigated for causing illnes	s. Th	is container has been in	my fri	umbles that is currently being r dge for a little over a week, and me strain of aerobic yeast that	I the package is quite		
	and coul	d be in this package. If yo	ou'd lil	ke to pick up this con air	ner/sar	nple to test, please contact me			
Re	elevant T	est/Laboratory Data		,			1 of 1		
	Test Nar	ne			Test	Date			
	Test Res	sult			Test	Unit			
	Low Tes	t Range			High	Test Range			
	More Info	ormation Available?							

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:30 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50752 | Department: CFSAN | RCT No.: RCT-1026018 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Ad	Iditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products	1 of 1			
	Suspect	Yes	=		
	Primary?	Yes	_		
	Туре	Drug/Biologi	_		
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek Crumbles			
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar			
	Strength	If Other			
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy	1 of 1			
	Expiration date	14-Nov-2022			
	Lot number				
	Dosage Form				
	Quantity	If Other			
	Frequency	If Other			
	How was it taken or used	If Other			
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of he product				

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:30 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50752 | Department: CFSAN | RCT No.: RCT-1026018 | CTU Triage Date: 27-Jun-2022 | Total Pag es: 5

	Give best estimate of duration		
	Is therapy still on-going?		
WI	ny was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
Ot	her identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
loc	cate them)		
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the		
	medical device when the problem		
	oc urred?		
	<u> </u>	NLY (such as pacemakers, breast mplants, etc.)	
Da	ate the implant was put in	Date the implant was taken out (If relevant)	
0 -	-ti E - Al til D \A/I		
Se	ction E - About the Person Wherson's Initials	(b) (6)	
	Sex Gender	Male Cisgender man/boy	
	Please Specify Other Gender	Cisgerider man/boy	
	Age (specify unit of time for age)		
	Date of Birth		
	Weight		
	Ethnicity (Choose only one)		
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Land Asian White	
		White	

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:30 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50752 | Department: CFSAN | RCT No.: RCT-1026018 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Lis	st known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
lPI	ease list all allergies (such as t	to drugs, foods, pollen or o hers)	
Lis	st any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	cations and medical devices b ng used.	
		<u> </u>	
Lis	st all over-the-counter medicati	ions and any vitamins, mineral, supplements, and herbal remedies being used.	
Se	ection F - About the Person Fill		
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(h) (h)	_
		(b) (6)	
ı	Number/Street	(b) (6)	
	City	(b) (6) (b) (6)	
	City State/Province	(b) (6) (b) (6)	
	City State/Province Country	(b) (6) (b) (6) (b) (6) UNITED STATES	
	City State/Province Country ZIP or Postal code	(b) (6) (b) (6) UNITED STATES (b) (6)	
	City State/Province Country ZIP or Postal code Telephone number	(b) (6) (b) (6) (b) (6) UNITED STATES (b) (6) (b) (6)	
	City State/Province Country ZIP or Postal code	(b) (6) (b) (6) UNITED STATES (b) (6)	

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:30 Page 4 of 5

Reporter Organization

CTU No.: FDA-CDER-CTU-2022-50752 | Department: CFSAN | RCT No.: RCT-1026018 | CTU Triage Date: 27-Jun-2022 | Total Pages: 5

Department			
Reporter Spe	eciality		
Today's date		27-Jun-2022	
company tha	rt this problem to the t makes the product turer/compounder)?		
		Yes	

Generated by: SYSTEM Generated on: 27-Jun-2022 19:46:30 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-50847 | Department: CFSAN | RCT No.: RCT-1026023 | DTU Trage Date: 28-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details					
Company Unit	CDER-CTU	Originating Account	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	27-Jun-2022	CTU Received Date	27-Jun-2022		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User	User			
User/Group					
Forward to Department					
Case Priority	Direct				

Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)		

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	18-May-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I consumed Daily Harvest Lentil Crumbles during the month of May and early June. I always thoroughly cooked the product and only ever had about half the recommended portion size with each meal. In total, I consumed 1.5 bags of the product between early May and mid June. The product has been recalled and I haven't consumed it in two weeks. On May 19, my Doctor ran a blood test which showed extremely elevated liver enzyme levels (about ten times the normal). I felt general fatigue and discomfort during this time. Further examinations followed but no cause could be determined. I am generally a healthy individual, don't take medicine or supplements that could impact my liver function and drink very minimal amounts of alcohol. In my latest blood test (June 17), my liver enzyme levels are still slightly elevated but much better. I will not consume any more Daily Harvest products and hope my enzyme levels will get back to normal, but I wanted to report this matter anyway to ensure Daily Harvest doesn't minimize the issue. I am happy to provide details of my blood tests if helpful. I'd also like to mention that I am shocked at how Daily Harvest has communicated and handled this situation. When I log in to the app, there is no mention of the recall. The product is even still featured on the app, even though it says they are "out of stock". There are no reviews on the app referring to health issues - I highly doubt that no one would have left a comment about this.

Relevant Test/Laboratory Data

1 of 4

Generated by: SYSTEM Generated on: 27-Jun-2022 20:46:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-50847 | Department: CFSAN | RCT No.: RCT-1026023 | CTU Triage Date: 28-Jun-2022 | Total Pages: 5

Test Name	AST	Test Date	18-May-2022
Test Result	324	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	High Test Range	32
More Information Available?			
Relevant Test/Laboratory Data			2 of 4
Test Name	ALT	Test Date	18-May-2022
Test Result	445	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	High Test Range	33
More Information Available?			
Relevant Test/Laboratory Data			3 of 4
Test Name	ALKALINE PHOSPHATAS E	Test Date	18-May-2022
Test Result	472	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	35	High Test Range	120
More Information Available?			
Relevant Test/Laboratory Data			4 of 4
Test Name	BILIRUBIN, DIRECT	Test Date	
Test Result	0.31	Test Unit	MILLIGRAMS PER DECIL ITRE
Low Test Range	0.0	High Test Range	0.3
More Information Available?			
Additional Comments			
Paction D. Draduct Augilability			
Section B - Product Availability	V		
Do you still have the product in case we need to evaluate it?	Yes		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
Section C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologi		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle,	Daily Harvest French Lentil	+ Leeks Crumbles	

Generated by: SYSTEM Generated on: 27-Jun-2022 20:46:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-50847 | Department: CFSAN | RCT No.: RCT-1026023 | CTU Triage Date: 28-Jun-2022 | Total Pages: 5

	or package (Include as many names as you see)					
	Name of the company that makes (or compounds) the roduct	Daily Harvest				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility			
	Strength		If Other			
	NDC number					
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply				
Dr	ug Therapy			1 of 1		
	Expiration date	23-Oct-2022				
	Lot number					
	Dosage Form					
	Quantity		If Other			
	Frequency		If Other			
	How was it taken or used		If Other			
	Date the person first started aking or using the product	05-May-2022				
	Date the person stopped taking or using the product	13-Jun-2022				
	Date the person reduced dose of he product					
	Give best estimate of duration					
	Is therapy still on-going?					
W	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to t	reat) 1 of 1		
	Food					
	Returned to Manufacturer On				_	
	Returned to Manufacturer On				_	
Se	ction D - About the Medical De	evice				
	Name of medical device					
	Name of the company that makes the medical device					
Otl loc	Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can ocate them)					

Generated by: SYSTEM Generated on: 27-Jun-2022 20:46:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-50847 | Department: CFSAN | RCT No.: RCT-1026023 | CTU Triage Date: 28-Jun-2022 | Total Pag es: 5

	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Cisgender woman/girl		
	Please Specify Other Gender			
	Age (specify unit of time for age)	42 Year(s)		
	Date of Birth			
	Weight			
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif Asian White Black or African American		
ll is	t known medical conditions (S	uch as diabetes, high blo	od pre ure, cancer, heart disease, or others)	
	r known medical conditions (o	aerras diabetes, nigh blo	sa pro-arc, sancer, near alsease, of others)	
Ple	ease list all allergies (such as t	o drugs, f <u>oods, pollen or</u> c	o hers)	
	t and other immediate informati	an about the marcan (aug	h as moking pregnancy alcohol use etc.)	

Generated by: SYSTEM Generated on: 27-Jun-2022 20:46:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-50847 | Department: CFSAN | RCT No.: RCT-1026023 | CTU Triage Date: 28-Jun-2022 | Total Pages: 5

Lis	st all current prescription medications and medical devices b ng used.	
Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	

ction F - About the Person Fill	ing Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(b) (6)	
Country	UNITED STATES	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	27-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 27-Jun-2022 20:46:25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-51065 | Department: CFSAN | RCT No.: RCT-1026295 | CTU Triage Date: 29-Jun-2022 | Total Pag as: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

ncident(Please Describe Below)

Basic Details	Basic Details					
Company Unit	CDER-CTU	Originating Ac ount	FAERS			
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority	Routine	·	,			
Override Auto Calculation Rule	No					
FDA Received Date	28-Jun-2022	CTU Received Date	28-Jun-2022			
CTU Triage Date		CTU Data Entry Date				
Report Type	Spontaneous	Report Classification	Drug			
Assign To	User	A				
User/Group						
Forward to Department	Ø					
Case Priority	Direct					
	•					
Contact						

	se porter	First Name	Last Name	Email Address		Phone	
		(b) (6)					
Se	ction A -	About the Problem					
		d of problem was it? Ill that apply)	Used a product incorrectly Noticed a problem with th	ide effect (including new or worseni y which could have or led to a probl le quality of the product ning from one product maker to and	em		
	Date the	problem oc urred	18-Jun-2022				
	Serious		Yes				
	Did any of the following happen? (Check all that apply)		Hospitalization - admitted Required help to prevent Disability or health problet Birth defect Life-threatening Death Other serious/important m	permanent harm	elow)		
	Other se	rious/important medical					

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

Daily Harvest: French Lentil & Leek Crumbles Exposure and Illne Timeline Lot#: L02-VE6BN L5-A 11:02 Best By Date: 10/23/2022 Consumed: 6/18/2022 approximately ½ cup of product cooked for 10 minutes on medium heat in sauté pan with a bsp of olive oil. Eaten with spinach that was sauteed after the crumbles around 9am. No other family members consumed the roduct. Illness onset: 6/18/2022 around 1pm. Feeling of indige on and abdominal discomfort begins. Able to work through the discomfort, but pain is slowly increasing. Daily Harvest Email Received: 6/18/2022 around 4:30pm. It states that perhaps customers are undercooking the lentils and to throw product away. I took pictures of the packaging with the lot number and any other pertinent information and threw it away. ER Visit: 6/18/2022 around 5 pm. Pain getting so bad that an emergency room visit is necessary. Right after I received the email, I Googled to see if I could find any more information about what may be making people sick. I found a reddit page that said people w re being diagnosed with hepatitis, elevated liver levels, and suspected liver damage. I didn't know if anything was related, but I mentioned it to the ER doctor. He ordered blood work and ultrasound. Ultrasound showed gallstones. Pain was unable to be controlled by prescription medication, so admitted to hospital overnight to have emergency surgery in the morning. Emergency gallbladder surgery: 6/19/2022 delayed to around 1pm. Cholecystectomy, no obvious complications. Left hospital around 5:30pm. Recovery Complications: 6/27/2022: Moderately ntense pain underneath xyphoid process, and to the right and I ft where pancreas and liver reside. Emergency CT scan

Generated by: SYSTEM Generated on: 28-Jun-2022 15:46:34 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51065 | Department: CFSAN | RCT No.: RCT-1026295 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 7

reveals nothing abnormal, no bile leak, etc. Blood tests reveal elevated AST and ALT levels. Surgeon suspects mild non-viral hepatitis (as liver irritation) but is otherwise stumped. Sugge a follow-up with primary care physician. Medications: 5-325 Oxycodone? consumed 6/19/2022-6/23/2022 as prescribed. Not needed for a few days as I was feeling good and recovering well before onset of abdominal pain on 6/27/2022. One pill taken 6/27/2022 several hours prior to CT scan and blood work.

Re	elevant Test/Laboratory Data			1 of 2	
	Test Name	AST - ASPARTATE AMIN OTRANSFERASE	Test Date	27-Jun-2022	
	Test Result	135	Test Unit	INTERNATIONAL UNITS PER LITRE	
	Low Test Range	5	High Test Range	32	
	More Information Available?				
Re	levant Test/Laboratory Data			2 of 2	
	Test Name	ALT - ALANINE AMINOTR ANSFERASE	Test Date	27-Jun-2022	
	Test Result	129	Test Unit	INTERNATIONAL UNITS PER LITRE	
	Low Test Range	5	High Test Range	33	
	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	& Leek Crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar			
	Strength		If Other		

Generated by: SYSTEM Generated on: 28-Jun-2022 15:46:34 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51065 | Department: CFSAN | RCT No.: RCT-1026295 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

	NDC number					
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?					
	Did the problem return if the rson started taking or using the roduct again?					
Dr	ug Therapy	1 of 1				
	Expiration date	23-Oct-2022				
	Lot number	L02-VE6BN L5-A				
	Dosage Form					
	Quantity	If Other				
	Frequency	If Other				
	How was it taken or used	If Other				
	Date the person first started aking or using the product	18-Jun-2022				
	Date the person stopped taking or using the product	18-Jun-2022				
	Date the person reduced dose of he product					
	Give best estimate of duration					
	Is therapy still on-going?	Yes				
	Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1					
Wi						
WI	ny was the person using the pr It was a vegan meal delivery servi					
WI						
	It was a vegan meal delivery serving the serving serving serving the serving s	ice.				
	It was a vegan meal delivery serving the serving of the serving serving the serving serving serving the serving servin	ice.				
	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that	ice.				
Se	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that makes the medical device	ice.				
Se	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that makes the medical device her identifying information (The	evice				
Se	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that makes the medical device her identifying information (The	evice				
Se	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that makes the medical device her identifying information (The	evice				
Se	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that makes the medical device her identifying information (The cate them)	evice				
Se	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that makes the medical device her identifying information (The eate them) Model Number Catalog Number	evice				
Se	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that makes the medical device her identifying information (The cate them) Model Number Catalog Number Lot Number	evice				
Se	Returned to Manufacturer On ction D - About the Medical De Name of medical device Name of the company that makes the medical device her identifying information (The ate them) Model Number Catalog Number Lot Number Serial Number	evice				

Generated by: SYSTEM Generated on: 28-Jun-2022 15:46:34 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51065 | Department: CFSAN | RCT No.: RCT-1026295 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 7

	Was someone operating the medical device when the problem oc urred?					
Fc	r implanted medical devices O	NLY (such as pacemaker	rs, breast mplants, etc.)			
=	ate the implant was put in		Date the implant was taken out (If relevant)			
Se	Section E - About the Person Who Had the Problem					
	Person's Initials	(b) (6)				
	Sex	Female			_	
	Gender	Cisgender woman/girl			_	
	Please Specify Other Gender					
	Age (specify unit of time for age)					
	Date of Birth	(b) (6)				
	Weight	83.25 kg				
	Ethnicity (Choose only one)	Not Hispanic/Latino				
	Race (Check all that apply)	American Indian or Alaska Nati	ive			
		Native Hawaiian or Other Pacif				
		Asian				
		White				
		Black or African American				
	at known madical conditions (C	uah as dishatas hish bla	ad mus time someon beaut discoor	or otherwal		
LIS	List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others) Hypothyroidism, Endometriosis, history of gestational diabetes (2019-2020), history of Hodgkin's Lymphoma (ABVD					
	Chemotherapy/Radiation)2003/20		(2019-2020), History of Hougkins Lym	priorita (ABVD		
					_	
Pl	ease list all allergies (such as t	o drugs, foods, pollen or o	o hers)			
	Tape adhesive Broc oli Seasonal					
Lis	st any other important informati	ion about the person (suc	h as moking, pregnancy, alcohol	use, etc.)		
ll is	st all current prescription medic	cations and medical device	es bing used			
	88 mcg Synthroid 0.35 mg Noreth	,				
		 				
					_	
LIS	st all over-the-counter medicati	ons and any vitamins, mil	neral , supplements, and herbal re	emedies being used.		

Generated by: SYSTEM Generated on: 28-Jun-2022 15:46:34 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51065 | Department: CFSAN | RCT No.: RCT-1026295 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

Prena	tamins	

ction F - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	28-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 28-Jun-2022 15:46:34 Page 5 of 5



CTU No.: FDA-CDER-CTU-2022-51111 | Department: CFSAN | RCT No.: RCT-1026407 | CTU Triage Date: 29-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	yed in the report are in EST(G	Wit-05.00) time zone					
Basic Deta							
Company L		CDER-CTU	Originating Ac ount	FAERS			
Source Medium		MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority		Routine					
Override Au	uto Calculation Rule	No					
FDA Receiv	ved Date	28-Jun-2022	CTU Received Date	28-Jun-2022			
CTU Triage	Date		CTU Data Entry Date				
Report Type	е	Spontaneous	Report Classification	Drug			
Assign To		User					
User/Group)						
Forward to	Department						
Case Priori	ty	Direct					
		<u>I</u>					
Contact							
Case	First Name	Last Name	Email Address	Phone			
Reporter							
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)			
Section A -	- About the Problem						
	nd of problem was it?						
	all that apply)		Were hurt or had a bad side effect (including new or worsening symptoms)				
		Used a product incorre	ectly which could have or led to a problem				
		Noticed a problem with the quality of the product					
		· · · · · · · · · · · · · · · · · · ·	itching from one product maker to another n	naker			
Date the	e problem oc urred	03-Jun-2022 Yes					
Serious							
	of the following happen?	Hospitalization - admitted or stayed longer					
(Check	all that apply)	Required help to preve	ent permanent harm				
		Disability or health prol	blem				
		Birth defect					
		Life-threatening					
		Death					
		Other serious/important medical incident(Please Describe Below)					
	erious/important medical						
	(Please Describe Below)	wit hannened (Inclu	de as many de ails as nossible	e FDA may reach out to you for			
any additio	nal documents if nece	essary)	de as many de ans as possible	e i BA may reach out to you for			
I consur	ned Daily Harvest French	Lentils and Leeks and	ended up having my gallbladder ta	aken out. My blood levels were			
			d it again (not knowing there was a				
			o take ain and anti-nausea meds.	I had new blood work done and			
levels a	re returning to pre-surgery	v levels. Now surgeon is referring me back to a gastro dr.					
Dolovest	Cost/Labaratary Data						
	est/Laboratory Data			1 of 1			
Test Na	me		Test Date				
Test Re	sult		Test Unit				
Low Tes	st Range		High Test Range				

Generated by: SYSTEM Generated on: 28-Jun-2022 20:16:26 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51111 | Department: CFSAN | RCT No.: RCT-1026407 | CTU Triage Date: 29-Jun-2022 | Total Pag

	More Information Available?				
Ad	dditional Comments				
	17 relevant lab results across 7 da levels before and after plus after t				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			\vdash
	This report is about	Food/Medical food			T
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil and Leek Crumbles			
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy o Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number			ı	
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?	Yes			
Dr	ug Therapy			1 of 1	
	Expiration date	10-Oct-2022			
	Lot number	L5-A			
	Dosage Form				
	Quantity	Other	If Other	12 Ounce(s)	
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	25-May-2022			
	Date the person stopped taking or using the product	27-Jun-2022			

Generated by: SYSTEM Generated on: 28-Jun-2022 20:16:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51111 | Department: CFSAN | RCT No.: RCT-1026407 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

	Date the person reduced dose of he product				
_	Give best estimate of duration				
	Is therapy still on-going?				
W		roduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
	Food	(
_					
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that				
	makes the medical device				
Ot	ther identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expira	tion date, if you can	
100	cate them)				
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem				
	oc urred?				
Fc	or implanted medical devices O	NLY (such as pacemake	rs. breast mplants, etc.)		
_	ate the implant was put in		Date the implant was taken out (If		
			relevant)		
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender		-		
	Age (specify unit of time for age)				
	Date of Birth	(b) (6)			
	Weight	69.75 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)				
		American Indian or Alaska Nati			
		Asian	I SIGNED		
	1	· · · · · · · · · · · · · · · · · · ·			

Generated by: SYSTEM Generated on: 28-Jun-2022 20:16:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51111 | Department: CFSAN | RCT No.: RCT-1026407 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

	White						
	Black or African American						
List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)						
none							
Please list all allergies (such as	lease list all allergies (such as to drugs, foods, pollen or o hers)						
none							
List any other important informa	ation about the person (such as moking, pregnancy, alcohol use, etc.)						
none							
List all current prescription med	lications and medical devices b ng used.						
zoloft 100 mg							
List all over-the-counter medica	ations and any vitamins, mineral , supplements, and herbal remedies being used.						
none							
Section F - About the Person F							
Primary?	Yes						
Reporter is Patient?							
Title	(b) (c)						
Last name	(b) (6)						
Middle Name	(b) (6)						
First name	(b) (6)						
Number/Street	(b) (6)						
City State/Province	(b) (6)						
State/Province							
Country	UNITED STATES						
ZIP or Postal code	(b) (6)						
Telephone number	(b) (6)						
Email address	(b) (6)						

Generated by: SYSTEM Generated on: 28-Jun-2022 20:16:26 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51111 | Department: CFSAN | RCT No.: RCT-1026407 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	28-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 28-Jun-2022 20:16:26 Page 5 of 5

BEST BY: 10/10/2022 L5-A 12:22

Preparing Crumbles:

dd to your favorite die

eze. Cook thorough

s 290, Total Fa

k time may vary to an internal temperature of 165°F. Fill leve

PERISHABLE, STORE FROZEN. Do.

(1) Let stand 70

d Sugars, 0% DVI Pr sium 486mg (10% D* MO % SU BUILD Nutrition Facts 3 Serving per container, Serv size: 4 oz (1139). Amouht per ser 18g (23% DV), Saturated Fat 2g (10% DV), Trans Fat 0g, Cholesterol 0mg (0% DV) Serving Carbohydrate 19g (7% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Include DV) Pot

% Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories day for general nutrition advice.

Ingredients: organic butternut squash, organic hemp seeds, organic cauliflower nos organic extra vign organic butternut squash, organic hemp seeds, organic cauliflower nos mushrooms organic bordanic lentils, organic rod localic portanic localic portanic lentils, organic rod localic portanic lentils, organic localic portanic portanic localic portanic portanic localic portanic porta organic french lentils, organic red lentils, organic tri-colored quinoa, organic cremini mushrooms, organic seeds, organic leeks, organic parslav water and lentils, organic tri-colored quinoa, organic parslav water made numeraseeds, rganic parslav water made numeraseeds organic parslav water made numeraseeds. organic mench lentils, organic red lentils, organic tri-colored quinoa, organic cremin mushics and a seeds, organic seeds, organic parallely, water, organic cassava root flour, organic porcini powder him and organic porcini powder him. seeds, creeks, organic parsley, water, organic tri-colored quinoa, organic flax seeds organic powder organic poordin powder, himalayan sea salt, organic apple cider vinegar, organic cortano powder, prowder, organic powder, organic powder, organic powder, organic powder, organic towder, organic parcini powder, himalayan sea salt, organic apple cider vinegaric corlandar seeds organic corlandar seeds powder, organic powder, organic tornato powder, organic white pepper, organic tornato powder, organic white pepper, organic tryme,

MADE IN A FACILITY THAT ALSO PROCESSES TREE NUTS. SOY, DAIRY, & SESAME DISTR. BY DAILY HARVEST INC. NEW YORK, NY 10013

LO2-VEGBN

"TATALSO PRO-

CTU No.: FDA-CDER-CTU-2022-51095 | Department: CFSAN | RCT No.: RCT-1026373 | CTU Triage Date: 29-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details					
Company Unit	CDER-CTU	Originating Ac ount	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	28-Jun-2022	CTU Received Date	28-Jun-2022		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User				
User/Group					
Forward to Department					
Case Priority	Direct				

Contact	Contact						
Case Reporter	First Name	Last Name	Email Address	Phone			
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)			

١	Section A - About the Problem				
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker			
	Date the problem oc urred	13-Jun-2022			
	Serious	Yes			
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)			

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

My Daily Harvest (DH) delivery arrived on June 10. I fully cook d the DH French Lentil + Leek crumbles to 175 degrees and ate them on top of the DH Tomatillo and Pepper Flatbread as a late lunch on June 12 (only consumed this meal once). I had a prolonged feeling of fullness after eating for hours with a pain starting in the upper right abdomen. I took 2 Advil and had ome sparkling water to try to alleviate the pain. I went to sl and woke up around 2-3am with the worst pain I have ever fe lt. Couldn't lay down and also too tired to stand so leaned against a wall. Pain lasted about 45-60 minutes. I took more Advil and arkling water. I was able to finally curl into a ball and sle ep on my right side. I could not sleep on my back or left side. I felt ok in the morning. Had breakfast and then the pain came back stronger than before. My skin was hot, I also had chills, I couldn't breathe well, and I was crying. The intense pain lasted around 30 minutes - 15 super intense, 15 of duller pain. The pain never really went away but lessened. Talked to a friend who has gastritis and tried Mylanta which sort of helped. Had on and off again hot skin and chills. Also had some collarbone and shoulder pain (not sure if related). Went to urgent care and they directed me to the ER as they thought it was gallbladder related. At the ER, they did some bloodwork and did an abdomen ultrasound. My gallbladder was ok so they didn't recommend any further action. The symptoms weren't super easy to diagnose but they landed on potential gastritis, GERD, or an ulcer. They gave me prescription Pepcid and Mylanta/Maalox and told me to ask my PCP for a referral to a GI specialist. Also the blood draw left a bruise although it was a quick draw, painless, but I don't usually bruise. Had an extremely hard time getting up the next few days. Slept on and off in the mornings, had more nergy in the evenings. Ate simple meals like broth and cracker , oatmeal, bread, etc for about a week. Had diarrhea a few

Generated by: SYSTEM Generated on: 28-Jun-2022 17:46:30 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51095 | Department: CFSAN | RCT No.: RCT-1026373 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 5

days. Ongoing fatigue lasted over a week and it was impossible o stay hydrated so started drinking alkaline water. DH sent out emails on June 17, 19, and 22 which helped me understand th cause which was something I already considered given was the only change to my diet/routine that I had made. This was my first time ordering Daily Harvest. I still have ongoing ain that seems to migrate from upper right abdomen to upper le ft abdomen to either side of my belly button. It's not pelvi ain but focused in the abdomen. I'm set to see a GI specialist in October but am not sure how to proceed in the meantime and am concerned about long-term damage given that I am an otherwise healthy 31 year old and have never experienced anything like this before. DH and the FDA are investigating but I wanted to submit a report in case it helps, to answer any other questions, and add to the existing report count. Thanks!

Б.					_
Rε	elevant Test/Laboratory Data			1 of 1	
	Test Name		Test Date		
	Test Result		Test Unit		
	Low Test Range		High Test Range		
	More Information Available?				
Ad	ditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in ase we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek crumb	les		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			

Generated by: SYSTEM Generated on: 28-Jun-2022 17:46:30 Page 2 of 5

Doesn't Apply

Did the problem return if the

CTU No.: FDA-CDER-CTU-2022-51095 | Department: CFSAN | RCT No.: RCT-1026373 | CTU Triage Date: 29-Jun-2022 | Total Pages: 5

	rson started taking or using the roduct again?			
Dr	rug Therapy			1 of 1
	Expiration date			
	Lot number			
	Dosage Form			
	Quantity		If Other	
	Frequency		If Other	
	How was it taken or used		If Other	
	Date the person first started aking or using the product	12-Jun-2022	54.6.	
	Date the person stopped taking or using the product	12-Jun-2022		
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
W	hy was the person using the pr	roduct? (such as what co	ondition was it supposed to tr	eat) 1 of 1
	Was a meal service - used for a lu	unchtime meal		
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device		_	
Ot	her identifying information (The	e model, catalog, lot, sei	ial, or UDI number, and the ϵ	expiration date, if you can
	Model Number			
	Catalog Number			
	Lot Number			
			_	
	Serial Number			
	Serial Number UDDI Number			
	UDDI Number			
Fc	UDDI Number Expiration date Was someone operating the medical device when the problem		ers, breast mplants, etc.)	
	UDDI Number Expiration date Was someone operating the medical device when the problem oc urred?		ers, breast mplants, etc.) Date the implant was taken ou relevant)	t (If

Generated by: SYSTEM Generated on: 28-Jun-2022 17:46:30 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51095 | Department: CFSAN | RCT No.: RCT-1026373 | CTU Triage Date: 29-Jun-2022 | Total Pages: 5

Se	ction E - About the Person Wi	no had the Problem					
	Person's Initials	Unspecified					
	Sex	Female					
	Gender	Cisgender woman/girl					
	Please Specify Other Gender						
	Age (specify unit of time for age)	31 Year(s)					
	Date of Birth						
	Weight	63.9 kg					
	Ethnicity (Choose only one)	Not Hispanic/Latino					
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American					
Lis	t known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)					
	n/a						
PΙ	ease list all allergies (such as t	to drugs, foods, pollen or o hers)					
	n/a						
Lis	t any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)					
	n/a						
Lis	st all current prescription medic	cations and medical devices b ng used.					
	n/a						
Lis	t all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.					
	Vitamin D, Women's Multivitamin						
Se	ction F - About the Person Fill	ing Out This Form 1 of 1					
	Primary?	Yes					
	Reporter is Patient?						
\square		<u>, </u>					

Generated by: SYSTEM Generated on: 28-Jun-2022 17:46:30 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51095 | Department: CFSAN | RCT No.: RCT-1026373 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 5

Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	28-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Generated by: SYSTEM Generated on: 28-Jun-2022 17:46:30 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-51101 | Department: CFSAN | RCT No.: RCT-1026381 | CTU Triage Date: 29-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details					
Company Unit	CDER-CTU	Originating Ac ount	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	28-Jun-2022	CTU Received Date	28-Jun-2022		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classification	Drug		
Assign To	User				
User/Group					
Forward to Department					
Case Priority	Direct				

Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
Section A - About the Problem						

Se	Section A - About the Problem				
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product			
	Data the muchlane on comment	Had problems after switching from one product maker to another maker	\vdash		
	Date the problem oc urred	29-May-2022			
	Serious	Yes			
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)			

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

I ate "French Lentil and Leek Crumbles" made by Daily Harvest (a meal delivery program) on the day that I experienced the worst gastrointestinal pain of my life. I was doubled over and had resulting elevated liver enzyme levels ongoing. I was in th hospital with inconclusive results. Still have pain.

R	Relevant Test/Laboratory Data 1 c				
	Test Name	LIVER ENZYME TEST	Test Date	29-May-2022	
	Test Result	850	Test Unit	MILLILITRES PER HOUR	
	Low Test Range	550	High Test Range	850	
	More Information Available?				

Generated by: SYSTEM Generated on: 28-Jun-2022 18:16:41 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51101 | Department: CFSAN | RCT No.: RCT-1026381 | CTU Triage Date: 29-Jun-2022 | Total Pag

Ad	ditional Comments				
	Liver levels were almost 10 times normal. Nothing but food bourne toxin or pathogen could explain the pain and the levels. All her tests were negative. Received notice of Daily Harvest Re call on June 17.				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			Т
	Primary?	Yes		_	T
	Туре	Drug/Biologi			T
	This report is about	Food/Medical food		_	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil and Leek Cr	rumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generi Biosimilar	y or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	17-Jun-2022			<u> </u>
	Lot number				L
	Dosage Form				<u> </u>
	Quantity		If Other		L
	Frequency		If Other		<u></u>
	How was it taken or used	Oral	If Other		\perp
	Date the person first started aking or using the product	29-May-2022		_	
	Date the person stopped taking or using the product	29-May-2022			
	Date the person reduced dose of	29-May-2022			

Generated by: SYSTEM Generated on: 28-Jun-2022 18:16:41 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51101 | Department: CFSAN | RCT No.: RCT-1026381 | CTU Triage Date: 29-Jun-2022 | Total Pages: 6

	Give best estimate of duration		
	Is therapy still on-going?		
Wł	ny was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	I had ordered a meal plan. It was	a new offering included.	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
O+	Name of the company that makes the medical device		
	ner identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast mplants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)		
	Date of Birth	16-Sep-1970	
	Weight	74.25 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White	

Generated by: SYSTEM Generated on: 28-Jun-2022 18:16:41 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51101 | Department: CFSAN | RCT No.: RCT-1026381 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 6

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
None.	
Please list all allergies (such as to drugs, foods, pollen or o hers)	
None.	
List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)	
N/A.	
List all current prescription medications and medical devices b ng used.	
None.	
List all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
Oc asional aspirin. Pepsid and prilosec suggested for the 10 days after acute attack and hospitalization that is the subject of his report. Have never previously used pepsid or prilosec.	
Section F. About the Derson Filling Out This Form	

ection F - About the Perso	Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(b) (6)	
Country	UNITED STATES	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		

Generated by: SYSTEM Generated on: 28-Jun-2022 18:16:41 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51101 | Department: CFSAN | RCT No.: RCT-1026381 | CTU Triage Date: 29-Jun-2022 | Total Pages: 6

Department		
Reporter Speciality		
Today's date	28-Jun-2022	
Did you report this probl company that makes the (the manufacturer/comp	product	
If you do NOT want your dentity disclosed to the manufacturer, please mathematical box (Confidentiality Req		

Generated by: SYSTEM Generated on: 28-Jun-2022 18:16:41 Page 5 of 5



CTU No.: FDA-CDER-CTU-2022-51084 | Department: CFSAN | RCT No.: RCT-1026333 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		-
FDA Received Date	28-Jun-2022	CTU Received Date	28-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Se	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
	Date the problem oc urred	13-Jun-2022	
	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
	Other serious/important medical ncident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

I woke at 1:15 am on 6/13/22 with severe pain all through my thoracic cavity. Along my upper back, sides and front of rib cage. I could not return to sleep or find any way to get comfor able. Used heating pad. Tried to take ibuprofen with crackers, but vomited. Pain diminished to discomfort around 4 am and I dozed on the sofa in a seated position. Decided to wait and head to urgent care. Ate a few crackers but discomfort and naus a remained. Took a shower. Discomfort escalated to pain. Vomited. Pain subsided. Went to urgent care. Urine sample taken. Doctor prescribed antibiotics and Tylenol for a bladder nfection. Napped. Went to pick up prescription. Nausea increas d. Ate plain noodles and took Tylenol and Cipro. Discomfort and nausea continued. Napped in seated position. Ate plain noodles and applesauce around 9 pm to take another does of Cipro and Tylenol. Vomited about 20 minutes later. Vomited again soon after that. Decided that likely not a bladder infection and would go to ER the next day. Pain and nausea decreased enough for me to sleep in bed. On 6/14/22 I ate Noka smoothie acket and Orgain protein shake in morning. Pain and nausea inc reased to the point I could only lay in bed, shaking all over. Took shower and went to ER. At ER, I gave urine and blood samples. They did an EKG, chest X-ray before a room was available. Waited several hours. Pain and nausea decreasedDoctor came to see me. Explained location of pain and vomiting. He informed me it was not a bladder infection. Based on location of pain and high liver enzyme levels in blood,

Generated by: SYSTEM Generated on: 28-Jun-2022 16:46:33 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51084 | Department: CFSAN | RCT No.: RCT-1026333 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 7

he suspected gallstones and ordered an ultrasound and CT scan. Waited several hours for those. Both the ultrasound and CT scan were clear. Doctor was not sure what caused the pain bu was worried about my liver levels. Questioned me about activities and travel. Had additional blood work taken to rule out acetaminophen and Hepatitis. My pain and nausea had decreased. I had been there 9 hours with no food or water. Doctor decided to send me home as I was no longer in pain or vomiting and my levels were not high enough that I needed to be admitted. He sent a message to my primary doctor and waited for a reply. I was told to see my primary doctor within 2 days for follow up and more blood work to make sure liver levels were not increasing. Ate more noodles and applesauce before going to sleep. 6/15/22 Woke with bad headache. Made appointment with doctor for 6/16/22. Headache remained throughout day. No appetite. 6/16/22 went to doctor. She also suspected gallstone that maybe passed. Blood sample taken and told to return in 1 week for additional blood. 6/17/22 Received email from Daily Harvest about customers reporting GI discomfort after eating French Lentil + Leek Crumbles. Sent the email to my doctor. Blood test showed liver levels down from tests on 6/14/22 but still elevated. 6/18/22 and 6/19/22 remained fatigued but feeling better. 6/20/22 felt more and mor fatigued throughout day. Felt like heart was beating rapidly. Started running a low-grade fever of 99-100.1 degrees. Covid te negative. Messaged doctor. Monitored temperature. 6/21/22 No more fever, but extreme fatigue throughout day. 6/23/22 More blood work done. Began to feel more normal but with bouts of fatigue. Results of blood work from 6/23/22 show two enzymes that were highest at ER continue to trend down, but another one has been increasing and is now out of the normal range.

levant Test/Laboratory Data			1 of 3
Test Name	ALANINE AMINOTRANSF ERASE (ALT) (SGPT)	Test Date	14-Jun-2022
Test Result	504	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	6	High Test Range	29
More Information Available?			
levant Test/Laboratory Data			2 of 3
Test Name	ASPARTATE AMINOTRA NSFERASE (AST) (SGOT)	Test Date	14-Jun-2022
Test Result	490	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	10	High Test Range	35
More Information Available?			,
levant Test/Laboratory Data			3 of 3
Test Name	ALKALINE PHOSPHATAS E (ALP)	Test Date	23-Jun-2022
Test Result	194	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	31	High Test Range	125
More Information Available?			
ditional Comments	<u>'</u>		
			
ction B - Product Availability			
Do you still have the product in case we need to evaluate it?	Yes		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes		

Generated by: SYSTEM Generated on: 28-Jun-2022 16:46:33 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51084 | Department: CFSAN | RCT No.: RCT-1026333 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek Crumb	oles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date	27-Sep-2022			
					_
	Lot number				
	Dosage Form				
	Dosage Form Quantity		If Other		
	Dosage Form		If Other		
	Dosage Form Quantity	Oral			
	Dosage Form Quantity Frequency	Oral 12-Jun-2022	If Other		
	Dosage Form Quantity Frequency How was it taken or used Date the person first started		If Other		
	Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking		If Other		
	Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of		If Other		
	Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	12-Jun-2022 Yes	If Other If Other		
	Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration	12-Jun-2022 Yes	If Other If Other	reat) 1 of 1	
]WY	Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	12-Jun-2022 Yes	If Other If Other	reat) 1 of 1	
]VVI	Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going?	12-Jun-2022 Yes	If Other If Other	reat) 1 of 1	
	Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? The person using the product of	Yes roduct? (such as what cor	If Other If Other	reat) 1 of 1	
	Dosage Form Quantity Frequency How was it taken or used Date the person first started aking or using the product Date the person stopped taking or using the product Date the person reduced dose of he product Give best estimate of duration Is therapy still on-going? Thy was the person using the product	Yes roduct? (such as what cor	If Other If Other	reat) 1 of 1	

Generated by: SYSTEM Generated on: 28-Jun-2022 16:46:33 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51084 | Department: CFSAN | RCT No.: RCT-1026333 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

	Name of the company that makes the medical device		
Oth loc	ner identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	·		
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		
Fo	r implanted medical devices Ω	DNLY (such as pacemakers, breast mplants, etc.)	
	ate the implant was put in	Date the implant was taken out (If	
		relevant)	
Se	ction E - About the Person Wh	no Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)	47 Year(s)	
	Date of Birth		
	Weight	78.75 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	
Lis	t known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
	none		
Ple	ease list all allergies (such as t	to drugs, foods, pollen or o hers)	
	none		

Generated by: SYSTEM Generated on: 28-Jun-2022 16:46:33 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51084 | Department: CFSAN | RCT No.: RCT-1026333 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 7

List any other important information about the person (such as moking, pregnan	cy, alcohol use, etc.)
List all current prescription medications and medical devices b ng used.	
Elst all carrett prescription medications and medical devices by high asca.	
Mirena IUD	
List all over-the-counter medications and any vitamins, mineral , supplements, ar	id herbal remedies being used.
Vitamins B12, D, C, zinc, magnesium	
Vitaminis B12, B, O, zino, magnesium	

tion F - About the Person Filli	
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	28-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 28-Jun-2022 16:46:33 Page 5 of 5

SHUBALES

a Flatbread. Serve Upgrade your empanada? rumbles truly work forget to add into your chill of -ayer into lasagna. Orumble on top of -eek lettuce wrap. in a tortilla. ese French ppy Joes.

COOK THOROUGHLY (340q)120z NET WI FROZEN,

ven in shepherd's

offing. Oh.

CTU No.: FDA-CDER-CTU-2022-51070 | Department: CFSAN | RCT No.: RCT-1026307 | CTU Triage Date: 29-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Ba	ısic Detai	ls						
С	ompany U	nit	CDE	R-CTU	Origii	nating Ac ount	FAERS	
S	ource Med	ium	MW	O (Drug)	Sour	ce Form Type	E2B XML 3500B	
Р	riority		Rou	Routine				
Override Auto Calculation Rule		No						
FDA Received Date		28-J	lun-2022	CTU	Received Date	28-Jun-2022		
C	TU Triage	Date			CTU	Data Entry Date		
R	eport Type		Spo	ntaneous	Repo	rt Classification	Drug	
A	ssign To		Use	r				
	ser/Group							
F	orward to [Department	\square					
С	ase Priority	/	Dire	ct				
Co	ntact							
	ase eporter	First Name		Last Name		Email Address	Phone	
V		(b) (6)		(b) (6)				
Se		About the Problem	_					
		d of problem was it? Il that apply)				uding new or worsening symptoms)		
				Jsed a product incorrectly which				
				Noticed a problem with the qua				
	Date the	problem oc urred		nad problems after switching from May-2022	rom one	product maker to another maker		
	Serious	<u>'</u>	Yes					
	Did any o	of the following happen?	П.					
	(Check a	Il that apply)		Hospitalization - admitted or sta Required help to prevent perma				
			\neg	Disability or health problem	anoni no			
				Birth defect				
				ife-threatening				
			닏	Death				
				Other serious/important medica		·		
		าat happened and hoง าal documents if nece			many	v de ails as possible FDA r	hay reach out to you	for
				,,	/eek. H	lad stomach pains, diarrhea, fe	ever, inability to sleep, c	old
		nd hands. Have been dea and other people's issue		with fatigue. Awaiting lat	owork 1	for liver function test - went to	doctor after hearing abo	out
	ne recai	and other people's issue						
_								
Re	elevant Te	est/Laboratory Data					1 of ′	1
	Test Nan	ne			Test	Date		
	Test Res	ult			Test	Unit		
	Low Test	Range			High	Test Range		
	More Info	ormation Available?						

Generated by: SYSTEM Generated on: 28-Jun-2022 16:16:28 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51070 | Department: CFSAN | RCT No.: RCT-1026307 | CTU Triage Date: 29-Jun-2022 | Total Pages: 5

Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			_
	Туре	Drug/Biologi			_
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest Leek & Lentil	Crumbles		
	Name of the company that makes (or compounds) the roduct				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of he product				

Generated by: SYSTEM Generated on: 28-Jun-2022 16:16:28 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51070 | Department: CFSAN | RCT No.: RCT-1026307 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 5

	Give best estimate of duration		
	Is therapy still on-going?		
WI	ny was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
	Name of the company that		
Ot	makes the medical device	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	ate them)	e model, catalog, lot, serial, or oblinumber, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the		
	medical device when the problem oc urred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast mplants, etc.)	
	ate the implant was put in	Date the implant was taken out (If	
		relevant)	
Se	ction E - About the Person Wh	o Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)	32 Year(s)	
	Date of Birth		
	Weight	65.25 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native	
		Native Hawaiian or Other Pacific Islander	
		Asian	
		White	
		Black or African American	

Generated by: SYSTEM Generated on: 28-Jun-2022 16:16:28 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51070 | Department: CFSAN | RCT No.: RCT-1026307 | CTU Triage Date: 29-Jun-2022 | Total Pages: 5

Lis	t known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	none	<u> </u>	
Dle	assa list all allergies (such as t	o drugs, foods, pollen or o hers)	
1 10	none	o drugs, roods, polien or o ners)	
	none		
LIS	t any otner important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	t all current prescription medic	cations and medical devices b ng used.	
Lis	t all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used	d.
Se	ction F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street		
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code		
	Telephone number		
	Email address		
	Fax		
	Reporter Organization		

Generated by: SYSTEM Generated on: 28-Jun-2022 16:16:28 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51070 | Department: CFSAN | RCT No.: RCT-1026307 | CTU Triage Date: 29-Jun-2022 | Total Pages: 5

Department		
Reporter Speciality		
Today's date	28-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 28-Jun-2022 16:16:28 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-51230 | Department: CFSAN | RCT No.: RCT-1026422 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		,
Override Auto Calculation Rule	No		
FDA Received Date	29-Jun-2022	CTU Received Date	29-Jun-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Sec	Section A - About the Problem				
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker			
	Date the problem oc urred	14-Jun-2022			
	Serious	Yes			
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)			

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

1 day after eating Lentil Crumbles from Daily Harvest, I started feeling body aches and fatigue. Hurt to brush my hair, all of my joints ached, but never had a fever. For the next 4 days, I had a range of symptoms. I completely lost my appetite; I couldn't eat anything more than a cracker or some noodles over he next 3 days. I had intense stomach and back pain and couldn't sleep on my right side. Felt continuously full and lik something was constricting my stomach. I was so exhausted that I couldn't brush my teeth without sitting down. It was hard to read or focus. My urine was dark, no matter how much I tri d to hydrate. Went to urgent care where urinalysis showed that I didn't have a UTI and my kidneys were fine. Took labs which revealed elevated liver enzymes. 2 weeks later, I still have a dull ache on the right side of my abdomen and back. Urine is st II dark.

Relevant Test/Laboratory Data 1 of 3			
Test Name	AST	Test Date	16-Jun-2022
Test Result	92	Test Unit	INTERNATIONAL UNITS PER LITRE

Generated by: SYSTEM Generated on: 29-Jun-2022 01:46:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51230 | Department: CFSAN | RCT No.: RCT-1026422 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

	Low Test Range	0	High Test Range	40	
	More Information Available?				
Re	elevant Test/Laboratory Data			2 of 3	
	Test Name	ALT	Test Date	16-Jun-2022	
	Test Result	194	Test Unit	INTERNATIONAL UNITS PER LITRE	
	Low Test Range	0	High Test Range	32	
	More Information Available?				
Re	levant Test/Laboratory Data			3 of 3	
	Test Name	ALKALINE PHOSPHATAS E	Test Date	16-Jun-2022	
	Test Result	182	Test Unit	INTERNATIONAL UNITS PER LITRE	
	Low Test Range	44	High Test Range	121	
	More Information Available?				
Αc	ditional Comments				
Se	ction B - Product Availability				
Se	Do you still have the product in	Yes			
Se	-	Yes Yes			
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture)			1 of 1	
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are			1 of 1	
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) action C - About the Products	Yes		1 of 1	
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ction C - About the Products Suspect	Yes		1 of 1	
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ction C - About the Products Suspect Primary?	Yes Yes Yes		1 of 1	
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ection C - About the Products Suspect Primary? Type	Yes Yes Yes Drug/Biologi	eek	1 of 1	
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ction C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many	Yes Yes Yes Drug/Biologi Food/Medical food	eek	1 of 1	
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ction C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the	Yes Yes Yes Drug/Biologi Food/Medical food Crumbles French Lentil + Le		1 of 1	
	Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ction C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many names as you see) Name of the company that makes (or compounds) the roduct Product Type(check all that	Yes Yes Yes Drug/Biologi Food/Medical food Crumbles French Lentil + Le Daily Harvest Over-the-Counter Compounded by a Pharmacy of Generi		1 of 1	

Generated by: SYSTEM Generated on: 29-Jun-2022 01:46:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51230 | Department: CFSAN | RCT No.: RCT-1026422 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No	
	Did the problem return if the rson started taking or using the roduct again?		
Dri	ug Therapy	1 of 1	
	Expiration date	23-Oct-2022	
	Lot number	L5-A 11:14	
	Dosage Form		
	Quantity	If Other	
	Frequency	If Other	
	How was it taken or used	Oral If Other	
	Date the person first started aking or using the product	11-Jun-2022	
	Date the person stopped taking or using the product	13-Jun-2022	
	Date the person reduced dose of he product		
	Give best estimate of duration		
	Is therapy still on-going?		
Wr	ny was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ction D - About the Medical De	vice	
	Name of medical device		
	Name of the company that makes the medical device		
Otl loc	ner identifying information (The ate them)	model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		

Generated by: SYSTEM Generated on: 29-Jun-2022 01:46:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51230 | Department: CFSAN | RCT No.: RCT-1026422 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

FC	r implanted medical devices C	NLY (such as pacemakers, breast mplants, etc.)
D	ate the implant was put in	Date the implant was taken out (If relevant)
Se	ection E - About the Person Wh	no Had the Problem
	Person's Initials	(b) (6)
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Age (specify unit of time for age)	35 Year(s)
	Date of Birth	
	Weight	60.75 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	
	(American Indian or Alaska Native Native Hawaiian or Other Pacific Islander
		Asian
		White
		Black or African American
Lis	st known medical conditions (S	such as diabetes, high blood pre ure, cancer, heart disease, or others)
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)
	ulfa, amoxicillin, minocycline	
Lis	st any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)
	et arry out or important important	
LIS	st all current prescription medic	cations and medical devices b ng used.
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.
	vitamin D	

Generated by: SYSTEM Generated on: 29-Jun-2022 01:46:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51230 | Department: CFSAN | RCT No.: RCT-1026422 | CTU Triage Date: 29-Jun-2022 | Total Pages: 7

tion F - About the Person Fill	ing Out This Form 1 of 1	
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street		
City	(b) (6)	
State/Province	(b) (6)	
Country	UNITED STATES	_
ZIP or Postal code		_
Telephone number	(b) (6)	
Email address	(b) (6)	_
Fax		_
Reporter Organization		
Department		_
Reporter Speciality		
Today's date	29-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 29-Jun-2022 01:46:25 Page 5 of 5

(Compost Me

I R N

eparing Crumbles:

Heat a lightly oiled skillet or non-stick pan over medium-high heat.

Add the desired amount of frozen Crumbles to the pan, breaking up any large clusters 0

Stirring frequently, sauté until nicely browned and thoroughly cooked to an internal temperature of 165°F, about 5-6 minutes 0

Let stand for 1-2 minutes. Enjoy on their own or add to your favorite dish.

STORE FROZEN. Do not thaw or refreeze. Cook thoroughly to an internal temperature of 165°F. Fill level and cook time may vary PERISHABLE.

Nutrition Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290 (19% 18g (23% DV), Saturated Fat 2g (10% DV), Trans Fat 0g, Cholesterol Omg (0% DV), Sodium 430mg (19% DV), Saturated Fat 2g (10% DV), Trans Fat 0g, Cholesterol Omg (0% DV), Sodium 430mg (10% DV), Saturated Fat 2g (10% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added Sugars) (10% DV), Vitamin D Omcg (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% DV), Iron 4mg (10% DV), Potassium 486mg (10% DV), Pot % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet 2,000 calo for general nutrition advice.

Ingredients organic butternut squash, organic hemp seeds, organic cauliflower rice, organic ganic french lentils, organic transfer and lentils, organic transfer and lentils, organic transfer and lentils, organic transfer and lentils, organic transfer and lentils, organic sack organic parsley, water, organic cassava root flour, organic flax seeds, organic sack organic porcein powder, himalayan sea salt, organic apple cider vinegar, organic onion powder.

MADE IN ADE IN ADE IN A COMMENT OF TRANSFER AND ORGANIC COLIANGER AND MADE IN A FACILITY THAT ALSO PROCESSES TREE NUTS, SOY, DAIRY, & SESAME

DISTR. BY DAILY HARVEST INC. NEW YORK, NY 10013

CTU No.: FDA-CDER-CTU-2022-51456 | Department: CFSAN | RCT No.: RCT-1026711 | CTU Triage Date: 29-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDI	ER-CTU	Origi	nating Ac ount	FAERS	
Source Medium		/O (Drug)	Source Form Type		E2B XML 3500B	
Priority	Rou	utine				
Override Auto Calculation	Rule No					
FDA Received Date	29-	Jun-2022	CTU	Received Date	29-Jun-2022	
CTU Triage Date			CTU	Data Entry Date		
Report Type	Spo	ontaneous	Repo	rt Classification	Drug	
Assign To	Use	er	1			
User/Group						
Forward to Department		1				
Case Priority	Dire					
	l .					_
Contact						
Case First Name		Last Name		Email Address	Phone	
Reporter		(b) (6)				_
(b) (6)		(b) (6)				
Section A - About the F	Problem					
What kind of problem (Check all that apply)		Were hurt or had a bad side ended a product incorrectly white Noticed a problem with the quarters.	ch could			
		Had problems after switching t	rom one	product maker to another maker		
Date the problem oc ı	urred 29-	29-Jun-2022				
Serious	Yes	Yes				
Did any of the followin (Check all that apply)		Hospitalization - admitted or st Required help to prevent perm Disability or health problem Birth defect Life-threatening Death Other serious/important medic	anent ha	ırm		
Other serious/importa ncident(Please Descr	ibe Below)					
4.Tell us what happene any additional docume	ed and how it h	nappened (Include as	many	de ails as possible FDA	may reach out to you for	
		er contaminated Daily Ha	arv pr	oducts. Located in (b) (6)		
Relevant Test/Laborato	ory Data				1 of 1	
Test Name	Jry Data		Test	Date		
Test Result			Test	Unit		
Low Test Range			High	Test Range		

Generated by: SYSTEM Generated on: 29-Jun-2022 15:46:21 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51456 | Department: CFSAN | RCT No.: RCT-1026711 | CTU Triage Date: 29-Jun-2022 | Total Pages: 5

	More Information Available?		
Ad	ditional Comments		
Se	ction B - Product Availability		
	Do you still have the product in case we need to evaluate it?	Yes	
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No	
Se	ction C - About the Products	1 of 1	
	Suspect	Yes	
	Primary?	Yes	
	Туре	Drug/Biologi	_
	This report is about	Food/Medical food	_
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Smoothies	
	Name of the company that makes (or compounds) the roduct	Daily Harvest	
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar	
	Strength	If Other	
	NDC number		_
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?		
	Did the problem return if the rson started taking or using the roduct again?		
Dr	ug Therapy	1 of 1	
	Expiration date		
	Lot number		
	Dosage Form		
	Quantity	If Other	
	Frequency	If Other	
	How was it taken or used	If Other	_
	Date the person first started aking or using the product		
	Date the person stopped taking or using the product		

Generated by: SYSTEM Generated on: 29-Jun-2022 15:46:21 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51456 | Department: CFSAN | RCT No.: RCT-1026711 | CTU Triage Date: 29-Jun-2022 | Total Pag es: 5

	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
Wł	ny was the person using the pr	roduct? (such as what con	ndition was it supposed to to	reat) 1 of 1
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the	expiration date, if you can
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast_mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken our relevant)	ut (If
Se	ection E - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Decline to answer		
	Gender	Decline to answer		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth			
	Weight			
	Ethnicity (Choose only one)			
	Race (Check all that apply)	American Indian or Alaska Nativ Native Hawaiian or Other Pacifi Asian		

Generated by: SYSTEM Generated on: 29-Jun-2022 15:46:21 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51456 | Department: CFSAN | RCT No.: RCT-1026711 | CTU Triage Date: 29-Jun-2022 | Total Pages: 5

		White Black or African American	
Lis	st known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	t any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	cations and medical devices b ng used.	
Lis	t all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
<u>د</u> د	ation F. About the Dorson Fill	ing Out This Form	
JOE	ction F - About the Person Fill Primary?	ing Out This Form 1 of 1 Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street		
	City		
	State/Province		
	Country	UNITED STATES	
	ZIP or Postal code		
	Telephone number		
	Email address		

Generated by: SYSTEM Generated on: 29-Jun-2022 15:46:21 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51456 | Department: CFSAN | RCT No.: RCT-1026711 | CTU Triage Date: 29-Jun-2022 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	29-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 29-Jun-2022 15:46:21 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-51680 | Department: CFSAN | RCT No.: RCT-1026862 | CTU Triage Date: 30-Jun-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Daois Data	ile		·				
Basic Deta		CDI	-D CTU	Origi	noting As quat	FAEDS	
Company U Source Med			ER-CTU	_	nating Ac ount	FAERS	
	iium		O (Drug)	Sour	ce Form Type	E2B XML 3500B	
Priority Output	to Coloulation Dula		ıtine				
	to Calculation Rule	No		0711	D : 1D :		
FDA Receiv		30-	Jun-2022		Received Date	30-Jun-2022	
CTU Triage		_			Data Entry Date		
Report Type	9	-	ontaneous	Repo	ort Classification	Drug	
Assign To		Use	er				
User/Group							
Forward to I	Department]				
Case Priorit	у	Dire	ect				
Contact							
Case Reporter	First Name		Last Name		Email Address	Phone	
\square	(b) (6)		(b) (6)		(b) (6)	(b) (6)	
	About the Problem						
	nd of problem was it?						
	all that apply)				luding new or worsening symptoms)		
			Used a product incorrectly which				
			Noticed a problem with the quality of the product				
Date the	problem oc urred	Had problems after switching from one product maker to another maker 26-Jun-2022					
Serious		Yes					
	of the following happen?						
	all that apply)	Hospitalization - admitted or stayed longer					
		Required help to prevent permanent harm					
			Disability or health problem				
			Birth defect _ife-threatening				
			Death				
			Other serious/important medical	al incide	nt(Please Describe Below)		
4.Tell us w	hat happened and how nal documents if nece	w it h	appened (Include as		y de ails as possible FDA	may reach out to you	for
Acute he		Joodi	<i>y</i>				
/ touto no	patitio						
Relevant T	est/Laboratory Data					1 of 1	
Test Nar		ALT	-	Test	Date	28-Jun-2022	
Test Res	sult	100	1	Test	Unit		
Low Tes	t Range			High	Test Range		
More Inf	ormation Available?						

Generated by: SYSTEM Generated on: 30-Jun-2022 04:46:23 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51680 | Department: CFSAN | RCT No.: RCT-1026862 | CTU Triage Date: 30-Jun-2022 | Total Pages: 5

Ad	lditional Comments		
Se	ection B - Product Availability		
	Do you still have the product in case we need to evaluate it?	No	_
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No	
Se	ection C - About the Products	1 of 1	
	Suspect	Yes	
	Primary?	Yes	
	Туре	Drug/Biologi	
	This report is about	Food/Medical food	_
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily harvest lentil crunch	
	Name of the company that makes (or compounds) the roduct		
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar	
	Strength	If Other	
	NDC number		
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No	
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply	
Dr	ug Therapy	1 of 1	
	Expiration date		
	Lot number		
	Dosage Form		
	Quantity	If Other	
	Frequency	If Other	
	How was it taken or used	If Other	
	Date the person first started aking or using the product		
	Date the person stopped taking or using the product		
	Date the person reduced dose of he product		

Generated by: SYSTEM Generated on: 30-Jun-2022 04:46:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51680 | Department: CFSAN | RCT No.: RCT-1026862 | CTU Triage Date: 30-Jun-2022 | Total Pag es: 5

	Give best estimate of duration				
	Is therapy still on-going?	Yes			
WI	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
	Food				
	Returned to Manufacturer On				-
		wine			_
SE	ection D - About the Medical De Name of medical device	evice			
	Name of the company that				_
	makes the medical device				
Ot	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the expiration date, i	f you can	
100	cate them)				
	Model Number				_
	Catalog Number				_
	Lot Number				_
	Serial Number				_
	UDDI Number				_
	Expiration date				_
	Was someone operating the				_
	medical device when the problem				
_	oc urred?				_
	r implanted medical devices O	NLY (such as pacemake	·		
יט	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection E - About the Person Wh	on Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			_
	Gender	Cisgender woman/girl			_
	Please Specify Other Gender				-
	Age (specify unit of time for age)	56 Year(s)			_
	Date of Birth		-		_
	Weight	65.25 kg			_
	Ethnicity (Choose only one)	Not Hispanic/Latino			_
	Race (Check all that apply)	American Indian or Alaska Nati	ve		_
		Native Hawaiian or Other Pacif			
		Asian			
		White			
		Black or African American			

Generated by: SYSTEM Generated on: 30-Jun-2022 04:46:23 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51680 | Department: CFSAN | RCT No.: RCT-1026862 | CTU Triage Date: 30-Jun-2022 | Total Pages: 5

LIS	·	such as diabetes, high blood pre ure, cancer, heart disease, or others)	
	Mild asthma		
PΙ	ease list all allergies (such as t	to drugs, foods, pollen or o hers)	
	Salmon		
Lis	st any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
	Noneh	3, p3,,,,	
ll is	st all current prescription medic	cations and medical devices b ng used.	
LIC	None	Battoris and medical devices biring used.	
	None		
LIS	st all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
 Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
00	Primary?	Yes	
	Reporter is Patient?		-
	Title		
	TIUC		
I	Last name	(b) (6)	
	Last name	(b) (6)	
	Middle Name		
	Middle Name First name	(b) (6)	
	Middle Name First name Number/Street	(b) (6) (b) (6)	
	Middle Name First name Number/Street City	(b) (6) (b) (6)	
	Middle Name First name Number/Street City State/Province	(b) (6) (b) (6) (b) (6)	
	Middle Name First name Number/Street City State/Province Country	(b) (6) (b) (6) (b) (6) (b) (6) UNITED STATES	
	Middle Name First name Number/Street City State/Province Country ZIP or Postal code	(b) (6) (b) (6) (b) (6) (b) (6) UNITED STATES (b) (6)	
	Middle Name First name Number/Street City State/Province Country ZIP or Postal code Telephone number	(b) (6) (b) (6) (b) (6) UNITED STATES (b) (6) (b) (6)	
	Middle Name First name Number/Street City State/Province Country ZIP or Postal code	(b) (6) (b) (6) (b) (6) (b) (6) UNITED STATES (b) (6)	

Generated by: SYSTEM Generated on: 30-Jun-2022 04:46:23 Page 4 of 5

Reporter Organization

CTU No.: FDA-CDER-CTU-2022-51680 | Department: CFSAN | RCT No.: RCT-1026862 | CTU Triage Date: 30-Jun-2022 | Total Pages: 5

Department		
Reporter Speciality		
Today's date	30-Jun-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 30-Jun-2022 04:46:23 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-51911 | Department: CFSAN | RCT No.: RCT-1027260 | CTU Triage Date: 01-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details						
Company Unit	CDER-CTU	Originating Ac ount	FAERS			
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B			
Priority	Routine					
Override Auto Calculation Rule	No					
FDA Received Date	30-Jun-2022	CTU Received Date	30-Jun-2022			
CTU Triage Date		CTU Data Entry Date				
Report Type	Spontaneous	Report Classification	Drug			
Assign To	User					
User/Group						
Forward to Department						
Case Priority	Direct					

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)	

S	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
	Date the problem oc urred	26-May-2022	
	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
	Other serious/important medical ncident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

I woke up in the early hours of 5/26 with severe epigastric pain that quickly led to nausea, dizziness, blurred vision and weating. I tried to get out of bed, and fell to the ground in ain making it hard to breath, stuck in child pose from that point forward. I could feel my heart rate slowing down, it quite literally felt like I was dying. I had to call an ambulance, and had trouble communicating with the EMT's due to the pain. I could not think straight and my ears were muffled with a loud ringing noise. My heart rate had dropped into the 30s, my blood pressur exceeded 140/90 (I have hypotension, and this is rare to happen), and I was perfusely sweating. Physicians at the ER did not know what was wrong with me, as I was describing the pain as centered in the area of my diaphragm/liver/gallbladder. CT scan and ultrasound did not indicate any immediate issue, beyond some swelling around the liver and stool build-up in the colon. Some blood tests were off. I was sent home with no diagnosis beyond assumed constipation. Later that day and the nixt morning, I saw my established PCP and Hem-Onc, respectively, both of whom started me on two ulcer medications reventatively. I saw no improvement from the medication, until the pain suddenly subsided 3 days later. During this time, I was basically bed-ridden and unable to eat.

Relevant Test/Laboratory Data

1 of 3

Generated by: SYSTEM Generated on: 30-Jun-2022 22:46:29 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-51911 | Department: CFSAN | RCT No.: RCT-1027260 | CTU Triage Date: 01-Jul-2022 | Total Pages: 5

Test Name		T4 D-4-	00 M 0000
	GLUCOSE	Test Date	26-May-2022
Test Result	134	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	70	High Test Range	100
More Information Available?			
elevant Test/Laboratory Data			2 of 3
Test Name	AST	Test Date	26-May-2022
Test Result	41	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	15	High Test Range	37
More Information Available?		·	
elevant Test/Laboratory Data			3 of 3
Test Name	LIPASE	Test Date	26-May-2022
Test Result	68	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	73	High Test Range	393
More Information Available?			
dditional Comments			
ection B - Product Availability Do you still have the product in case we need to evaluate it?	Yes		
Do you still have the product in	Yes No		
Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture)			1 of 1
Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture)			1 of 1
Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ection C - About the Products	No		1 of 1
Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ection C - About the Products Suspect	No Yes		1 of 1
Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ection C - About the Products Suspect Primary?	No Yes Yes		1 of 1
Do you still have the product in case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ection C - About the Products Suspect Primary? Type	Yes Yes Drug/Biologi	Crumbles	1 of 1
case we need to evaluate it? Do you have a picture of the roduct? (check yes if you are ncluding a picture) ection C - About the Products Suspect Primary? Type This report is about Name of the product as it appears on the box, bottle, or package (Include as many	Yes Yes Drug/Biologi Food/Medical food	Crumbles	1 of 1

Generated by: SYSTEM Generated on: 30-Jun-2022 22:46:29 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-51911 | Department: CFSAN | RCT No.: RCT-1027260 | CTU Triage Date: 01-Jul-2022 | Total Pages: 5

	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dru	ug Therapy			1 of 1	
	Expiration date	10-Oct-2022			
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product				
	Date the person stopped taking or using the product				
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
Wr	ny was the person using the pr	oduct? (such as what co	ndition was it supposed to ti	reat) 1 of 1	
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device	54100			T
	Name of the company that				
	makes the medical device				<u> </u>
Otl loc	ner identifying information (The ate them)	e model, catalog, lot, seri	al, or UDI number, and the	expiration date, if you can	
	Model Number				
	Catalog Number		-		
	Lot Number			-	
	Serial Number				
	UDDI Number				
	Expiration date				

Generated by: SYSTEM Generated on: 30-Jun-2022 22:46:29 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-51911 | Department: CFSAN | RCT No.: RCT-1027260 | CTU Triage Date: 01-Jul-2022 | Total Pages: 5

	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)				
	Date of Birth	(b) (6)			
	Weight	63 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati	ive		
		Native Hawaiian or Other Pacif	iic Islander		
		Asian			
		White			
		Black or African American			
Lis	st known medical conditions (S	uch as diabetes, high blo	od pre ure, cancer, heart disease	e, or others)	
	Hypogammaglobulinemia, hypote	nsion, Raynaud's disease			
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o	o hers)	·	
	Sulfa, tetracycline, vancomycin, c blackberries	lindamycin, penicilin, minocyc	oline, amoxycillin; casein, albumin, glut	en, raspberries/	
Lis	st any other important informati	on about the person (suc	h as moking, pregnancy, alcohol	use, etc.)	
	N/a				
Lis	st all current prescription medic	cations and medical devic	es b ng used.		
	Adderall, midodrine, albuterol inha				
Lis	st all over-the-counter medicati	ons and any vitamins, mil	neral , supplements, and herbal re	emedies being used.	

Generated by: SYSTEM Generated on: 30-Jun-2022 22:46:29 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-51911 | Department: CFSAN | RCT No.: RCT-1027260 | CTU Triage Date: 01-Jul-2022 | Total Pag es: 5

Vitamin C, vitamin B12, vitamin D, magnesium, quercetin	

ection F - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	30-Jun-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 30-Jun-2022 22:46:29 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52243 | Department: GFSAN | RCT No.: RCT-1027449 | DTU Trage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	2011	200 (200 200 40	12.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	
FDA Received Date	01-Jul-2022	CTU Received Date	01-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b) (6)	(b) (6)	(b) (6)	(b) (6)	

Section A - About the Problem		- 1
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	01-May-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Hello, I am a freelance food writer and contributor to HuffPost. On April 14, 2022, I received a sample of Daily Harvest Crumbles as part of a launch promotion. (I have emails from the company confirming this). A couple weeks later, during a cold(b) (6) April, I made a batch of chili with the crumbles. It was my lunch on Thursday April 28 and Friday April 29. On Saturday, April 30, I began to experience severe intestinal pain, dark urine, jaundiced eyes and other symptoms. On May 1, I went to the ED, where tests showed elevated liver levels. I'm reporting this now, since I've just heard about the recall. I'm also asking what recourse there will be for customers -- well, in my case, not a customer but a media professional -- whose health has been affected.

elevant Test/Laboratory	Data		1 of 1
Test Name	ALKALINE PHOSPHATAS E	Test Date	01-May-2022
Test Result	506	Test Unit	
Low Test Range	40	High Test Range	150

Generated by: SYSTEM Generated on: 01-Jul-2022 14:16:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52243 | Department: CFSAN | RCT No.: RCT-1027449 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food		_	
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest crumbles			
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength	Biosimilai	If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	28-Apr-2022			
	Date the person stopped taking or using the product	29-Apr-2022			

Generated by: SYSTEM Generated on: 01-Jul-2022 14:16:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52243 | Department: CFSAN | RCT No.: RCT-1027449 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
Wł		roduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
	To eat	\			
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that				
	makes the medical device				
Otl	her identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the expirat	tion date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				_
	UDDI Number				
	Expiration date				
	Was someone operating the				_
	medical device when the problem				
	oc urred?				
	r implanted medical devices O	NLY (such as pacemake	. ,		
Da	ate the implant was put in		Date the implant was taken out (If relevant)		
0 -	-ti	a libratita a Dualatana	,		_
Se	ction E - About the Person Wh Person's Initials	no Had the Problem			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender	Ologender Wornan/gill			_
	Age (specify unit of time for age)	65 Year(s)			
	Date of Birth	05 Tear(s)			
		67.5 kg			_
	Weight Ethnicity (Chaosa only one)	67.5 kg			_
	Ethnicity (Choose only one)				
	Race (Check all that apply)	American Indian or Alaska Nat			
		Native Hawaiian or Other Pacit	fic Islander		
		│			

Generated by: SYSTEM Generated on: 01-Jul-2022 14:16:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52243 | Department: CFSAN | RCT No.: RCT-1027449 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

		White Black or African American	
ll ic	et known modical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
LIS	st known medical conditions (3	uch as diabetes, high blood pre-dre, cancer, heart disease, or others)	
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	st any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	ations and medical devices b ng used.	
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	

Generated by: SYSTEM Generated on: 01-Jul-2022 14:16:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52243 | Department: CFSAN | RCT No.: RCT-1027449 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	01-Jul-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 01-Jul-2022 14:16:22 Page 5 of 5

Last Name

CTU No.: FDA-CDER-CTU-2022-52255 | Department: GPSAN | RCT No.: RCT-1027475 | DTU Trage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Contact

Case

First Name

Basic Details		200 (200) 200 (200)	-2.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No	4	
FDA Received Date	01-Jul-2022	CTU Received Date	01-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Email Address

Phone

Reporter	(b) (6)	(b) (d)	(b) (6)	
Section A	- About the Problem	4	-180	
	rind of problem was it? c all that apply)	Used a product incorrecti Noticed a problem with the	de effect (including new or worsening sympo y which could have or led to a problem he quality of the product thing from one product maker to another maker	
Date ti	ne problem occurred	09-Jun-2022		
Seriou	s	Yes		
	y of the following happen? call that apply)	Hospitalization - admitted Required help to prevent Disability or health proble Birth defect Life-threatening Death Other serious/important in	permanent harm	
	serious/important medical	Y.C.		1

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

My boyfriend has a subscription to daily harvest. I am holidaying in the USA to visit him and I ate the daily harvest French lentil and leek crumbles on the 3rd of June and started to feel unwell the next day with nausea and upper abdominal pain that wouldn't go away. On the specific day I noticed that my urine was dark (cannot be sure when that started) and I was still experiencing nausea, feeling faint and upper abdominal pain. I vomited 4 times this day and my urine continued to be dark for about 4 days. I didn't go to hospital or a doctor however just wanted to mention that I believe I was sick from these lentils so you can understand the scope of how many people it impacted and hopefully I can get an answer on what it was and if I need to follow up with any additional tests on my liver etc.

elevant Test/Laboratory Data		1 of 1
Test Name	Test Date	1 7 7 7 7 7
Test Result	Test Unit	4, 10

Generated by: SYSTEM Generated on: 01-Jul-2022 14:46:37 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52255 | Department: CFSAN | RCT No.: RCT-1027475 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Low Test Range		High Test Range		
	More Information Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French lentil + leek crumble	s		
	Name of the company that makes (or compounds) the roduct Product Type(check all that apply)	Daily Harvest Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	03-Jun-2022			

Generated by: SYSTEM Generated on: 01-Jul-2022 14:46:37 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52255 | Department: CFSAN | RCT No.: RCT-1027475 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Date the person stopped taking or using the product	04-Jun-2022	
	Date the person reduced dose of he product		
	Give best estimate of duration		
	Is therapy still on-going?		
W	hy was the person using the pr	roduct? (such as what condition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On		
Se	ection D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		_
	her identifying information (The	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
loc	cate them)		
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast_mplants, etc.)	
D	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ection E - About the Person Wh	no Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)	29 Year(s)	
	Date of Birth		
	Weight	73 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	

Generated by: SYSTEM Generated on: 01-Jul-2022 14:46:37 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52255 | Department: CFSAN | RCT No.: RCT-1027475 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

		Asian	
		White White	
		Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	st any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	ations and medical devices b ng used.	
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
C.	ection F - About the Person Fill	ing Out This Form 1 of 1	
06	Primary?	Yes	
	Reporter is Patient?	163	+
	Title		+
	Last name	(b) (6)	+
	Middle Name		+
	First name	(b) (6)	
	Number/Street		+
	City		+
	State/Province		+
	Country	(b) (6)	
	ZIP or Postal code		
	Telephone number		
	Email address	(b) (6)	+
i .	Email address	(b) (d)	

Generated by: SYSTEM Generated on: 01-Jul-2022 14:46:37 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52255 | Department: CFSAN | RCT No.: RCT-1027475 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	01-Jul-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 01-Jul-2022 14:46:37 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52289 | Department: CFSAN | RCT No.: RCT-1027593 | CTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	yed in the report are in EST(G	wir-05.00) time zone			
Basic Deta		ODED OTH		<i>i</i> : • •	EAEDO.
Company L		CDER-CTU		nating Ac ount	FAERS
Source Me	dium	MWO (Drug)	Sour	ce Form Type	E2B XML 3500B
Priority		Routine			
Override Au	uto Calculation Rule	No			
FDA Recei	ved Date	01-Jul-2022	СТИ	Received Date	01-Jul-2022
CTU Triage	Date		CTU	Data Entry Date	
Report Typ	e	Spontaneous	Repo	ort Classification	Drug
Assign To		User			
User/Group					
Forward to	Department				
Case Priori	ty	Direct			
Contact					
Case Reporter	First Name	Last Name		Email Address	Phone
\square	(b) (6)	(b) (6)		(b) (6)	(b) (6)
Section A	- About the Problem				
What kind of problem was it? (Check all that apply) Date the problem oc urred Serious Did any of the following happen? (Check all that apply)		Used a product incomplete Noticed a problem of Had problems after 26-Jun-2022 Yes Hospitalization - ad Required help to proper Disability or health Birth defect Life-threatening Death	orrectly which could with the quality of the switching from one switching from the switch	product maker to another maker	
ncident 4.Tell us wany addition	onal documents if nece ned Daily Harvest lentil cru	essary) umbles on 6/22/2022	2. On 6/26/2022	y de ails as possible FDA had back pain, sore muscles st. Received testing on 7/1/20	
mplicat			————	St. Necessed testing on 77 172	JZZ Showing iivoi
Relevant T	est/Laboratory Data				1 of 1
Test Na	me		Test	Date	
Test Re	sult		Test	Unit	
Low Tes	st Range		High	Test Range	

Generated by: SYSTEM Generated on: 01-Jul-2022 20:16:43 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52289 | Department: CFSAN | RCT No.: RCT-1027593 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

_	·				
	More Information Available?				
Ad	Iditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes		_	
	Туре	Drug/Biologi		_	
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest Lentil and lee	k crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number		1	1	
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product Date the person stopped taking				
	or using the product				

Generated by: SYSTEM Generated on: 01-Jul-2022 20:16:43 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52289 | Department: CFSAN | RCT No.: RCT-1027593 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

	Date the person reduced dose of he product				
	Give best estimate of duration	_			
	Is therapy still on-going?	_			
W	hy was the person using the pr	roduct? (such as what con	dition was it supposed to tr	reat) 1 of 1	
		·			
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot	her identifying information (The	e model, catalog, lot, seria	ıl, or UDI number, and the ϵ	expiration date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast mplants, etc.)		
Di	ate the implant was put in		Date the implant was taken ou relevant)	t (If	
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)	44 Year(s)			
	Date of Birth				
	Weight	76.5 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Natir			

Generated by: SYSTEM Generated on: 01-Jul-2022 20:16:43 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52289 | Department: CFSAN | RCT No.: RCT-1027593 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

		White Black or African American	
Lis	t known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	None		
PΙε	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	None		
Lis	·	on about the person (such as moking, pregnancy, alcohol use, etc.)	
	NA		
Lis		cations and medical devices b ng used.	
	None		
Lis	t all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
100	ction F - About the Person Fill	ing Out This Form 1 of 1	
00	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6) (b) (6)	
	Email address	(0) (0)	1

Generated by: SYSTEM Generated on: 01-Jul-2022 20:16:43 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52289 | Department: CFSAN | RCT No.: RCT-1027593 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	01-Jul-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 01-Jul-2022 20:16:43 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52292 | Department: CFSAN | RCT No.: RCT-1027599 | CTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Ва	sic Deta	ils							
Company Unit			CDER-CTU		Originating Ac ount		FAERS		
Source Medium		MWO (Drug)		Source Form Type		E2B XML 3500B			
Pr	iority		Rou	Routine					
O۱	erride Au	to Calculation Rule	No	No					
FE	A Receiv	ed Date	0J-1	ful-2022	CTU	Received Date	0J-f ul-2022		
С	ΓU Triage	Date			CTU	Data Entry Date			
Re	eport Type)	Spc	ontaneous	Repo	ort Classi/ication	Drug		
As	sign To		Use	er					
Us	serv6roup								
Fc	rward to I	Department	\overline{Z}						
Ca	ase Priorit	y	Dire						
Со	ntact								
	ase eporter	First Name		Last Name		Email Address	Phone		
\overline{v}	1	(b) (6)		(b) (6)		(b) (6)	(b) (6)		
		About the Problem							
		d o/ problem was it?							
(Check all that apply)									
			Used a product incorrectly which could have or led to a problem						
				Noticed a problem with the qua					
	Date the	problem oc urred	Had problems a/ter switching /rom one product maker to another maker J8-f un-2022						
	Serious	p. 65.6 65 4 64	No						
		o/ the /ollowing happen?							
		all that apply)		Hospitalization - admitted or sta	•	_			
				Required help to prevent permanent harm					
				Disability or health problem Birth de/ect					
				Li/e-threatening					
				Death					
			Other seriouswimportant medical incident(Please Describe Below)						
		nat happened and how nal documents i/ nece	w it h	appened (7nclude as		y details as possible FDA	may reach out to you /or		
	7ate leek and lentil crumbles /rom Daily Harvest around 8:30 AM and became quite sick beginning that evening. The /ollowing day17had /ever1diarrhea and abdominal pain. The day a/ter1coincidentally17had a physical scheduled and blood tests were aken. My liver enzymes were in the 400 range. Doctors were concerned and 7was /airly ill the neYt /ew days. My cholesterol is high but the Dr. told me not to take simvastatin. 7have lust retested and will get the eYam results tomorrow. 7also had an abdominal ultrasound.								
Re	levant T	estwaboratory Data					J o/ J		
	Test Nar	·		MPREHENSTAE META	Test	Date	20-f un-2022		
	Test Res	sult	וטם	LIVIAINEL	Test	Unit			
	Low Tes	t Range			Hiah	Test Range			
		ormation Available?							

Generated by: S, STEM G nerated on: 0J-f ul-2022 22:J6:2J Page J o/ 5

CTU No.: FDA-CDER-CTU-2022-52292 | Department: CFSAN | RCT No.: RCT-1027599 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Ac	Additional Comments						
	AST- UW 4J9 ALT UW 466						
Se	ection B - Product Availability						
	Do you still have the product in	No					
	case we need to evaluate it? Do you have a picture o/ the roduct? (check yes i/ you are ncluding a picture)	No					
Se	ection C - About the Products	J o/ J	_				
	Suspect	,e					
	Primary?	,e					
	Туре	Drug⊮Biologi	_				
	This report is about	Foodwedical /ood					
	Name o/ the product as it appears on the boY1bottle1 or package (7hclude as many names as you see)	Daily Harvest -French Leek and Lentil Crumble					
	Name o/ the company that makes (or compounds) the roduct	Daily Harvest					
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy or an Outsourcing Facility Generi Biosimilar					
	Strength	7 Other					
	NDC number						
	Did the problem stop a/ter the rson reduced the dose or opped taking or using the roduct?						
	Did the problem return i/ the rson started taking or using the roduct again?	Doesn't Apply					
Dr	ug Therapy	J o/ J					
	EY ration date						
	Lot number						
	Dosage Form						
	Quantity	7 Other					
	Frequency	7 Other					
	How was it taken or used	7 Other					
	Date the person /irst started aking or using the product	J8-f un-2022					
	Date the person stopped taking or using the product	J8-f un-2022					
	Date the person reduced dose of he product						

Generated by: S, STEM G nerated on: 0J-f ul-2022 22:J6:2J Page 2 o/ 5

CTU No.: FDA-CDER-CTU-2022-52292 | Department: CFSAN | RCT No.: RCT-1027599 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

	Give best estimate o/ duration		
	7 therapy still on-going?	,e	
Wł	ny was the person using the pr	roduct? (such as what condition was it supposed to treat) J o/ J	
	Returned to Manu/acturer On		
Se	ction D - About the Medical De	evice	
	Name o/ medical device		
	Name o/ the company that makes the medical device		
Otl		e model1catalog1lot1serial1or UD7number1and the eYpiration date1i/ you can	
100			
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDD7Number		
	EY ration date		
	Was someone operating the medical device when the problem		
	oc urred?		
	r implanted medical devices O		
Da	ate the implant was put in	Date the implant was taken out (7 relevant)	
Se	ction E - About the Person Wh	no Had the Problem	
	Person's 7hitials	(b) (6)	
	SeY	Female	
	Gender	Cisgender womanwgirl	
	Please Speci/y Other Gender		
	Age (speci/y unit o/ time /or age)		
	Date o/ Birth	(b) (6)	
	Weight	90.65 kg	
	Ethnicity (Choose only one)	Not Hispanicwatino	
	Race (Check all that apply)	American Thdian or Alaska Native	
		Native Hawaiian or Other Paci/ic 7lander	
		Asian	
		White	

Generated by: S, STEM G nerated on: 0J-f ul-2022 22:J6:2J Page 3 o/ 5

CTU No.: FDA-CDER-CTU-2022-52292 | Department: CFSAN | RCT No.: RCT-1027599 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

List known medical conditions (Such as diabetes1high blood pressure1cancer1heart disease1or others)					
high cholesterol		_			
Please list all allergies (such as t	o drugs1/oods1pollen or others)				
pollen1grasses1weeds					
List any other important in/ormat	ion about the person (such as smoking1pregnancy1alcohol use1etc.)				
Γ	σ μ σ σ σ σ σ σ σ σ σ σ σ σ σ σ σ σ σ σ				
I ist all current prescription medic	cations and medical devices b ng used.				
simvastatin1myrbetric1dorzalomic					
ll ist all over-the-counter medicati	ons and any vitamins1minerals1supplements1and herbal remedies being used.				
none	ons and any vitamins minerals isapplements rand herbar remedies being asea.				
Section F - About the Person Fill	ing Out This Form J o/ J				
Primary?	,e				
Reporter is Patient?					
Title					
Last name	(b) (6)				
Middle Name					
First name	(b) (6)				
Numberv6treet	(b) (6)				
City					
City	(b) (6)				
State Province	(b) (6)				

Generated by: S, STEM G nerated on: 0J-f ul-2022 22:J6:2J Page 6 o/ 5

(b) (6)

(b) (6)

Telephone number

Reporter Organization

Email address

FaY

CTU No.: FDA-CDER-CTU-2022-52292 | Department: CFSAN | RCT No.: RCT-1027599 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Department	
Reporter Speciality	
Today's date	0J-f ul-2022
Did you report this problem to company that makes the produ (the manu/acturerwompounde	ct
7 you do NOT want your dentity disclosed to the manu/acturer1please mark this boY(Con/identiality Requested	

Generated by: S, STEM G nerated on: 0J-f ul-2022 22:J6:2J Page 5 o/ 5

CTU No.: FDA-CDER-CTU-2022-52296 | Department: CFSAN | RCT No.: RCT-1027603 | CTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	ayed in the report are in EST(G	M I -05	:00) time zone					
Basic Deta								
Company l		_	ER-CTU	_	nating Ac ount	FAERS		
Source Me	dium	MW	O (Drug)	Sour	ce Form Type	E2B XML 3500B		
Priority Override Auto Coloulation Bule		Rou	Routine					
Override A	uto Calculation Rule	No						
FDA Received Date		01-	Jul-2022	CTU	Received Date	01-Jul-2022		
CTU Triage	e Date			CTU	Data Entry Date			
Report Typ	e	Spc	ontaneous	Repo	rt Classification	Drug		
Assign To		Use	er					
User/Group	o							
Forward to	Department	oxdot]					
Case Prior	ity	Dire	ect					
Contact								
Case Reporter	First Name		Last Name		Email Address	Phone		
\square	(b) (6)		(b) (6)		(b) (6)	(b) (6)		
Section A	- About the Problem							
	nd of problem was it?							
	all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)						
		Used a product incorrectly which could have or led to a problem						
		Noticed a problem with the quality of the product						
Date th	e problem oc urred	☐ Had problems after switching from one product maker to another maker 28-May-2022						
Serious		Yes						
	of the following happen?							
	all that apply)		Hospitalization - admitted or sta	-	_			
	,	Required help to prevent permanent harm						
			☐ Disability or health problem					
			Birth defect					
			Life-threatening					
		Death						
	erious/important medical t(Please Describe Below)	Other serious/important medical incident(Please Describe Below)						
4.Tell us w	,	w it h	appened (Include as	many	de ails as possible FDA	may reach out to you for		
Became	e ill after consuming Daily	Harve	est French Leek Crumble		onic pain on right upper abdo lasted 4 days. I thought perha			
gall blad	dder attack. I didn't connec	ct it to	the food. I ate the same	e produ	inasted 4 days. I thought permi act again on 16th June. The sa the notification from Daily Har	ame pains and symptoms		
ogethe	r.				·			
Relevant	Гest/Laboratory Data	ſ		ı		1 of 1		
Test Na	ame			Test	Date			
Test Re	esult			Test	Unit			
Low Te	st Range			High	Test Range			

Generated by: SYSTEM Generated on: 01-Jul-2022 22:46:23 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52296 | Department: CFSAN | RCT No.: RCT-1027603 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

_		Υ			
	More Information Available?				
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi		_	
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Leek	Crumbles		
	Name of the company that makes (or compounds) the roduct				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product Date the person stopped taking				
	or using the product				

Generated by: SYSTEM Generated on: 01-Jul-2022 22:46:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52296 | Department: CFSAN | RCT No.: RCT-1027603 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
Wł	ny was the person using the pr	roduct? (such as what cor	ndition was it supposed to tr	eat) 1 of 1	
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Otl	her identifying information (The ate them)	e model, catalog, lot, seria	al, or UDI number, and the ϵ	expiration date, if you can	
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken ou relevant)	t (If	
Se	ction E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)	53 Year(s)			
	Date of Birth				
	Weight	55.35 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacifi Asian			

Generated by: SYSTEM Generated on: 01-Jul-2022 22:46:23 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52296 | Department: CFSAN | RCT No.: RCT-1027603 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

		White Black or African American	
Lis	st known medical conditions (S	Such as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
Lis	st any other important informati	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	cations and medical devices b ng used.	
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.	
IC o	ation F. About the Derson Fill	ing Out This Form	
JOE	ection F - About the Person Fill Primary?	ing Out This Form 1 of 1 Yes	
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	ĺ

Generated by: SYSTEM Generated on: 01-Jul-2022 22:46:23 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52296 | Department: CFSAN | RCT No.: RCT-1027603 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	01-Jul-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 01-Jul-2022 22:46:23 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52328 | Department: CFSAN | RCT No.: RCT-1027640 | CTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	sic Deta	ils			
	ompany U		CDER-CTU	Originating Ac ount	FAERS
-	ource Med		MWO (Drug)	Source Form Type	E2B XML 3500B
Priority		au an an an an an an an an an an an an an	Routine	, ,,	
Override Auto Calculation Rule		to Calculation Pule	No		
	DA Receiv		02-Jul-2022	CTU Received Date	02-Jul-2022
-			02-Jul-2022		02-Jul-2022
-	ΓU Triage		0	CTU Data Entry Date	Down
	eport Type	•	Spontaneous	Report Classification	Drug
	sign To		User		
	ser/Group				
Fc	rward to I	Department			
Ca	ase Priorit	у	Direct		
	ntact	I			
	ase eporter	First Name	Last Name	Email Address	Phone
V	_	(b) (6)	(b) (6)	(b) (6)	(b) (6)
		About the Problem			
		nd of problem was it? all that apply)		effect (including new or worsening symptoms) which could have or led to a problem	
	Did any (Check a	nal documents if nece	Had problems after switchin 01-Jul-2022 Yes Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important mew it happened (Include essary)	g from one product maker to another maker	*
an	Did any (Check a Check a	of the following happen? all that apply) hat happened and how nal documents if necently harvest lentils for lunc	Had problems after switchin 01-Jul-2022 Yes Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important mew it happened (Include essary)	stayed longer rmanent harm dical incident(Please Describe Below) as many de ails as possible FDA	*
an	Did any (Check a Check a	of the following happen? all that apply) hat happened and hownal documents if necesthy harvest lentils for lund without any other explanest/Laboratory Data	Had problems after switchin 01-Jul-2022 Yes Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important mew it happened (Include essary)	g from one product maker to another maker stayed longer rmanent harm dical incident(Please Describe Below) as many de ails as possible FDA a painful stomach problems. They dete	cted highly elevated liver

K	elevant Test/Laboratory Data			1 01 1
	Test Name	ALANINE AMINO TRANS	Test Date	01-Jul-2022
	Test Result	227	Test Unit	CELLS PER MICROLITR E
	Low Test Range	5	High Test Range	31
	More Information Available?			

Generated by: SYSTEM Generated on: 02-Jul-2022 12:46:23 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52328 | Department: CFSAN | RCT No.: RCT-1027640 | CTU Triage Date: 05-Jul-2022 | Total Pages: 6

Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes			
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			_
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French lentil and leek crum	bles		
	Name of the company that makes (or compounds) the roduct	Daily harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number			,	
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	23-Oct-2022			
	Lot number	L5a 12:46			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	30-Jun-2022			
	Date the person stopped taking or using the product	30-Jun-2022			
	Date the person reduced dose of he product				

Generated by: SYSTEM Generated on: 02-Jul-2022 12:46:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52328 | Department: CFSAN | RCT No.: RCT-1027640 | CTU Triage Date: 05-Jul-2022 | Total Pages: 6

	Give best estimate of duration			
	Is therapy still on-going?	Yes		
WI	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to treat)	1 of 1
	Food			
	Returned to Manufacturer On			
Se	ection D - About the Medical De	evice		
	Name of medical device			
	Name of the company that makes the medical device			
Ot	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expiration date, i	if you can
loc	cate them)			
	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the			
	medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemake	s, breast mplants, etc.)	
	ate the implant was put in		Date the implant was taken out (If	
			relevant)	
Se	ction E - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Cisgender woman/girl		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth	(b) (6)		
	Weight	72 kg		
	Ethnicity (Choose only one)	Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati	ve	
		Native Hawaiian or Other Pacif		
		Asian		
		White		
		Black or African American		

Generated by: SYSTEM Generated on: 02-Jul-2022 12:46:23 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52328 | Department: CFSAN | RCT No.: RCT-1027640 | CTU Triage Date: 05-Jul-2022 | Total Pages: 6

List known medical condi	tions (Such as diabetes, high bloo	d pre lure, cancer, heart disease, or ϵ	others)
N/a			
Please list all allergies (si	uch as to drugs, foods, pollen or o	hers)	
N/a		-	
	formation about the person (such	as moking, pregnancy, alcohol use,	etc.)
Breast feeding			
List all current prescriptio	n medications and medical device	s b ng used.	
Post natal vitamins	nedications and any vitamins, min-	eral , supplements, and herbal remed	lies being used.
Post natal vitamins			
Section F - About the Per	son Filling Out This Form		1 of 1
Primary?	Yes		
Reporter is Patient?			
Title			
Last name	(b) (6)		
Middle Name			
First name	(b) (6)		
Number/Street	(b) (6)		
City	(b) (6)		
State/Province	(b) (6)		
Country	UNITED STATES		
ZIP or Postal code			
	(b) (6)		
Telephone number	(b) (6)		
	(b) (6)		

Generated by: SYSTEM Generated on: 02-Jul-2022 12:46:23 Page 4 of 5

Reporter Organization

CTU No.: FDA-CDER-CTU-2022-52328 | Department: CFSAN | RCT No.: RCT-1027640 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 6

Department		
Reporter Speciality		
Today's date	02-Jul-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

Generated by: SYSTEM Generated on: 02-Jul-2022 12:46:23 Page 5 of 5

BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI TARA

LO2-VEGEN BEST BY 10/23/2022 LS-4 12:46

Compost Me

Preparing Crumbles:

- ① Heat a lightly oiled skillet or non-stick pan over medium-high heat.
- Add the desired amount of frozen Crumbles to the pan, breaking up any large clusters.
- Stirring frequently, sauté until nicely browned and thoroughly cooked to an internal temperature of 165°F, about 5-6 minutes.
- 4 Let stand for 1-2 minutes. Enjoy on their own or add to your favorite dish.

PERISHABLE. STORE FROZEN. Do not thaw or refreeze. Cook thoroughly to an internal temperature of 165°F, Fill level and cook time may vary.

Nutrition Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total Fat 18g (23% DV), Saturated Fat 2g (10% DV), Trans Fat 0g, Cholesterol 0mg (0% DV), Sodium 430mg (19% DV), Total Carbohydrate 19g (7% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added Sugars, 0% DV), Protein 13g (15% DV), Vitamin D 0mcg (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% DV), The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients: organic butternut squash, organic hemp seeds, organic cauliflower rice, organic extra virgin olive oil, organic french lentils, organic red lentils, organic tri-colored quinoa, organic cremini mushrooms, organic tara flour, organic leeks, organic parsley, water, organic cassava root flour, organic flax seeds, organic sacha inchi powder, chia seeds, organic porcini powder, himalayan sea salt, organic apple cider vinegar, organic onion powder, nutritional yeast, organic garlic powder, organic tomato powder, organic white pepper, organic coriander seeds, organic mustard powder, organic thyme

MADE IN A FACILITY THAT ALSO PROCESSES TREE NUTS, SOY, DAIRY, & SESAME.

CTU No.: FDA-CDER-CTU-2022-52302 | Department: CFSAN | RCT No.: RCT-1027612 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	·	
Override Auto Calculation Rule	No		
FDA Received Date	0J-f ul-2022	CTU Received Date	0J-f ul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classi/ication	Drug
Assign To	User		
Userv@roup			
Forward to Department			
Case Priority	Direct		
	•		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - A9out the Pro9lem		
What 7 nd o/ pro9lem was it1 (Chec7 all that apply)	Were hurt or had a 9ad side e//ect (including new or worsening symptoms) Used a product incorrectly which could have or led to a pro9lem Noticed a pro9lem with the 6uality o/ the product 8 ad pro9lems a/ter switching /rom one product ma7er to another ma7 r	
Date the pro9lem oc urred	Jk-f un-2022	
Serious	?e	
Did any o/ the /ollowing happer (Chec7 all that apply)	8 ospitalization - admitted or stayed longer Re6uired help to prevent permanent harm Disa9ility or health pro9lem Birth de/ect Li/e-threatening Death Other seriouswimportant medical incident(Please Descri9e Below)	

bITell us what happened and how it happened (qclude as many details as possi9le FDA may reach out to you /or any additional documents i/ necessary)

qate the Daily 8 arvest French Lentil H Lee7 Crum9les meal on f une Y+2022I q9egan having dar7 colored urine on f une Jk+2022+/ollowed soon 9y discolored stool+a /ew days later qcame down with a low grade /ever+/atigue+nausea and acid re/lu, which lead to uncontrolla9le vomitingl Full 9ody itching 9egan kw20w2 and it was un9eara9lel qwent to the Emergency Room on kw2J 9ecause o/ the vomiting that would not stop and the itchingl Blood tests were run which showed liver enzymes were 5, higher than normal and 9iliru9in was highl An ultrasound and CT were done 9ut showed nothing suspiciousl qwas discharged /rom the hospital and was re/erred to a liver specialist in (b) (6) who qhad an appointment with todayl Additional 9loodwor7 was su9mitted today /or testing and qam waiting on the results o/ thosel qreceived an email /rom Daily 8 arvest regarding the recall o/ this product and my symptoms have aligned with many others who have eaten this productl

Re	Relevant TestvLa9oratory Data J o/					
	Test Name	ALT	Test Date	22-f un-2022		
	Test Result	ЗЈҮ	Test Unit	ONTERNATONAL UNOTS PER LOTRE		

Generated 9y: S?STEM G nerated on: 0J-f ul-2022 23:bk:34 Page J o/ 5

CTU No.: FDA-CDER-CTU-2022-52302 | Department: CFSAN | RCT No.: RCT-1027612 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Į.	Low Test Range	5	8 gh Test Range	k0
	More φ/ormation Availa9le1			J
Re	elevant Testwa9oratory Data			2 o/ 5
	Test Name	Bd_dRUBdN	Test Date	22-f un-2022
	Test Result	21'	Test Unit	Md_LdGRAMS PER DECd_ dTRE
	Low Test Range	12	8 gh Test Range	JI3
	More qn/ormation Availa9le1			
Re	elevant Test\u00c4a9oratory Data			3 o/ 5
	Test Name	LoPASE	Test Date	22-f un-2022
	Test Result	k'	Test Unit	qNTERNATαρNAL UNαTS PER LαTRE
	Low Test Range	Jk	8 gh Test Range	k3
	More φ/ormation Availa9le1			
Re	elevant Testkla9oratory Data			b o/ 5
	Test Name	AST	Test Date	22-f un-2022
	Test Result	Y0	Test Unit	qNTERNATαρNAL UNαTS PER LαTRE
	Low Test Range	J2	8 gh Test Range	b4
	More φ/ormation Availa9le1			
Re	elevant Testkla9oratory Data			5 o/ 5
	Test Name	ALKALONE P8 OS	Test Date	22-f un-2022
	Test Result	J' k	Test Unit	¢NTERNAT¢DNAL UN¢TS PER L¢TRE
			O ale Took Down	Jb0
	Low Test Range	b0	8 gh Test Range	350
	Low Test Range More φ/ormation Availa9le1	ь0	8 gn Test Range	350
Ac		b0	8 gn Test Range	350
	More φ/ormation Availa9le1	b0	8 gn Test Range	
	More φ/ormation Availa9le1	b0	8 gn Test Range	
	More φ/ormation Availa9le1	No	8 gn Test Range	
	More φ/ormation Availa9le1 dditional Comments ection B - Product Availa9ility Do you still have the product in		8 gn Test Range	
Se	More φ/ormation Availa9le1 Idditional Comments Ection B - Product Availa9ility Do you still have the product in case we need to evaluate it1 Do you have a picture o/ the product1 (chec7 yes i/ you are	No	8 gn Test Range	J o/ J
Se	More qn/ormation Availa9le1 Idditional Comments Ection B - Product Availa9ility Do you still have the product in case we need to evaluate it1 Do you have a picture o/ the product1 (chec7 yes i/ you are ncluding a picture)	No	8 gn Test Range	
Se	More qn/ormation Availa9le1 Idditional Comments Ection B - Product Availa9ility Do you still have the product in case we need to evaluate it1 Do you have a picture o/ the product1 (chec7 yes i/ you are ncluding a picture) Ection C - A9out the Products	No No	8 gn Test Range	

Generated 9y: S?STEM G nerated on: 0J-f ul-2022 23:bk:34 Page 2 o/ 5

CTU No.: FDA-CDER-CTU-2022-52302 | Department: CFSAN | RCT No.: RCT-1027612 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	This report is a9out	FoodwMedical /ood			
	Name o/ the product as it appears on the 9o, +9ottle+ or pac7age (qclude as many names as you see)	Daily 8 arvest French Lentil	H Lee7 Crum9les		
	Name o/ the company that ma7 (or compounds) the roduct	Daily 8 arvest			
	Product Type(chec7 all that apply)	Over-the-Counter Compounded 9y a Pharmacy o Generi Biosimilar	or an Outsourcing Facility		
	Strength		q Other		
	NDC num9er				
	Did the pro9lem stop a/ter the rson reduced the dose or opped ta7 ng or using the roduct1				
	Did the pro9lem return i/ the rson started ta7 ng or using the roduct again1				
Dr	ug Therapy			J o/ J	
	E, ration date				
	Lot num9er				
	Dosage Form				
	Kuantity		d Other		
	Fre6uency		q Other		
	8 ow was it ta7 n or used		q Other		
	Date the person /irst started a7 ng or using the product				
	Date the person stopped ta7 ng or using the product				
	Date the person reduced dose o/ he product				
	Give 9est estimate o/ duration				
	q therapy still on-going1				
WI	ny was the person using the pr	oduct1 (such as what con	ndition was it supposed to tr	reat) J o/ J	
	Returned to Manu/acturer On				
Ca	ation D. Alout the Medical De	ovice			
Se	ection D - A9out the Medical De Name o/ medical device	evice			
	Name o/ the company that ma7 the medical device				
Ot	her identi/ying in/ormation (The	e model+catalog+lot+seria	al+or UDqnum9er+and the	e, piration date+i/ you can	

Generated 9y: S?STEM G nerated on: 0J-f ul-2022 23:bk:34 Page 3 o/ 5

CTU No.: FDA-CDER-CTU-2022-52302 | Department: CFSAN | RCT No.: RCT-1027612 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Model Num9er					
	Catalog Num9er					
	Lot Num9er					
	Serial Num9er					
	UDDqNum9er					
	E, ration date					
	Was someone operating the medical device when the pro9lem oc urred1					
Fo	r implanted medical devices O	NL? (such as pace	ema7eı	rs+9reast implants+etcl)		
Da	ate the implant was put in			Date the implant was ta7en out (q relevant)		
Se	ction E - A9out the Person Wh	o 8 ad the Pro9lem	า			
	Person@ quitials	(b) (6)				
	Se,	Male				
	Gender	(b) (6)				
	Please Speci/y Other Gender					
	Age (speci/y unit o/ time /or age)					
	Date o/ Birth	(b) (6)				
	Weight	J00IY7g				
	Ethnicity (Choose only one)	Not 8 anicwLatino				
	Race (Chec7 all that apply)	American qidian or A Native 8 awaiian or O Asian White Blac7 or A/rican Ame	ther Paci/			
ll is	t 7nown medical conditions (S	uch as dia9etes+hi	iah 910	od pressure+cancer+heart diseas	se+or others)	
126	Nonel	aon do didoctes i III	911 010	oa procedio oanoci-neart disea.	01-01-01-101-01-01-01-01-01-01-01-01-01-	
Ple	ease list all allergies (such as t	o drugs+/oods+pol	len or o	others)		
	Nonel					
		an after the name	\n /aa	h as mo7ing+pregnancy+alcoho	l	

Generated 9y: S?STEM G nerated on: 0J-f ul-2022 23:bk:34 Page b o/ 5

CTU No.: FDA-CDER-CTU-2022-52302 | Department: CFSAN | RCT No.: RCT-1027612 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

		,
	Nonel	
Lic	t all surrent prescription medications and medical devices 0, na yeard	
LIS	t all current prescription medications and medical devices 9 ng usedl	
	Nonel	
Lio	t all over the counter medications and any vitamina (minerale) complements (and herf) all remedica fixing yearl	
LIS	t all over-the-counter medications and any vitamins+minerals+supplements+and her9al remedies 9eing usedl	
	Multi vitamins	

ction F - A9out the Person F		,
Primary1	?e	
Reporter is Patient1		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Num9erv6treet	(b) (6)	
City	(b) (6)	
Statew Province	(b) (c)	
Country	UNqTED STATES	
Zф or Postal code	(b) (6)	
Telephone num9er	(b) (6)	
Email address	(b) (6)	
Fa,		
Reporter Organization		
Department		
Reporter Speciality		
Today@ date	0J-f ul-2022	
Did you report this pro9lem to the company that ma7 the product (the manu/acturerwoompounder)	t	
q you do NOT want your dentity disclosed to the manu/acturer+please mar7 this 9o, (Con/identiality Re6uested)		

Generated 9y: S?STEM G nerated on: 0J-f ul-2022 23:bk:34 Page 5 o/ 5

CTU No.: FDA-CDER-CTU-2022-52333 | Department: CFSAN | RCT No.: RCT-1027648 | CTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		'
Override Auto Calculation Rule	No		
FDA Received Date	02-Jul-2022	CTU Received Date	02-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		<u>'</u>
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)

$ S\epsilon$	ction A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem	
		Noticed a problem with the quality of the product	
		Had problems after switching from one product maker to another maker	+
	Date the problem oc urred	14-Jun-2022	
	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
	Other serious/important medical ncident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

I ate Daily Harvest Lentil Crumbles late on June 14th. Starting on June 15th, I had high fever(102), nausea, vomiting, stomach cramps and fatigue. Spent June 15th and 16th ill and in bed. Yellow tint in eyes and very yellow urine started. After not improving, went to Urgent Care on June 19th and was prescribed anti-nausea medicine. After more rest and medicine did improve. However, just received blood work results, July 2nd, and liver enzymes are elevated.

Relevant Test/Laboratory Data				
Test Name	BILIRUBIN, TOTAL	Test Date	01-Jul-2022	
Test Result	3.1	Test Unit	MICROGRAMS PER DEC	

Generated by: SYSTEM Generated on: 02-Jul-2022 15:46:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52333 | Department: CFSAN | RCT No.: RCT-1027648 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

	Low Test Range	0.2	High Test Range	1.0	
	More Information Available?				
Re	elevant Test/Laboratory Data			2 of 4	
	Test Name	GOT/AST	Test Date	01-Jul-2022	
	Test Result	70	Test Unit	MILLIGRAMS PER LITRE	
	Low Test Range	<=37	High Test Range		
	More Information Available?				
Re	elevant Test/Laboratory Data			3 of 4	
	Test Name	GPT/ALT	Test Date	01-Jul-2022	
	Test Result	352	Test Unit	MILLIGRAMS PER LITRE	
	Low Test Range	<64	High Test Range		
	More Information Available?				
Re	elevant Test/Laboratory Data			4 of 4	
	Test Name	ALKALINE PHOSPHATAS E	Test Date	01-Jul-2022	
	Test Result	143	Test Unit	MILLIGRAMS PER LITRE	
	Low Test Range	45	High Test Range	117	
	More Information Available?				
Ac	dditional Comments				
	My doctor can comment as neede	ed.			
	,				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	Yes			
	Do you have a picture of the	Yes			
	roduct? (check yes if you are ncluding a picture)				
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	+ Leek Crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter			

Generated by: SYSTEM Generated on: 02-Jul-2022 15:46:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52333 | Department: CFSAN | RCT No.: RCT-1027648 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 7

			Compounded by a Pharmacy or an Outsourcing Facility Generi			
		Biosimilar				
	Strength		If Other			
	NDC number					
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?					
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply				
Dr	ug Therapy			1 of 1		
	Expiration date	10-Oct-2022				
	Lot number	L5-A 07:53				
	Dosage Form					
	Quantity		If Other			
	Frequency		If Other			
	How was it taken or used		If Other			
	Date the person first started aking or using the product	14-Jun-2022				
	Date the person stopped taking or using the product	14-Jun-2022				
	Date the person reduced dose of he product					
	Give best estimate of duration					
	Is therapy still on-going?					
W	hy was the person using the pr	oduct? (such as what co	ndition was it supposed to	treat) 1 of 1		
	D					
	Returned to Manufacturer On					
Se	ection D - About the Medical De	evice				
	Name of medical device					
	Name of the company that makes the medical device					
	her identifying information (The cate them)	e model, catalog, lot, seri	al, or UDI number, and the	expiration date, if you can		
	Model Number					
	Catalog Number					
	Catalog Number Lot Number					

Generated by: SYSTEM Generated on: 02-Jul-2022 15:46:25 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52333 | Department: CFSAN | RCT No.: RCT-1027648 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 7

	UDDI Number					
	Expiration date					
	Was someone operating the medical device when the problem oc urred?					
Fo	r implanted medical devices O	NLY (such as pacemakers	s, breast mplants, etc.)			
Da	ate the implant was put in		Date the implant was taken out (If relevant)			
Se	ction E - About the Person Wh	no Had the Problem			i	
	Person's Initials	(b) (6)				
	Sex	Female				
	Gender	Cisgender woman/girl				
	Please Specify Other Gender					
	Age (specify unit of time for age)					
	Date of Birth	(b) (6)				
	Weight	55.35 kg				
	Ethnicity (Choose only one)	Not Hispanic/Latino				
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Asian White Black or African American				
ll is	t known medical conditions (S	uch as diabetes, high bloo	d pre ure cancer heart disease	e or others)		
Lis	t known medical conditions (S	uch as diabetes, high bloo	d pre ure, cancer, heart disease	e, or others)		
Lis		uch as diabetes, high bloo	d pre ure, cancer, heart disease	e, or others)		
Lis		uch as diabetes, high bloo	d pre ure, cancer, heart disease	e, or others)		
Lis		uch as diabetes, high bloo	d pre ure, cancer, heart disease	e, or others)		
	Na			e, or others)		
				e, or others)		
	Na ease list all allergies (such as t			e, or others)		
	Na ease list all allergies (such as t			e, or others)		
	Na ease list all allergies (such as t			e, or others)		
IPI6	Na ease list all allergies (such as t Na	o drugs, foods, pollen or o				
IPI6	Na ease list all allergies (such as t Na	o drugs, foods, pollen or o	hers)			
IPI6	Na ease list all allergies (such as t Na	o drugs, foods, pollen or o	hers)			
IPI6	Na ease list all allergies (such as t Na	o drugs, foods, pollen or o	hers)			
IPI6	Na ease list all allergies (such as t Na	o drugs, foods, pollen or o	hers)			
Ple	Na ease list all allergies (such as t Na	o drugs, foods, pollen or o	hers) as moking, pregnancy, alcohol			
Ple	ease list all allergies (such as t Na	o drugs, foods, pollen or o	hers) as moking, pregnancy, alcohol			
Ple	ease list all allergies (such as to Na t any other important information to the content of the	o drugs, foods, pollen or o	hers) as moking, pregnancy, alcohol			
Ple	ease list all allergies (such as to Na t any other important information to the content of the	o drugs, foods, pollen or o	hers) as moking, pregnancy, alcohol			

List all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.

Generated by: SYSTEM Generated on: 02-Jul-2022 15:46:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52333 | Department: CFSAN | RCT No.: RCT-1027648 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

Vitamin	

ction F - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	02-Jul-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 02-Jul-2022 15:46:25 Page 5 of 5

MBL

NET WT. 12oz (340g)

sloppy Joes. Dare we say stuff into an empanada? These French Lentil + Leek Orumbles trulywork with in a lettuce wrap. Layer into lasagna. Upgrade your Tossina tortilla. Crumble on top of a Flatbread. Serve anything. Oh, don't forget to add into your offili. eveninshepherd's pie. We could go on.

CTU No.: FDA-CDER-CTU-2022-52338 | Department: CFSAN | RCT No.: RCT-1027652 | CTU Trage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200 (200) 200 (200)	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	02-Jul-2022	CTU Received Date	02-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	29-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

The recalled daily harvest leek and lentil product. The date is from the ER visit. One serving was eaten, it has resulted in almost having my gallbladder removed. Liver enzyme numbers are outrageously high. We spent hours in the emergency room and more working with doctors and batteries of urine, blood, and cat scan tests. It has causes intense abdominal pain, dark urine, loss of sleep, exhaustion, and this is while I am trying to get pregnant.

Relevant Test/Laboratory Data			1 of 4
Test Name	AST	Test Date	01-Jul-2022
Test Result	222	Test Unit	INTERNATIONAL UNITS PER LITRE

Generated by: SYSTEM Generated on: 02-Jul-2022 16:16:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52338 | Department: CFSAN | RCT No.: RCT-1027652 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Low Test Range	40	q gh Test Range	30
More Information Availa7lek		-	
elevant Test/La7oratory Data			2 of I
Test Name	ALT	Test Date	04-Jul-2022
Test Result	I 13	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	К	q gh Test Range	2H
More Information Availa7lek			
elevant Test/La7oratory Data			3 of I
Test Name	BILIRUBIN	Test Date	04-Jul-2022
Test Result	2.2	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	0.2	q gh Test Range	4.2
More Information Availa7lek			
elevant Test/La7oratory Data			l of l
Test Name	AL' ALINE Pq OSPq ATE	Test Date	04-Jul-2022
Test Result	4K6	Test Unit	INTERNATIONAL UNITS PER MILLILITRE
Low Test Range	34	q gh Test Range	425
More Information Availa7lek			,
Iditional Comments			
ection B - Product Availa7ility	s. The initial results were from	n June 2Hand the num7ers have 7e	en going up.
1	Ne		
Do you still have the product in case we need to evaluate itk	No		
Do you have a picture of the productk (checb yes if you are ncluding a picture)	No		
ection C - A7out the Products			4 of 4
Suspect	Yes		
Primaryk	Yes		
Туре	Drug/Biologi		
This report is a7out	Food/Medical food		
Name of the product as it appears on the 7ox, 7ottle, or pacbage (Include as many names as you see)	French Lentil Q Leeb Crum	7les	
Name of the company that	Daily q arvest		

Generated 7y: SYSTEM Generated on: 02-Jul-2022 4K·4K·25 Page 2 of 5

mab (or compounds) the

roduct

Receipt No: RCT-4021K52 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-52338 | Department: CFSAN | RCT No.: RCT-1027652 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

	Product Type(checb all that apply)	Over-the-Counter Compounded 7y a Pharmacy Generi	y or an Outsourcing Facility		
	Chan a sh	Biosimilar	If Other		
	Strength		If Other		
	NDC num7er				
	Did the pro7lem stop after the rson reduced the dose or opped tab ng or using the roductk	No			
	Did the pro7lem return if the rson started tab ng or using the roduct againk	Doesn't Apply			
Dr	ug Therapy				4 of 4
	Expiration date				
	Lot num7er				
	Dosage Form				
	Zuantity		If Other		
	Fre?uency		If Other		
	q ow was it tab n or used		If Other		
	Date the person first started ab ng or using the product	20-Jun-2022		,	
	Date the person stopped tab ng or using the product				
	Date the person reduced dose of he product				
	Give 7est estimate of duration				
	Is therapy still on-goingk				
W	ny was the person using the pr	oductk (such as what co	ondition was it suppos	sed to treat)	4 of 4
	It was dinner				
	Returned to Manufacturer On				
Se	ection D - A7out the Medical De	evice			
	Name of medical device	J 100			
	Name of the company that mab the medical device				
Ot	her identifying information (The cate them)	e model, catalog, lot, se	rial, or UDI num7er, a	nd the expiration dat	e, if you can
	Model Num7er				
	Catalog Num7er				
	Lot Num7er				

Generated 7y: SYSTEM Generated on: 02-Jul-2022 4K:4K:25 Page 3 of 5

Receipt No: RCT-4021K52 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-52338 | Department: CFSAN | RCT No.: RCT-1027652 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

	Serial Num7er				
	UDDI Num7er				
	Expiration date				
	Was someone operating the medical device when the pro7lem oc urredk				
Fo	or implanted medical devices C	NLY (such as pacemab re	s, 7reast mplants, etc.)		
D	ate the implant was put in		Date the implant was tab n out (If relevant)		
Se	ection E - A7out the Person Wh	no q ad the Pro7lem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)	36 Year(s)			
	Date of Birth	.,			
	Weight	HH bg			
	Ethnicity (Choose only one)	Not q anic/Latino			
	Race (Checb all that apply)	American Indian or Alasba Nati			
		l .			
LIS	st bnown medical conditions (S	such as dia/etes, high /lo	od pre ure, cancer, heart disease	e, or otners)	
PΙ	ease list all allergies (such as t	o drugs, foods, pollen or o	hers)		
L					
Lis	st any other important informat	ion a7out the person (suc	h as mob ng, pregnancy, alcoho	ol use, etc.)	
	at all aurrant are existing market	actions and wedical desir	2 7 ng ugad		
Lis	st all current prescription medic	cations and medical device	es r ng usea.		

Generated 7y: SYSTEM Generated on: 02-Jul-2022 4K:4K:25 Page I of 5

CTU No.: FDA-CDER-CTU-2022-52338 | Department: CFSAN | RCT No.: RCT-1027652 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

List	all over-the-counter medications and any vitamins, mineral, supplements, and her7al remedies 7eing used.	
		<u> </u>

ction F - A7out the Person Fill	ing Out This Form 4 of 4
Primaryk	Yes
Reporter is Patientk	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Num7er/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
9IP or Postal code	(b) (6)
Telephone num7er	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	02-Jul-2022
Did you report this pro7lem to the company that mab the product (the manufacturer/compounder)k	No
If you do NOT want your dentity disclosed to the manufacturer, please marb this 7ox (Confidentiality Re?uested):	No

Generated 7y: SYSTEM Generated on: 02-Jul-2022 4K·4K·25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52358 | Department: GFSAN | RCT No.: RCT-1027680 | CTU Trage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	12.22	
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	02-Jul-2022	CTU Received Date	02-Jul-2022	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User	- 6		
User/Group				
Forward to Department				
Case Priority	Direct			

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b) (6)	(p) (e)	(b) (6)	(b) (6)	

What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	21-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
Other serious/important medical incident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I cooked Daily Harvest French Lentil & Leek Crumbles on June 12 (using a meat thermometer to temp) and ate approx 3-4 oz between June 12-14 and threw them out immediately when I received the company email later that week. I started presenting symptoms of liver problems on June 21. I had abdominal cramps, fever, body aches on June 21-22 and then noticed skin itchiness and dark urine starting on June 23. Urgent care confirmed bilirubin in my urine on the 24th and further blood tests (x2) revealed elevated liver enzymes. I just had an ultrasound on July 1 and am awaiting results.

lelevant Test/Laborato	ry Data		1 of 5
Test Name	ALKALINE PHOSPHATAS E	Test Date	26-Jun-2022
Test Result	202	Test Unit	INTERNATIONAL UNITS PER LITRE

Generated by: SYSTEM Generated on: 02-Jul-2022 22:16:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52358 | Department: CFSAN | RCT No.: RCT-1027680 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Low Test Range	37	High Test Range	127		
More Information Available?					
Relevant Test/Laboratory Data			2 of 5		
Test Name	ALANINE AMINOTRANSF ERASE	Test Date	26-Jun-2022		
Test Result	171	Test Unit	INTERNATIONAL UNITS PER LITRE		
Low Test Range	5	High Test Range	46		
More Information Available?					
Relevant Test/Laboratory Data			3 of 5		
Test Name	ASPARTATE AMINOTRA NSFERASE	Test Date	26-Jun-2022		
Test Result	112	Test Unit	INTERNATIONAL UNITS PER LITRE		
Low Test Range	11	High Test Range	40		
More Information Available?					
Relevant Test/Laboratory Data			4 of 5		
Test Name	BILIRUBIN, TOTAL	Test Date	26-Jun-2022		
Test Result	2.4	Test Unit	MICROGRAMS PER DEC		
Low Test Range	0	High Test Range	1.3		
More Information Available?					
Relevant Test/Laboratory Data	Relevant Test/Laboratory Data 5 of				
Test Name	BILIRUBIN, DIRECT	Test Date	26-Jun-2022		
Test Result	1.1	Test Unit	MICROGRAMS PER DEC		
Low Test Range	0	High Test Range	0.3		
More Information Available?					
Additional Comments					
Section B - Product Availability					
Do you still have the product in case we need to evaluate it?	No				
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No				
Section C - About the Products			1 of 1		
Suspect	Yes				
Primary?	Yes				
	50				

Generated by: SYSTEM Generated on: 02-Jul-2022 22:16:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52358 | Department: CFSAN | RCT No.: RCT-1027680 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil & Leek Crumb	oles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	12-Jun-2022			
	Date the person stopped taking or using the product	14-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?	Yes			
Wh	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to to	reat) 1 of 1	
	Food				
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Otl	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the	expiration date, if you can	

Generated by: SYSTEM Generated on: 02-Jul-2022 22:16:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52358 | Department: CFSAN | RCT No.: RCT-1027680 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Model Number			
	Catalog Number			
	Lot Number			
	Serial Number			
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	no Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Cisgender woman/girl		
	Please Specify Other Gender			
	Age (specify unit of time for age)	41 Year(s)		
	Date of Birth			
	Weight	50.4 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif Asian White Black or African American		
l ic	t known medical conditions (S	uch as diabetes, high blo	od pre ure, cancer, heart disease, or others)	
	N/A	den as diabetes, high blo	od pre-dre, cancer, fleart disease, or others)	
PΙε	ease list all allergies (such as t	o drugs, foods, pollen or o	o hers)	
	Penicillin, fish, shellfish, cipro			
	4 4l i 4i 4 i f 4i		h as moking pregnancy alcohol use etc.)	

Generated by: SYSTEM Generated on: 02-Jul-2022 22:16:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52358 | Department: CFSAN | RCT No.: RCT-1027680 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Lis	st all current prescription medications and medical devices b ng used.	
	Zovia 1/35	
Lis	st all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.	
	Vitamin C, Sugar Bear Hair Daily Vitamin, Desert Botanicals Inflammaid, AL-R-G, Immunaid, and Sleep/Stress Formulas	

tion F - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	02-Jul-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 02-Jul-2022 22:16:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52400 | Department: CFSAN | RCT No.: RCT-1027726 | CTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

	lyed in the report are in EST(G	IVI I -03	.00) time zone					
Basic Deta		000	-D OTH	0	ti A t	FAFDO		
Company L			ER-CTU		nating Ac ount	FAERS		
Source Medium			()		E2B XML 3500B			
Priority			Routine					
Override Auto Calculation Rule		No						
FDA Recei	ved Date	03-1	1ul-2022	CTU	Received Date	03-1ul-2022		
CTU Triage	Date			CTU	Data Entry Date			
Report Typ	е	Spo	ntaneous	Repo	rt Classi8 ation	Drug		
Assign To		Use	r					
UserJGroup)							
Forf ard to	Department]					
Case Priori	ty	Dire	ect			_		
Contact								
Case Reporter	First Name		Last Name		Email Address	Phone		
\square	(b) (6)		(b) (6)		(b) (6)	(b) (6)		
	- Axout the Proxlem							
	nd o8proxlem f as it? all that apply)				ding nef or f orsening symptoms)			
		Used a product incorrectly f hich could have or led to a proxlem						
		Noticed a proxlem f ith the quality o8the product						
5.4				om one	product maker to another maker			
	e proxlem occurred	65-1un-2022						
Serious		Yes						
	o8the &llof ng happen? all that apply)	Hospitalization - admitted or stayed longer						
(Oncor	an triat apply)	Required help to prevent permanent harm						
		Disaxility or health proxlem						
		Birth de8						
		╎╠╵	Li8-threatening					
		Death						
LA T. II. C		Other seriousJmportant medical incident(Please Descrix Belof) f it happened (Include as many details as possixle FDA may reach out to you & or						
4w ell us f anv additio	hat happened and hot onal documents i8nece	ıt h ssar	appened (Include as v)	many	details as possixle FDA i	may reach out to you & or		
I ate sor	me crumxles in eggs at f	ork on	1 1une 65x2022wThat ev		f hen I tried to eat dinner I f as			
					p in the emergency room and ill my stomach f as completely			
ome mo	ore testing done to solve t	he my	stery and doctors f re	th inki	ng some minor version o8rhax	domyolysis xut xlood		
l I		evate	d liver enzymewUntil my	xoss s	sent me this article I had never	really 8gured out f hat		
happen	eaw	-						
Relevant T	estLaxoratory Data					6 086		
Test Na	·			Test	Date			
Test Re	sult			Test	Unit			
Lof Tes	st Range			High	Test Range			
More In	&rmation Availaxle?							

Generated xy: SYSTEM Generated on: 03-1ul-2022 6. :4. :22 Page 6 o85

CTU No.: FDA-CDER-CTU-2022-52400 | Department: CFSAN | RCT No.: RCT-1027726 | CTU Triage Date: 05-Jul-2022 | Total Pages: 6

A	dditional Comments				
S	ection B - Product Availax lity				
	Do you still have the product in case f need to evaluate it?	No			
	Do you have a picture o8the product? (check yes i8you are ncluding a picture)	Yes			
S	ection C - Axout the Products			6 086	
П	Suspect	Yes			
	Primary?	Yes			_
	Туре	Drug.Biologic			_
	This report is axout	Food Medical & ood			_
	Name o8the product as it appears on the xo' xxottlex or package (Include as many names as you see)	Crumxles			
	Name o8the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded xy a Pharmacy Generi Biosimilar	or an Outsourcing Facility		
	Strength		I8Other		
	NDC numx r				
	Did the proxlem stop a8 r the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the proxlem return i8the rson started taking or using the roduct again?	Doesn, Apply			
D	rug Therapy			6 086	
	E' ration date				
	Lot numx r				
	Dosage Form				
	Quantity		18Other		
	Frequency		18Other		
	Hof f as it taken or used		18Other		
	Date the person 8rst started aking or using the product	65-1un-2022			
	Date the person stopped taking or using the product	65-1un-2022			
	Date the person reduced dose o8 he product				

Generated xy: SYSTEM Generated on: 03-1ul-2022 6. :4. :22 Page 2 o85

CTU No.: FDA-CDER-CTU-2022-52400 | Department: CFSAN | RCT No.: RCT-1027726 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 6

	Give xest estimate o8duration		
	Is therapy still on-going?		
Wh	ny f as the person using the pr	oduct? (such as f hat condition f as it supposed to treat) 6 o86	
	Food		
	Returned to Manu&cturer On		
Se	ction D - Axout the Medical De	evice	
	Name o8medical device		
	Name o8the company that makes the medical device		
	ner identi&jing in&rmation (The ate them)	e modelxcatalogxlotxserialxor UDI numxerxand the e' piration datexi8you can	
100			
	Model Numx r		
	Catalog Numx r		
	Lot Numx r		
	Serial Numx r		
	UDDI Numx r		
	E' ration date		
	Was someone operating the medical device f hen the proxlem oc urred?		
Fo	r implanted medical devices O	NLY (such as pacemakersxxreast implantsxetcw)	
	ate the implant f as put in	Date the implant f as taken out (I8 relevant)	
Se	ction E - Axout the Person Wh	o Had the Proxlem	
	Person, Initials	(b) (6)	
	Se'	Female	
	Gender	Cisgender man koy	
	Please Speci&y Other Gender		
	Age (speci8y unit o8time 8or age)	2Z Year(s)	
	Date o8Birth		
	Weight	54 kg	
	Ethnicity (Choose only one)	Not Hispanic Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Haf aiian or Other Paci8 Islander Asian White	

Generated xy: SYSTEM Generated on: 03-1ul-2022 6. :4. :22 Page 3 o85

CTU No.: FDA-CDER-CTU-2022-52400 | Department: CFSAN | RCT No.: RCT-1027726 | CTU Triage Date: 05-Jul-2022 | Total Pages: 6

Li	st knof n medical conditions (S	Such as diaxetesxhigh xlood pressurexcancerxheart diseasexor others)
PΙ	ease list all allergies (such as	to drugsx&odsx ollen or others)	
Li	st any other important in&rmat	ion axout the person (such as smokingxpregnancyxalcohol usexetcw)	
Li	st all current prescription medic	cations and medical devices x ng usedw	
	SertralinexspironolactonexFlonas		
Li	st all over-the-counter medicat	ions and any vitaminsxmineralsxsupplementsxand herxal remedies x	ng usedw
	Ixupro8n		
Se	ection F - Axout the Person Fill	ing Out This Form	6 086
	Primary?	Yes	
	Reporter is Patient?		
	Title		

Section F - Axout the Perso	n Filling Out This Form	6 o86
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Numxer&treet	(b) (6)	
City	(b) (6)	
State Province	(b) (6	
Country	UNITED STATES	
6IP or Postal code	(b) (6)	
Telephone numx r	(b) (6)	
Email address	(b) (6)	
Fa'		
Reporter Organization		

Generated xy: SYSTEM Generated on: 03-1ul-2022 6. :4. :22 Page 4 o85

CTU No.: FDA-CDER-CTU-2022-52400 | Department: CFSAN | RCT No.: RCT-1027726 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 6

Department		
Reporter Speciality		
Today, date	03-1ul-2022	
Did you report this proxlem to the company that makes the product (the manu&cturer&compounder)?		
l8you do NOT f ant your dentity disclosed to the manu&cturerxplease mark this xo' (Con8dentiality Requested):	No	

Generated xy: SYSTEM Generated on: 03-1ul-2022 6. :4. :22 Page 5 o85

(b) (6)

CTU No.: FDA-CDER-CTU-2022-52408 | Department: CFSAN | RCT No.: RCT-1027736 | CTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		1
Override Auto Calculation Rule	No		
FDA Received Date	03-Jul-2022	CTU Received Date	03-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Se	ection A - About the Problem		
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
	Date the problem oc urred	22-Jun-2022	
	Serious	Yes	
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	
	Other serious/important medical ncident(Please Describe Below)		

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

Tuesday night, 6/21/22, my family and I ate the leek crumbles a a part of our dinner. Wednesday morning, 6/22/22, I woke up feeling exhausted and had a low fever (around 100F) - I called out of work and went to my local urgent care to be tested for COVID-19. My tests for COVID-19 and the flu came back negative. The urgent care physician prescribed Zofran for nausea. I had no respiratory symptoms but was still experiencing fever, achiness, chills, and exhaustion. I took Tylenol and motrin throughout the afternoon to help bring down my fever, but it continued to climb. Around 10PM, my temperature hit 103F, and my wife drove me to the emergency room. We were at the ER until approx 2AM the following morning, Thursday, 6/23/22, when I was released. During my time at the ER, the doctors completed another set of COVID and flu tests, drew blood, and took a urine sample. They were able to get my temperature down but could not tell us what was causing the extreme fever and/or nausea and exhaustion. Thursday, 6/23/22, my symptoms continued. Friday, 6/24/22, I started having extreme upper stomach pain and acid reflux. I returned to urgent care where they prescribed me something for GERD and let me know that his was likely a response to extreme dehydration from having such a high temperature. Throughout the weekend, I continued to experience extreme stomach pain and a low fever. On Sunday afternoon, 6/26/22, I noticed a post on social media that mentioned an issue with the Daily Harvest product that I consum d on Tuesday night. I checked my email and discovered

Generated by: SYSTEM Generated on: 03-Jul-2022 20:46:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52408 | Department: CFSAN | RCT No.: RCT-1027736 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

that the Daily Harvest team had reached out to notify me that I was shipped a potentially harmful product. I received this ema I on 6/22/22 but had not opened it yet. After reviewing the contents of the email and others posts about similar symptoms, I contacted my doctor to request bloodwork. On Tuesday, 6/28, I went into my doctor's office and had bloodwork done. I continued to experience the same symptoms - fever, exhaustion, and stomach pain. I also began to experience itchiness and noticed dark urine. On Wednesday, 6/29/22, my doctor called to let me know my liver enzyme levels were extremely elevated and had me later tested for Hepatitis. I will be getting an ultrasound on my liver and will be going in to do another round of bloodwork to check my liver enzyme levels.

П	January Tartill also materia. Data			1 -5 1	
RE	elevant Test/Laboratory Data			1 of 1	
	Test Name		Test Date		
	Test Result		Test Unit		
	Low Test Range		High Test Range		
	More Information Available?				
Ac	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in	No			
	case we need to evaluate it?	110			
	Do you have a picture of the roduct? (check yes if you are	No			
	ncluding a picture)				
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it	French Leek and Lentil Cru	mbles		
	appears on the box, bottle, or package (Include as many				
	names as you see)				
	Name of the company that makes (or compounds) the	Daily Harvest			
	roduct				
	Product Type(check all that apply)	Over-the-Counter			
	арріу)	Compounded by a Pharmacy of	or an Outsourcing Facility		
		Generi			
	Strength	Biosimilar	If Other		
	NDC number		II Ottlei		
	Did the problem stop after the	Yes			
	rson reduced the dose or	163			
	opped taking or using the roduct?				
	Did the problem return if the	Doesn't Apply			
	rson started taking or using the				

Generated by: SYSTEM Generated on: 03-Jul-2022 20:46:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52408 | Department: CFSAN | RCT No.: RCT-1027736 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form			,	
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	21-Jun-2022		1	
	Date the person stopped taking or using the product	21-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
Wł	ny was the person using the pr	roduct? (such as what co	ndition was it supposed to t	reat) 1 of 1	
	Dinner				
	Returned to Manufacturer On				
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot	ner identifying information (The	e model, catalog, lot, seri	al, or UDI number, and the	expiration date, if you can	
loc	ate them)				
	Model Number				
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urred?				
Fo	r implanted medical devices O	NLY (such as pacemake	rs, breast mplants, etc.)		
Da	ate the implant was put in		Date the implant was taken ou relevant)	ıt (If	
Se	ction E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			

Generated by: SYSTEM Generated on: 03-Jul-2022 20:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52408 | Department: CFSAN | RCT No.: RCT-1027736 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)	34 Year(s)	
	Date of Birth		
	Weight	81 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
Lis	Race (Check all that apply) st known medical conditions (S	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
		,	
Lis	st any other important informati	on about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	st all current prescription medic	ations and medical devices b ng used.	
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	
Se	ection F - About the Person Fill	ing Out This Form 1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title		
	Last name	Lombardi	

Generated by: SYSTEM Generated on: 03-Jul-2022 20:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52408 | Department: CFSAN | RCT No.: RCT-1027736 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	03-Jul-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 03-Jul-2022 20:46:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52376 | Department: ISPSAN | RCT No.: RCT-1027696 | DTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	A 10 A 10	200000000000000000000000000000000000000	12.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	03-Jul-2022	CTU Received Date	03-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	A Company		3. 8 (4.7) (4.7	
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	06-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4 Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Around June 1st, I ate Daily Harvest French Lentil + Leek Crumbles and experienced severe gastrointestinal issues. It took roughly three days for the pain to subside a bit, and I found that very unusual, but just threw the lentils away and pushed through. About a week later, on June 6th, the gastrointestinal pain returned as intensely as it did the first time, and again I assumed, it would subside. However, the pain continued to intensify, and by June 8th my husband brought me to the Emergency Room at (b) (6)

They gave me several medications, which only lowered my pain minimally until finally administering morphine and sending me home. They did an ultrasound and ran blood tests and couldn't figure out what the cause was, but did notice extremely elevated liver enzymes, which didn't correlate to my healthy lifestyle or my spotless ultrasound. They said it could be stomach ulcers or gastritis and connected me with a GI doctor. The GI doctor scoped my upper intestinal track, esophagus, and even took biopsies of my stomach and intestines to check for multiple chronic conditions. All came back negative. They said everything looked excellent, and the GI doctor shared his strong opinion that my pain and elevated liver enzyme levels is directly correlated to the Lentil Crumbles. Since June 9th, I have changed my entire diet and lifestyle drastically, feeling very confused and helpless about my sudden

health conditions. I have cut out caffeine, alcohol, gluten, dairy and sugar--all in an attempt to heal this episode, and still when

Generated by: SYSTEM Generated on: 03-Jul-2022 10:46:26 Page 1 of 5

eat even a small amount of any of those, I have immediate pain in my belly.

CTU No.: FDA-CDER-CTU-2022-52376 | Department: CFSAN | RCT No.: RCT-1027698 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Relevant Test/Laboratory Data			1 of 4
Test Name	ALK PHOS	Test Date	08-Jun-2022
Test Result	134 unit/L	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	35	High Test Range	117
More Information Available?			
televant Test/Laboratory Data			2 of 4
Test Name	AST	Test Date	08-Jun-2022
Test Result	402 unit/L	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	High Test Range	35
More Information Available?			
elevant Test/Laboratory Data			3 of 4
Test Name	ALT	Test Date	08-Jun-2022
Test Result	205 unit/L	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	High Test Range	35
More Information Available?			
elevant Test/Laboratory Data			4 of 4
Test Name	EGD	Test Date	23-Jun-2022
Test Result	normal images	Test Unit	
Low Test Range		High Test Range	
More Information Available?		l	J
dditional Comments	l.		
I have the documentation of all El on 6/23/22 ection B - Product Availability	R visit as well as all of my r u	Its from (b) (6)	for the scoping
·	T		
Do you still have the product in case we need to evaluate it?	No		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No		
ection C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologi		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle,	Daily Harvest Lentil Crumbl	es	

Generated by: SYSTEM Generated on: 03-Jul-2022 10:46:26 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52376 | Department: CFSAN | RCT No.: RCT-1027698 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

	or package (Include as many names as you see)				
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency	As needed	If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	30-May-2022			
	Date the person stopped taking or using the product	01-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
W	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to t	reat) 1 of 1	
	food				
	Returned to Manufacturer On				_
	Returned to Manufacturer On				_
Se	ction D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot loc	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the	expiration date, if you can	

Generated by: SYSTEM Generated on: 03-Jul-2022 10:46:26 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52376 | Department: CFSAN | RCT No.: RCT-1027698 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Model Number			\vdash		
	Catalog Number			+		
	Lot Number			+		
	Serial Number			+		
	UDDI Number			+		
	Expiration date					
	Was someone operating the medical device when the problem oc urred?					
Fo	r implanted medical devices O	NLY (such as pacemaker	s, breast mplants, etc.)			
Da	ate the implant was put in		Date the implant was taken out (If relevant)			
Se	ction E - About the Person Wh	o Had the Problem				
	Person's Initials	(b) (6)		$\overline{\Box}$		
	Sex	Female				
	Gender	Cisgender woman/girl	Cisgender woman/girl			
	Please Specify Other Gender					
	Age (specify unit of time for age)					
	Date of Birth	(b) (6)				
	Weight	53.1 kg				
	Ethnicity (Choose only one)	Hispanic/Latino				
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif Asian White Black or African American				
ll is	t known medical conditions (S	uch as diabetes, high blo	od pre ure, cancer, heart disease, or others)			
	Tamomi medical conditions (C	aon de diabetes, mgn blo	expression, recent alcodes, or others)			
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o	o hers)			
			h as moking pregnancy alcohol use etc.)			

Generated by: SYSTEM Generated on: 03-Jul-2022 10:46:26 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52376 | Department: CFSAN | RCT No.: RCT-1027698 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Lis	st all current prescription medications and medical devices b ng used.	
Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	

ction F - About the Person Fil	ling Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	03-Jul-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

Generated by: SYSTEM Generated on: 03-Jul-2022 10:46:26 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52369 | Department: CFSAN | RCT No.: RCT-1027691 | CTU Triage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Deta	ile	WI I -US	.00) time zone				
		CDI	ED CTU	Origi	nating As aunt		ERS
Company U		CDER-CTU		Originating Ac ount			
Source Medium			O (Drug)	Sour	ce Form Type	EZI	B XML 3500B
Priority			ıtine				
Override Auto Calculation Rule		No					
FDA Receiv	red Date	03-	Jul-2022	CTU	Received Date	03-	-Jul-2022
CTU Triage	Date			CTU	Data Entry Date		
Report Type	•	Spo	ontaneous	Repo	ort Classification	Dru	g
Assign To		Use	r				
User/Group							
Forward to I	Department	\overline{Z}	4				
Case Priorit	V	Dire	_	-			
	,						
Contact							
Case	First Name		Last Name		Email Address	Р	Phone
Reporter							
\square	(b) (6)	(b) (6)		(b) (6)		(b) (6)	
Section A -	A8out the Pro8lem						
	nd of pro8lem was itk all that apply)		Used a product incorrectly which Noticed a pro8lem with the ?ua	ch could			
Date the	pro8lem oc urred		Jun-2022	TOTTI OTTE	product maper to another map r		
Serious		Не					
	of the following happenk all that apply)		q ospitalization - admitted or sta Re?uired help to prevent perm Disa8ility or health pro8lem Birth defect Life-threatening Death Other serious/important medica	anent ha	arm		
ncident(rious/important medical Please Descri8e Below)						
6.Tell us war any addition	hat happened and how nal documents if nece	v it h ssar	appened (1nclude as y)	man	y details as possi8le FDA	may re	each out to you for
	ed the Daily q arvest prod found on my la8s. Starte				d low grade fevers. Necb ain out tests all negative	and a8r	normal liver

Relevant Test/La8oratory Data 7 of 7					
	Test Name	AST	Test Date	07-Jul-2022	
	Test Result	I 34	Test Unit	UNITS PER M1LL1TRE	
	Low Test Range	70	q gh Test Range	12	

Generated 8y: SHSTEM G nerated on: 03-Jul-2022 06:71 :22 Page 7 of 5

CTU No.: FDA-CDER-CTU-2022-52369 | Department: CFSAN | RCT No.: RCT-1027691 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	More 1nformation Availa8lek				
Ad	ditional Comments				
	q ad also an a8normal Alt alb phos	sp and ldh Necb and scalp pa	in very intense All preceded 8y	itching and necb and chest rash	
Se	ction B - Product Availa8ility				
	Do you still have the product in case we need to evaluate itk	No			
	Do you have a picture of the productk (checb yes if you are ncluding a picture)	No			
Se	ction C - A8out the Products			7 of 7	
	Suspect	He			
	Primaryk	He		-	
	Туре	Drug/Biologi			
	This report is a8out	Food/Medical food			
	Name of the product as it appears on the 80xx80ttlex or pacbage (1nclude as many names as you see)	Daily q arvest French Lentil			
	Name of the company that mab (or compounds) the roduct	Daily q arvest			
	Product Type(checb all that apply)	Over-the-Counter Compounded 8y a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		1 Other		
	NDC num8er				
	Did the pro8lem stop after the rson reduced the dose or opped tab ng or using the roductk	No			
	Did the pro8lem return if the rson started tab ng or using the roduct againk	Doesn, Apply			
Dr	ug Therapy			7 of 7	
	Expiration date				
	Lot num8er			-	
	Dosage Form			-	
	' uantity		1 Other		
	Fre?uency		1 Other		
	q ow was it tab n or used		1 Other		
	Date the person first started ab ng or using the product	22-Jun-2022			
	Date the person stopped tab ng	22-Jun-2022			

Generated 8y: SHSTEM G nerated on: 03-Jul-2022 06:71 :22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52369 | Department: CFSAN | RCT No.: RCT-1027691 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	Date the person reduced dose of he product				
	Give 8est estimate of duration				_
	1 therapy still on-goingk	He			_
W		roductk (such as what co	ndition was it supposed to treat)	7 of 7	
	Returned to Manufacturer On				_
	<u> </u>				=
Se	ection D - A8out the Medical De	evice			
	Name of medical device				
	Name of the company that mab the medical device				
Ot loc	her identifying information (The cate them)	e modelxcatalogxlotxseria	alxor UD1num8erxand the expira	tion datexif you can	
	Model Num8er				
	Catalog Num8er				
	Lot Num8er				
	Serial Num8er				
	UDD1Num8er				
	Expiration date				
	Was someone operating the medical device when the pro8lem oc urredk				
Fc	or implanted medical devices O	NLH (such as pacemabe	rsx8reast implantsxetc.)		
D	ate the implant was put in		Date the implant was taben out (f relevant)		
Se	ection E - A8out the Person Wh	no q ad the Pro8lem			
	Person,s 1nitials	(b) (6)			
	Sex	Male			
	Gender	Cisgender man/8oy			
	Please Specify Other Gender				
	Age (specify unit of time for age)				
	Date of Birth	(b) (6)			
	Weight	Q6.75 bg			
	Ethnicity (Choose only one)	q anic/Latino			
	Race (Checb all that apply)	American 1ndian or Alasba Nat Native q awaiian or Other Pacit Asian			

Generated 8y: SHSTEM G nerated on: 03-Jul-2022 06:71:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52369 | Department: CFSAN | RCT No.: RCT-1027691 | CTU Triage Date: 05-Jul-2022 | Total Pag

		White Blacb or African American	
Lis	t bnown medical conditions (S	uch as dia8etesxhigh 8lood pressurexcancerxheart diseasexor others)	
	Pre dia8etes q TN hx of pulmonar		
Ple	ease list all allergies (such as t	o drugsxfoodsx ollen or o hers)	
	Gadolinium		
Lis		on a8out the person (such as mob ingxpregnancyxalcohol usexetc.)	
	Non smob r rare etoh		
Lis		cations and medical devices 8 ng used.	
	Rosuvastatin 6etia Warfarin Zalsa	artan Z D3 Tadalafil	
Lis	t all over-the-counter medicati	ons and any vitaminsxmineralsxsupplementsxand her8al remedies 8eing used.	
	Z d3		
Se	ction F - A8out the Person Fill	ing Out This Form 7 of 7	
	Primaryk	He	
	Reporter is Patientk		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Num8er/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UNITED STATES	
	61P or Postal code	(b) (6)	
	Telephone num8er	(b) (6)	
	Email address	(b) (6)	

Generated 8y: SHSTEM G nerated on: 03-Jul-2022 06:7I :22 Page 6 of 5

CTU No.: FDA-CDER-CTU-2022-52369 | Department: CFSAN | RCT No.: RCT-1027691 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today, date	03-Jul-2022	
Did you report this pro8lem to the company that mab the product (the manufacturer/compounder)k	Не	
f you do NOT want your dentity disclosed to the manufacturerxplease marb this 8ox (Confidentiality Re?uested):	No	

Generated 8y: SHSTEM G nerated on: 03-Jul-2022 06:71 :22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52954 | Department: CFSAN | RCT No.: RCT-1028175 | CTU Triage Date: 06-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	05-Jul-2022	CTU Received Date	05-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	,	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem oc urred	28-May-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

I started to feel ill, and got worse over the next few days. Symptoms included dark urine, urgency to urinate, aches, chills and fatigue. Also nausea with vomiting. Was diagnosed over the phon as urinary tract infection, started antibiotic and ran lab tests. Had adverse reaction to antibiotic, or perhaps additional symptom of the problem (itchy skin). After further consultation with doctor stopped the antibiotic and ran further lab tests. B gan to feel better after a few days, liver numbers did not ret urn to normal for almost 2 weeks.

R	elevant Test/Laboratory Data	a 1 of 4			
	Test Name	ALT	Test Date	30-May-2022	
	Test Result	305	Test Unit		
	Low Test Range	0	High Test Range	41	
	More Information Available?				

Generated by: SYSTEM Generated on: 05-Jul-2022 21:46:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52954 | Department: CFSAN | RCT No.: RCT-1028175 | CTU Triage Date: 06-Jul-2022 | Total Pages: 5

Re	elevant Test/Laboratory Data			2 of 4	
	Test Name	BILIRUBIN, TOTAL	Test Date	02-Jun-2022	
	Test Result	1.5	Test Unit		
	Low Test Range	.2	High Test Range	1.2	
	More Information Available?				
Rε	elevant Test/Laboratory Data			3 of 4	
	Test Name	BILIRUBIN DIRECT	Test Date	02-Jun-2022	
	Test Result	.6	Test Unit		
	Low Test Range	0	High Test Range	.6	
	More Information Available?				
Re	elevant Test/Laboratory Data			4 of 4	
	Test Name	AST	Test Date	02-Jun-2022	
	Test Result	66	Test Unit		
	Low Test Range	10	High Test Range	40	
	More Information Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
00	Suspect	Yes		1011	
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest Leek and Len	til Crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		

Generated by: SYSTEM Generated on: 05-Jul-2022 21:46:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52954 | Department: CFSAN | RCT No.: RCT-1028175 | CTU Triage Date: 06-Jul-2022 | Total Pages: 5

	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	09-May-2022			
	Date the person stopped taking or using the product	23-May-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-going?				
W	ny was the person using the pr	oduct? (such as what cor	ndition was it supposed to tr	reat) 1 of 1	
	Food				
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that makes the medical device				
Ot	her identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the	expiration date, if you can	
loc	cate them)				
	Mandal Niverbara				
	Model Number				
	Catalog Number Lot Number				_
	Serial Number				
	UDDI Number				
	Expiration date				

Generated by: SYSTEM Generated on: 05-Jul-2022 21:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52954 | Department: CFSAN | RCT No.: RCT-1028175 | CTU Triage Date: 06-Jul-2022 | Total Pag es: 5

Was someone operating the medical device when the problem oc urred?			
For implanted medical devices C	NLY (such as pacemake	rs, breast mplants, etc.)	
Date the implant was put in		Date the implant was taken out (If relevant)	
Section E - About the Person Wi	no Had the Problem		
Person's Initials	(b) (6)		
Sex	Female		
Gender	Cisgender woman/girl		
Please Specify Other Gender			
Age (specify unit of time for age)			
Date of Birth	(b) (6)		
Weight			
Ethnicity (Choose only one)	Not Hispanic/Latino		
Race (Check all that apply)	American Indian or Alaska Nat	tive	
	Native Hawaiian or Other Paci	fic Islander	
	Asian		
	White		
	Black or African American		
List known medical conditions (S	Such as diabetes, high blo	ood pre ure, cancer, heart disease	e, or others)
Low thyroid, mild asthma			
Please list all allergies (such as	to drugs, foods, pollen or	o hers)	
Seasonal grass allergy	· · · · · · · · · · · · · · · · · · ·		
List any other important informat	ion about the person (suc	ch as moking, pregnancy, alcohol	use, etc.)
List all current prescription medic	cations and medical devic	es b ng used.	
Levethyroid, asthma inhaler			
List all over-the-counter medicat	ions and any vitamins, mi	neral , supplements, and herbal r	emedies being used.

Generated by: SYSTEM Generated on: 05-Jul-2022 21:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52954 | Department: CFSAN | RCT No.: RCT-1028175 | CTU Triage Date: 06-Jul-2022 | Total Pages: 5

Claritin	

ection F - About the Person Fill	ing Out This Form 1 of 1	
Primary?	Yes	
Reporter is Patient?		
Title		_
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province	(b) (e)	
Country	UNITED STATES	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	05-Jul-2022	۰
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	_

Generated by: SYSTEM Generated on: 05-Jul-2022 21:46:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52773 | Department: IRPSAN | RCT No.: RCT 4027985 | DTU Trage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200 (200) 200 (200)	2000
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	05-Jul-2022	CTU Received Date	05-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	10	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	Unspecified
Age	28 Year(s)
Date of Birth	
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Weight	59.4 kg
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	Asian American Indian or Alaska Native Black or African American White Native Hawaiian or Other Pacific Islander

Type of Report (check all that apply)	□ Adverse Event □ Product Use/Medication Error □ Product Problem (e.g., defects/malfunctions) □ Problem with Different Manufacturer of Same Medicine	
Serious	Yes	
Outcome Attributed to Adverse Event (Check all that apply)	Death Life Threatening Hospitalization (initial or prolonged) Other Serious or Important Medical Events Disability or Permanent Damage	

Generated by: SYSTEM Generated on: 05-Jul-2022 13:46:29 Page 1 of 4

CTU No.: FDA-CDER-CTU-2022-52773 | Department: CFSAN | RCT No.: RCT-1027986 | CTU Triage Date: 05-Jul-2022 | Total Pages: 4

		Congenital Anomaly/Birth Defects						
		Required Intervention to Prevent Permanent Impairment/Damage						
	Date of Death							
	Date of Event	17-Jun-2022						
	Date of this Report	05-Jul-2022						
De	Describe Event, Problem or Product Use Error							
	Describe Event, Problem, or Product Use Error: This event has bin self reported to the FDA by the patient already. I am filing healthcare submitted report for purposes of communication/availability of medical professional to corroborate information and as an additional resource for ongoing investigation 28yo priviously healthy Fipresented to ER 6/9 with abdominal pain, elevated LFTs (3 digit range) and CT scan showing portal LAN, no bill dillor gallstones seen for office visit 6/13, LFT rising, symptoms improved readmitted 6/17 with fever and severe abdominal pain workup included MRI/MRCP, EUS with FNA of hilar LN, EUS guided liver biopsy, blood cultures, viral testing. Infinite ous workup (routine culture, HBV/HAV/EBV/CMV all negative). Biopsies w/nonspecific inflammation although+eosinophils ?allergic reaction pt had consumed Daily Harvest lentil and leek crumbles prior to 6/9 ER visit and again on 6/16 prior to hospi alization 6/17							
Re	levant Test/Laboratory Data			1 of 1				
	Test Name		Test Date					
	Test Result		Test Unit		\vdash			
	Low Test Range		High Test Range		\square			
			Trigit Test Natige					
	More Information Available?							
Ad	ditional Comments							
Ot	Other Relevant History, Including Preexisting Medical Condition							
C.	PRODUCT AVAILABILITY							
	Product Available for Evaluation? (Do not send product to FDA)	No						
	Returned to Manufacturer on							
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No						
D.	D. PRODUCT(S) 1 of 1							
	Suspect	Yes						
	Primary?	Yes						
	Туре	Drug/Biologi						
	This report involves:	Food/Medical food						
Na	Name,Strength,Manufacturer/Compounder (from product label)							
	Product Name Daily Harvest Lentil and Leek crumbles							
	Strength		If Other					

Generated by: SYSTEM Generated on: 05-Jul-2022 13:46:29 Page 2 of 4

CTU No.: FDA-CDER-CTU-2022-52773 | Department: CFSAN | RCT No.: RCT-1027986 | CTU Triage Date: 05-Jul-2022 | Total Pages: 4

	Manufacturer/Compounder				
	NDC# or Unique ID				
	Product Type(check all that apply)	OTC Compounded Generi Biosimilar			
	Event Abated After Use Stopped or Dose Reduced?	Yes			
	Event Reappeared after Reintroduction ?	Yes			
Dr	ug Therapy			1 of 1	
	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				
	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				
Dia	agnosis for Use (indication)			1 of 1	
E.	SUSPECT MEDICAL DEVICE				
E.	SUSPECT MEDICAL DEVICE Brand Name				
E.		.			
E.	Brand Name				
E.	Brand Name Common Device Name				
E.	Brand Name Common Device Name Procode				
E.	Brand Name Common Device Name Procode Manufacturer Name				
E.	Brand Name Common Device Name Procode Manufacturer Name City				
E.	Brand Name Common Device Name Procode Manufacturer Name City State				
E.	Brand Name Common Device Name Procode Manufacturer Name City State Model #				
E.	Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot #				
E.	Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog #				
E.	Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date				
E.	Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Serial #				
E.	Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Serial # Unique Identifier (UDI)#	Health Professional			
E.	Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Serial # Unique Identifier (UDI)#				

Generated by: SYSTEM Generated on: 05-Jul-2022 13:46:29 Page 3 of 4

CTU No.: FDA-CDER-CTU-2022-52773 | Department: CFSAN | RCT No.: RCT-1027986 | CTU Triage Date: 05-Jul-2022 | Total Pages: 4

	If Implanted, Give Date						
	If Explanted, Give Date				-		
	Is this a single-use device that was reprocessed and reused on a patient?				-		
	If Yes for the above field, Enter Name and Address of Reprocessor						
	Was this device serviced by a hird party?						
F	OTHER (CONCOMITANT) ME	EDICAL PRODUCTS					
_	CONCOMITANT MEDICAL PROD						
G	REPORTER				1 of	F 1	
Ο.	Primary?	Yes			1 01		
	Reporter is Patient?	103					_
	Title				_		
	Last Name	(b) (6)			_		
	Middle Name	(6) (6)					_
		(b) (C)			_		
	First Name	(b) (6)			_		
	Address	(b) (6)			_		
	City	(b) (6)					
	State/Province/Region				1		
	Country	UNITED STATES	If Other				_
	ZIP/Postal Code	(b) (6)					
	Phone	(b) (6)			_		
	Email	(b) (6)					
	Fax						
	Reporter Organization						
	Department				_		
	Reporter Speciality				_		
	Health Professional?	Yes			7		
	Oc upation	Physician	If Other				
	Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer					
	If you do NOT want your identity disclosed to the manufacturer	No					

Generated by: SYSTEM Generated on: 05-Jul-2022 13:46:29 Page 4 of 4

CTU No.: FDA-CDER-CTU-2022-52788 | Department: GPSAN | RCT No. RCT-1028002 | DTU Trage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	05-Jul-2022	CTU Received Date	05-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

Contact					
Case Reporter	First Name	Last Name	Email Address	Phone	
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)	

What kind of problem was it?		
(Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms)	
(Check all triat apply)	Used a product incorrectly which could have or led to a problem	
	Noticed a problem with the quality of the product	
	Had problems after switching from one product maker to another maker	
Date the problem occurred	24-Jun-2022	
Serious	Yes	
Did any of the following happen?	Hospitalization - admitted or stayed longer	
(Check all that apply)	Required help to prevent permanent harm	
	170	
	Disability or health problem	
1	Birth defect	
	Life-threatening	
	Death	
	Other serious/important medical incident(Please Describe Below)	

4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

1) 6/15; ate Daily Harvest Crumbles with lentils 2) 6/24; started nausea, unexplained itching, dark Urine 3) 6/30; issues had not resolved, spoke with physician. 4) 7/1: blood work done; clear, obvious, liver distress. All Liver blood work comes back elevated indicating an issue 5) 7/5; physician advising not to exercise, drink plenty of fluids, monitor symptoms

elavant Test/Laboratory	Data		1 of A
Test Name	BILIRUBIN	Test Date	01-Jul-2022
Test Result	1.6	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	0	High Test Range	1.2

Generated by: SYSTEM Generated on: 05-Jul-2022 14:16:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52788 | Department: CFSAN | RCT No.: RCT-1028002 | CTU Triage Date: 05-Jul-2022 | Total Pag

More Information Availablek			
Relevant Test/Laboratory Data			2 of H
Test Name	ALKALINE Pq OSPq ATE	Test Date	07-Jul-2022
Test Result	74Q	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	Н	q gh Test Range	727
More Information Availablek			
Relevant Test/Laboratory Data			3 of H
Test Name	AST SGOT	Test Date	07-Jul-2022
Test Result	17	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	q gh Test Range	НО
More Information Availablek			
Relevant Test/Laboratory Data			Hof H
Test Name	ALT SGPT	Test Date	07-Jul-2022
Test Result	207	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	0	q gh Test Range	32
More Information Availablek			
Additional Comments			,
Section B - Product Availability			
Do you still have the product in case we need to evaluate itk	No		
Do you have a picture of the productk (chec6 yes if you are ncluding a picture)	No		
Section C - About the Products			7 of 7
Suspect	Yes		
Primaryk	Yes		
Туре	Drug/Biologi		
This report is about	Food/Medical food		
Name of the product as it appears on the boxxbottlex or pac6age (Include as many names as you see)	Daily harvest crumbles Lent	il	
Name of the company that ma6 (or compounds) the roduct	Daily q arvest		
Product Type(chec6 all that apply)	Over-the-Counter		

Generated by: SYSTEM Generated on: 05-Jul-2022 7H71:25 Page 2 of 5

Receipt No: RCT-702Q002 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-52788 | Department: CFSAN | RCT No.: RCT-1028002 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 5

					1
		Compounded by a Pharmac	y or an Outsourcing Facility		
		Generi			
		Biosimilar			
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped ta6 ng or using the roductk	No			
	Did the problem return if the rson started ta6 ng or using the roduct againk	Doesn't Apply			
Dr	ug Therapy			7 of 7	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Fre?uency		If Other		
	q ow was it ta6 n or used		If Other		
	Date the person first started a6 ng or using the product	75-Jun-2022		,	
	Date the person stopped ta6 ng or using the product	75-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	Is therapy still on-goingk				
\ A.4	hy was the nerson using the nr	oductk (such as what c	ondition was it supposed	to treat) 7 of 7	
۷۷۱	ity was the person using the pr	oudoux (oud); do illiat o			
۱۷۷	Food				
VVI					
VVI					
VVI	Food				
	Food Returned to Manufacturer On				
	Returned to Manufacturer On ection D - About the Medical De				
	Returned to Manufacturer On ection D - About the Medical De				
Se	Returned to Manufacturer On ection D - About the Medical De Name of medical device Name of the company that ma6 the medical device	evice			
Se	Returned to Manufacturer On ection D - About the Medical De Name of medical device Name of the company that ma6 the medical device	evice		the expiration datexif you can	
Se	Returned to Manufacturer On ection D - About the Medical De Name of medical device Name of the company that ma6 the medical device her identifying information (The	evice		the expiration datexif you can	
Se	Returned to Manufacturer On ection D - About the Medical De Name of medical device Name of the company that ma6 the medical device her identifying information (The	evice		the expiration datexif you can	
Se	Returned to Manufacturer On ection D - About the Medical De Name of medical device Name of the company that ma6 the medical device her identifying information (The	evice		the expiration datexif you can	
Se	Returned to Manufacturer On ection D - About the Medical De Name of medical device Name of the company that ma6 the medical device her identifying information (The	evice		the expiration datexif you can	
Se	Returned to Manufacturer On ection D - About the Medical De Name of medical device Name of the company that ma6 the medical device her identifying information (The	evice		the expiration datexif you can	
Se	Returned to Manufacturer On ection D - About the Medical De Name of medical device Name of the company that ma6 the medical device her identifying information (The cate them) Model Number	evice		the expiration datexif you can	

Generated by: SYSTEM Generated on: 05-Jul-2022 7H71:25 Page 3 of 5

Receipt No: RCT-702Q002 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-52788 | Department: CFSAN | RCT No.: RCT-1028002 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem oc urredk				
Fo	r implanted medical devices O	NLY (such as pacema6er	rsxbreast implantsxetc.)		
Di	ate the implant was put in		Date the implant was ta6 n out (If relevant)		
Se	ction E - About the Person Wh	o q ad the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender				
	Age (specify unit of time for age)				
	Date of Birth	(b) (6)			
	Weight	55.Q6g			
	Ethnicity (Choose only one)	Not q anic/Latino			
	Race (Chec6 all that apply)	American Indian or Alas6a Nati Native q awaiian or Other Pacif Asian White			
		☐ Blac6 or African American			
II ic	t frown modical conditions (S		od proceurovcapeoryheart diseas	cover ethers	
Lis	<u> </u>		od pressurexcancerxheart diseas	sexor others)	
Lis	t 6nown medical conditions (S An6losing spondylitis		od pressurexcancerxheart diseas	sexor others)	
Lis	<u> </u>		od pressurexcancerxheart diseas	sexor others)	
Lis	<u> </u>		od pressurexcancerxheart diseas	sexor others)	
	An6losing spondylitis	uch as diabetesxhigh blo		sexor others)	
	<u> </u>	uch as diabetesxhigh blo		sexor others)	
	An6losing spondylitis	uch as diabetesxhigh blo		sexor others)	
	An6losing spondylitis	uch as diabetesxhigh blo		sexor others)	
	An6losing spondylitis	uch as diabetesxhigh blo		sexor others)	
Ple	An6losing spondylitis ease list all allergies (such as t	uch as diabetesxhigh blo			
Ple	An6losing spondylitis ease list all allergies (such as t	uch as diabetesxhigh blo	hers)		
Ple	An6losing spondylitis ease list all allergies (such as to	uch as diabetesxhigh blo	hers)		
Ple	An6losing spondylitis ease list all allergies (such as to	uch as diabetesxhigh blo	hers)		
Ple	An6losing spondylitis ease list all allergies (such as to	uch as diabetesxhigh blo	hers)		
Ple	An6losing spondylitis ease list all allergies (such as to	uch as diabetesxhigh bloom of our of the person (suc	hers) h as mo6 ingxpregnancyxalcoho		
Ple	An6losing spondylitis ease list all allergies (such as too	uch as diabetesxhigh bloom of our of the person (suc	hers) h as mo6 ingxpregnancyxalcoho		
Ple	An6losing spondylitis ease list all allergies (such as to any other important information of Breastfeeding, month old baby at all current prescription medical	uch as diabetesxhigh bloom of our of the person (suc	hers) h as mo6 ingxpregnancyxalcoho		
Ple	An6losing spondylitis ease list all allergies (such as to any other important information of Breastfeeding, month old baby at all current prescription medical	uch as diabetesxhigh bloom of our of the person (suc	hers) h as mo6 ingxpregnancyxalcoho		

List all over-the-counter medications and any vitaminsxmineralsxsupplementsxand herbal remedies being used.

Generated by: SYSTEM Generated on: 05-Jul-2022 7H71:25 Page Hof 5

Receipt No: RCT-702Q002 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-52788 | Department: CFSAN | RCT No.: RCT-1028002 | CTU Triage Date: 05-Jul-2022 | Total Pages: 5

ection F - About the Person Fill	ing Out This Form 7 of 7	
Primaryk	Yes	
Reporter is Patientk		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	-
State/Province	(b)(6	
Country	UNITED STATES	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		-
Department		-
Reporter Speciality		
Today's date	05-Jul-2022	-
Did you report this problem to the company that ma6 the product (the manufacturer/compounder)k	Yes	
If you do NOT want your dentity disclosed to the manufacturerxplease mar6 this box (Confidentiality Re?uested):	No	

Generated by: SYSTEM Generated on: 05-Jul-2022 7H71:25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-52777 | Department: CFSAN | RCT No. RCT-1027989 | CTU Trage Date: 05-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Det	ails		A # 10 TH A 10 A	20.00		
Company	Unit	CDER-CTU	Originating Account	FAERS		
Source Me	edium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority		Routine	F			
Override A	uto Calculation Rule	No				
FDA Rece	ived Date	05-Jul-2022	CTU Received Date	05-Jul-2022		
CTU Triag	e Date		CTU Data Entry Date			
Report Typ	DB .	Spontaneous	Report Classification	Drug		
Assign To		User				
User/Group						
Forward to Department						
Case Priority		Direct				
Contact	WATER TO	1000 0000		1000		
Case	First Name	Last Name	Email Address	Phone		
Reporter						

ection A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	02-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Hello? on 6/2/22 I went to urgent care because of pain in the center of my chest under the sternum, and the pain radiated across my upper front chest between to my shoulders. I also had a slight fever. After checking me out for possible cardiac issues, urgent care sent me home with a recommendation to go to ER for further tests. I went to ER where they checked me for a variety of things and ran blood tests. The final thing they did was an abdomen ultrasound to rule out a gall bladder attack of some kind. I remember them saying something about elevated liver numbers. They then diagnosed me with gastritis and sent me home to follow a low acid diet for a month. The hospital has the result of my tests. Please let me know if someone wants me to have the hospital share the medical findings. Michelle

Relevant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	
Low Test Range	High Test Range	

Generated by: SYSTEM Generated on: 05-Jul-2022 13:46:38 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52777 | Department: CFSAN | RCT No.: RCT-1027989 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

FDA 3500B Form

	More ന്യാrmation Availa. le6				
Ad	ditional Comments				
Se	ection B - Product Availa. lity				
	Do you still have the product in case / need to evaluate it6	be			
	Do you have a picture oJthe product6 (chec6 yes iJyou are ncluding a picture)	be			
Se	ection C - A. out the Products			l oJl	
	Suspect	be			
	Primary6	be			
	Туре	DrugfBiologi			
	This report is a. out	FoodfMedical Jood			
	Name oJthe product as it appears on the . oVq. ottleq or pac6age (?clude as many names as you see)	Crum. les			
	Name oJthe company that ma6 (or compounds) the roduct	Daily 1 arvest			
	Product Type(chec6 all that apply)	Over-the-Counter Compounded . y a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		ર્ીOther		
	NDC num. r				
	Did the pro. lem stop aJ r the rson reduced the dose or opped ta6 ng or using the roduct6				
	Did the pro. lem return iJthe rson started ta6 ng or using the roduct again6	Doesn k Apply			
Dr	ug Therapy			ا ا ا	
	EV ration date	2, -Sep-2022			
	Lot num. r	L5-A I 3:0H			
	Dosage Form				
	Zuantity		યુOther		
	Fre7uency		યુOther		
	1 o/ / as it ta6 n or used	Oral	યother		
	Date the person Jrst started a6 ng or using the product	20-May-2022			
	Date the person stopped ta6 ng	02-4un-2022			

Generated . y: SbSTEM G nerated on: 05-4ul-2022 I 3:kY:39 Page 2 oJ5

Receipt No: RCT-I 02, H9H FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-52777 | Department: CFSAN | RCT No.: RCT-1027989 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

	Date the person reduced dose oJ he product				
_	Give . est estimate oJduration		·-		
	? therapy still on-going6				_
W		roduct6 (such as / hat co	ndition / as it supposed to treat)	l oJl	
	x egetarian bod	(_
	Returned to Manu acturer On				
Se	ection D - A. out the Medical De	evice			
	Name oJmedical device				
	Name oJthe company that				
	ma6 the medical device				
Ot	her identiJying inJormation (The cate them)	e modelqcatalogqlotqseria	alqor UD?num. erqand the eVpira	tion dateqiJyou can	
100					
	Model Num. r				_
	Catalog Num. r				
	Lot Num. r		-		
	Serial Num. r		·		_
	UDD?Num. r				
	EV ration date				
_					_
	Was someone operating the medical device / hen the pro. lem				
	oc urred6				
Fc	r implanted medical devices O	NLb (such as pacema6e	rsq. reast implantsqetc.)		
D	ate the implant / as put in		Date the implant / as ta6en out (থ		
			relevant)		
Se	ection E - A. out the Person Wh	no 1 ad the Pro. lem			
	Personk ?nitials	(b) (6)			
	SeV	Female			
	Gender	Not selected			
	Please SpeciJy Other Gender		_		
	Age (speciJy unit oJtime Jbr age)				
	Date oJBirth	(b) (6)			
	Weight				
	Ethnicity (Choose only one)				
	Race (Chec6 all that apply)	☐ American ઋdian or Alas6a Nat	tive		
		Native 1 a/ aiian or Other Paci.			
		Asian			

Generated . y: SbSTEM G nerated on: 05-4ul-2022 I 3:kY:39 Page 3 oJ5

Receipt No: RCT-I 02, H9H FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-52777 | Department: CFSAN | RCT No.: RCT-1027989 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

		White Blac6 or A-lican American					
Li	st 6no/ n medical conditions (S	Such as dia. etesghigh . lo	od pressuregcancergheart	diseasegor others)			
PΙ	lease list all allergies (such as to drugsqbodsqpollen or others)						
Lis	st any other important in໓rmat	ion a. out the person (suc	ch as mo6 ingqpregnancyq	alcohol useqetc.)			
Li	st all current prescription medic	cations and medical device	es . ng used.				
Li	st all over-the-counter medicat	ions and any vitaminsqmi	neralsqsupplementsqand h	er. al remedies . ng used.			
0	· · · · · · · · · · · · · · · · · · ·						
56	ection F - A. out the Person Fill Primary6	be		ا ا ا			
	Reporter is Patient6	be		_			
	Title						
	Last name	(b) (6)		_			
	Middle Name			_			
	First name	(b) (6)		_			
	Num. rfStreet	(b) (6) q					
	City	(b) (6)					
	StatefProvince	(b) (6)					
	Country	UN?TED STATES	-				
	' 'P' or Postal code	(b) (6)					
	Telephone num. r	(b) (6)					
	Email address	(b) (6)					

Generated . y: SbSTEM G nerated on: 05-4ul-2022 I 3:kY:39 Page k oJ5

Receipt No: RCT-I 02, H9H FDA 3500B Form

CTU No.: FDA-CDER-CTU-2022-52777 | Department: CFSAN | RCT No.: RCT-1027989 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

FaV		
Reporter Organization		
Department		
Reporter Speciality		
Todayks date	05-4ul-2022	
Did you report this pro. lem to the company that ma6 the product (the manuacturerfcompounder)6	be	
②you do NOT / ant your dentity disclosed to the manuJacturerqplease mar6 this . oV(ConJdentiality Re7uested):	No	

Generated . y: SbSTEM G nerated on: 05-4ul-2022 I 3:kY:39 Page 5 oJ5

CTU No.: FDA-CDER-CTU-2022-52827 | Department: CFSAN | RCT No.: RCT-1028142 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

All dates displayed in the report are in EST(GMT-05:00) time zone

Ва	sic Deta	ils		,			
	ompany U		CDE	ER-CTU	Origi	nating Ac ount	FAERS
Sc	ource Med	lium	MW	O (Drug)	Sour	ce Form Type	E2B XML 3500B
Pr	iority		Rou	tine			
Override Auto Calculation Rule		No					
FDA Received Date		05-6	Gul-2022	CTU	Received Date	05-6ul-2022	
CTU Triage Date				CTU	Data Entry Date		
Report Type		Spo	ntaneous	Repo	rt ClassiJ ation	Drug	
Assign To		Use	r				
Us	serfGroup						
Fo	or/ ard to I	Department	\overline{Z}				
Ca	ase Priorit	у	Dire	ect			
Со	ntact						
	ase eporter	First Name		Last Name		Email Address	Phone
V	1	(b) (6)		(b) (6)		(b) (6)	(b) (6)
Se	ction A -	Akout the Proklem					
	Date the Serious Did any (Chec? a	od oJproklem / as itq all that apply) proklem occurred oJthe Jollo/ ng happenq all that apply)		Jsed a product incorrectly / hid Noticed a proklem / ith the Hua / ad proklems aJ r s / itching J Sun-2022 / ospitalization - admitted or sta ReHuired help to prevent perma Disakility or health proklem Birth deJ .i.J-threatening Death	ch could ality oJth rom one ayed lon anent ha	ger	
I .T an	y additio	nal documents iJnece	ssar	y)		/ details as possikle FDA m	
	xordered a bod product Jom Daily Yarvest called French Lentil, Lee? crumkles on 9f5f22 / hich / as delivered to me on 9f8f22. AJer consuming the product' / hich x repared as direct ed on the pac?aging' xk gan e+ riencing gastrointestinal proklems including nausea' vomiting' diarrhea' and stomach cramping. xalso e+ rienced J ever and Latigue.						
Re	levant T	estfLakoratory Data					b oJb
	Test Nar	me			Test	Date	
	Test Res	sult			Test	Unit	
	Lo/ Tes	t Range			Y gh	Test Range	
	More xn.J	brmation Availakleq					

Generated ky: S4STEM G nerated on: 05-6ul-2022 b8:I 9:5b Page b oJ5

CTU No.: FDA-CDER-CTU-2022-52827 | Department: CFSAN | RCT No.: RCT-1028142 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

Ac	dditional Comments					
Se	ection B - Product Availak lity				<u> </u>	
	Do you still have the product in case / need to evaluate itq	4e				
	Do you have a picture oJthe productq (chec? yes iJyou are ncluding a picture)	4e				
Se	ection C - Akout the Products			b o.	lb	
	Suspect	4e				
	Primaryq	4e				
	Туре	DrugfBiologi				
	This report is akout	FoodfMedical Jood				
	Name oJthe product as it appears on the ko+' kottle' or pac?age (xnclude as many names as you see)	French Lentil, Lee? Crumkles				
	Name oJthe company that ma? (or compounds) the roduct	Daily Yarvest				
	Product Type(chec? all that apply)	Over-the-Counter Compounded ky a Pharmacy of Generi Biosimilar	Compounded ky a Pharmacy or an Outsourcing Facility Generi			
	Strength		xJOther			
	NDC numk r					
	Did the proklem stop aJ r the rson reduced the dose or opped ta? ng or using the roductq	No				
	Did the proklem return iJthe rson started ta? ng or using the roduct againq	Doesn@Apply				
Dr	ug Therapy			b o.	lb	
	E+ ration date	09-Nov-2022				
	Lot numk r					
	Dosage Form		T			
	7 uantity	Other	xJOther	b Bag		
	FreHuency		xJOther			
	Yo/ / as it ta? n or used		xJOther			
	Date the person Jrst started a? ng or using the product	bb-6un-2022				
	Date the person stopped ta? ng or using the product	bb-6un-2022				
	Date the person reduced dose of he product					

Generated ky: S4STEM G nerated on: 05-6ul-2022 b8:I 9:5b Page 2 oJ5

CTU No.: FDA-CDER-CTU-2022-52827 | Department: CFSAN | RCT No.: RCT-1028142 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 7

	Give kest estimate oJduration		
	x therapy still on-goingq	4e	
WI	ny / as the person using the pr	oductq (such as / hat condition / as it supposed to treat) b oJb	
	Nutrition		
	Returned to Manuacturer On		
Se	ction D - Akout the Medical De	evice	
	Name oJmedical device		
	Name oJthe company that ma? the medical device		
	her identiJying inJormation (The ate them)	e model' catalog' lot' serial' or UDxnumker' and the e+piration date' iJyou can	
	Model Numk r		
	Catalog Numk r		
	Lot Numk r		
	Serial Numk r		
	UDDxNumk r		
	E+ ration date		
	Was someone operating the medical device / hen the proklem oc urredq		
Fo	r implanted medical devices O	NL4 (such as pacema?ers' kreast implants' etc.)	
	ate the implant / as put in	Date the implant / as ta?en out (xl relevant)	
Se	ction E - Akout the Person Wh	o Yad the Proklem	
	Person@ xnitials	(b) (6)	
	Se+	Female	
	Gender	Cisgender / omanfgirl	
	Please SpeciJy Other Gender		
	Age (speciJy unit oJtime Jbr age)	38 4 ar(s)	
	Date oJBirth		
	Weight	51.9 ?g	
	Ethnicity (Choose only one)		
	Race (Chec? all that apply)	American xndian or Alas?a Native Native Ya/ aiian or Other PaciJ x lander Asian White Blac? or A.tican American	

Generated ky: S4STEM G nerated on: 05-6ul-2022 b8:I 9:5b Page 3 oJ5

CTU No.: FDA-CDER-CTU-2022-52827 | Department: CFSAN | RCT No.: RCT-1028142 | CTU Triage Date: 05-Jul-2022 | Total Pag es: 7

Lis	st ?no/ n medical conditions (S	Such as diaketes' high klood pressure' cancer' heart disease' or others)				
IPI	ease list all allergies (such as t	to drugs' bods' ollen or o hers)				
	No allergies					
	· ·					
Lis	st any other important in brmati	ion akout the person (such as mo? ing' pregnancy' alcohol use' etc.)				
	<u> </u>					
Lis	st all current prescription medic	cations and medical devices k ng used.				
	ist all over-the-counter medications and any vitamins' mineral ' supplements' and herkal remedies k ng used.					
Lis	st all over-the-counter medicati	ions and any vitamins' mineral 'supplements' and herkal remedies k ng us	ed.			
Lis	t all over-the-counter medicati	ions and any vitamins' mineral 'supplements' and herkal remedies k ng us	ed.			
Lis	t all over-the-counter medicati	ions and any vitamins' mineral 'supplements' and herkal remedies k ng us	ed.			
Lis	t all over-the-counter medicati	ions and any vitamins' mineral 'supplements' and herkal remedies k ng us	ed.			
Lis	t all over-the-counter medicati	ions and any vitamins' mineral 'supplements' and herkal remedies k ng us	ed.			
	ection F - Akout the Person Fill	ling Out This Form b o				
	ection F - Akout the Person Fill Primaryq					
	ection F - Akout the Person Fill	ling Out This Form b o				
	ection F - Akout the Person Fill Primaryq Reporter is Patientq	ling Out This Form b o				
	ection F - Akout the Person Fill Primaryq Reporter is Patientq Title	ling Out This Form b o				
	ection F - Akout the Person Filli Primaryq Reporter is Patientq Title Last name	ling Out This Form b o				
	Poction F - Akout the Person Fill Primaryq Reporter is Patientq Title Last name Middle Name	ling Out This Form boo. 4e (b) (6)				
	Primaryq Reporter is Patientq Title Last name Middle Name First name	ling Out This Form b o. 4e (b) (6)				
	Primaryq Reporter is Patientq Title Last name Middle Name First name Numk rfStreet	b o. 4e (b) (6) (b) (6)				
	Primaryq Reporter is Patientq Title Last name Middle Name First name Numk rfStreet City	b o. 4e (b) (6) (b) (6) (b) (6) (b) (6)				
	Primaryq Reporter is Patientq Title Last name Middle Name First name Numk rfStreet City StatefProvince	b o. 4e (b) (6) (b) (6) (b) (6) (b) (6)				
	Primaryq Reporter is Patientq Title Last name Middle Name First name Numk rfStreet City StatefProvince Country	(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)				

Generated ky: S4STEM G nerated on: 05-6ul-2022 b8:I 9:5b Page I oJ5

Fa+

Reporter Organization

CTU No.: FDA-CDER-CTU-2022-52827 | Department: CFSAN | RCT No.: RCT-1028142 | CTU Triage Date: 05-Jul-2022 | Total Pages: 7

Department		
Reporter Speciality		
Today@ date	05-6ul-2022	
Did you report this procompany that ma? to the manu acturer fco	the product	
xJyou do NOT / ant y dentity disclosed to manu.acturer' please ko+ (ConJdentiality F	the e mar? this	

Generated ky: S4STEM G nerated on: 05-6ul-2022 b8:I 9:5b Page 5 oJ5

BUTTERNUT SQUASH HEMP SEED SEED WASH CREMINI CREMINI CREATIVE TARA

ong Crumbles:

partial lightly oiled skillet or non-stick pan over medium-high heat the desired amount of frozen Crumbles to the pan, breaking up

large claus seaking up seaking up to large frequently, sauté until nicely browned and thoroughly cooked to the same temperature of 165°F, about 5-6 minutes. sirring frequency, but the state of 165°F, about 5-6 minutes.

To an investigation of the stand for 1-2 minutes. Enjoy on their own or add to your favorite dish.

PERSHABLE STORE FROZEN. Do not thaw or refreeze. Cook thoroughly PERISHABLE 3 TO COOK thorough the state of 165°F. Fill level and cook time may vary.

Nation Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total from Facts 3 Serving per container, Serving per serving: Calories 290, Total from Facts 3 Serving per container, Serving per Hittin Facts 3 Serving per container, On Cholesterol Omg (0% DV), Sodium 430mg (19% DV), To Saturated Fat 2g (10% DV), Trans Fat Og, Cholesterol Omg (0% DV), Sodium 430mg (19% DV), To Saturated Fat 2g (10% DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 3g (Includes 0g Added Sugars 03 DV), Total Sugars 04 DV), Total Sugars 04 DV, Tota Saturated Fat 2g (10% DV), Trail Sugars 3g (Includes 0g Added Sugars, 0% DV), Total Sugars 3g (Includes 0g Added Sugars, 0% DV), Protein 19g (7% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added Sugars, 0% DV), Protein 19g (7% DV), Dietary Fiber 5g (18% DV), Iron 4mg (20% DV), Potential Sugars, 0% DV), Protein 19g (7% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potential Sugars, 0% DV), Protein 19g (7% DV), Protein 19g With 19g (7% DV), Dietary 11Der og tion 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% DV). The With 19g (7% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% DV). The MADN Vitamin D Umcg 10% DVI, Galcius a serving of food contributes to a daily diet 2,000 calories a day is use

Ingritita organic butternut squash, organic hemp seeds, organic cauliflower rice, organic extra virginded). organisach lentils, organic red lentils, organic tri-colored quinoa, organic cremini mushrooms, organicas lour organic parsley, water, organic cassava root flour, organic flax seeds, organic sacha inchi powercha seaturgatio porcini powder, himalayan sea salt, organic apple cider vinegar, organic onion powder, nutritiva east organic galic powder, organic tomato powder, organic white pepper, organic coriander seeds, organic notation powder organic thyme.

MADENIA FACILITY THAT ALSO PROCESSES TREE NUTS, SOY, DAIRY, & SESAME.

DISTR BY DAILY HARVEST INC. NEW YORK, NY 10013

CTU No.: FDA-CDER-CTU-2022-52999 | Department: CFSAN | RCT No.: RCT-1028221 | CTU Triage Date: 06-Jul-2022 | Total Pages: 6

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Ac ount	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		,
Override Auto Calculation Rule	No		
FDA Received Date	06-Jul-2022	CTU Received Date	06-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	•	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Se	Section A - About the Problem				
	What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker			
	Date the problem oc urred	17-Jun-2022			
	Serious	Yes			
	Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)			
	Other serious/important medical				
	ncident(Please Describe Below)				

4.Tell us what happened and how it happened (Include as many de ails as possible FDA may reach out to you for any additional documents if necessary)

I understand that the FDA is aware of Daily Harvest's recall of Lentil "crumbles", however I want to make sure that you are all of aware of them misleading their customers. I received the following email AFTER they were aware of people coming down with liness, in my opinion hiding the real reasons for the item being out of stock and lying to customers to retain their business. ——Due to high demand we are *temporarily* stocked out of our French Lentil + Leek Crumbles. We wanted to let you know since you have one or more in your box for next week. Next week's box will still arrive — it'll just be a little lighter. You won't be charged if you were scheduled to receive French Lentil + Leek Crumbles in your upcoming box. If you'd like a replacement, we recommend our Red Lentil + Cumin Harvest Bowl. You can make adjustments to your order here anytime before Sunday 6/19 at 6pm EST. We'll be sure to let you know when it comes back. We really appreciate your patience, and if you have any questions, just reply to this email or visit our Help Page for other contact options. Taylor Customer Care Team Daily Harvest

Relevant Test/Labo	ratory Data		1 of 1
Test Name		Test Date	

Generated by: SYSTEM Generated on: 06-Jul-2022 09:16:32 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-52999 | Department: CFSAN | RCT No.: RCT-1028221 | CTU Triage Date: 06-Jul-2022 | Total Pages: 6

	Test Result		Test Unit		
	Low Test Range		High Test Range		
	More Information Available?			,	
Ad	ditional Comments				
Se	ction B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the	Yes			
	roduct? (check yes if you are ncluding a picture)				
Se	ction C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes	-		
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil + Leek Crumb	oles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?				
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		

Generated by: SYSTEM Generated on: 06-Jul-2022 09:16:32 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-52999 | Department: CFSAN | RCT No.: RCT-1028221 | CTU Triage Date: 06-Jul-2022 | Total Pages: 6

	Date the person first started aking or using the product			
	Date the person stopped taking or using the product			
	Date the person reduced dose of he product			
	Give best estimate of duration			
	Is therapy still on-going?			
Wł	ny was the person using the pr	roduct? (such as what cor	ndition was it supposed to treat) 1 of 1	
	Returned to Manufacturer On			
Se	ction D - About the Medical De	evice		
	Name of medical device			П
	Name of the company that makes the medical device			
Otl	ner identifying information (The	e model, catalog, lot, seria	al, or UDI number, and the expiration date, if you can	
IOC	ate them)			
	Madal Niverbar			
	Model Number			-
	Catalog Number			+-
	Lot Number			-
	Serial Number			+
	UDDI Number			-
	Expiration date			-
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices C	NLY (such as pacemake	rs, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	no Had the Problem		
	Person's Initials	Unspecified		Т
	Sex	Decline to answer		
	Gender	Decline to answer		+
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth			
	Weight			+
	Ethnicity (Choose only one)			+

Generated by: SYSTEM Generated on: 06-Jul-2022 09:16:32 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-52999 | Department: CFSAN | RCT No.: RCT-1028221 | CTU Triage Date: 06-Jul-2022 | Total Pages: 6

	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
Lis	st known medical conditions (S	uch as diabetes, high blood pre ure, cancer, heart disease, or others)	
	none		
Ple	ease list all allergies (such as t	o drugs, foods, pollen or o hers)	
	none		
l ic	et any other important informat	ion about the person (such as moking, pregnancy, alcohol use, etc.)	
	n/a	on about the person (such as moking, pregnancy, aconordise, etc.)	T
	II/a		
LIS		cations and medical devices b ng used.	<u> </u>
	none		
Lis	st all over-the-counter medicati	ons and any vitamins, mineral, supplements, and herbal remedies being used.	<u> </u>
	none		
20	ection F - About the Person Fill	ing Out This Form 1 of 1	
00	Primary?	Yes	T
	Reporter is Patient?		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Number/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (b) (c)	
	Country	UNITED STATES	
	ZIP or Postal code	(b) (6)	
	ZII UI FUSIAI UUUE		

Generated by: SYSTEM Generated on: 06-Jul-2022 09:16:32 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-52999 | Department: CFSAN | RCT No.: RCT-1028221 | CTU Triage Date: 06-Jul-2022 | Total Pages: 6

Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	06-Jul-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 06-Jul-2022 09:16:32 Page 5 of 5

to me

HARVEST DAILY

(9) (q)

Due to high demand we are *temporarily* stocked out of our French Lentil + Leek Crumbles. We wanted to let you know since you have one or more in your box for next week.

Lentil + Cumin Harvest Bowl. You can make adjustments to your order here charged if you were scheduled to receive French Lentil + Leek Crumbles in Next week's box will still arrive — it'll just be a little lighter. You won't be your upcoming box. If you'd like a replacement, we recommend our Red anytime before Sunday 6/19 at 6pm EST.

We'll be sure to let you know when it comes back.

We really appreciate your patience, and if you have any questions, just reply to this email or visit our Help Page for other contact options.

Customer Care Team Daily Harvest Taylor

CTU No.: FDA-CDER-CTU-2022-53143 | Department | IPSAN | RCT No. | RCT-1028361 | ICTU Trage Date: 06-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	A	200000000000000000000000000000000000000	-1-2
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	06-Jul-2022	CTU Received Date	06-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department			
Case Priority	Direct		

ontact		T.			
ase eporter	First Name	Last Name	Email Address	Phone	
a e	(b) (6)	(b) (6)	(b) (6)	(b) (6)	
ction A	- About the Problem				
(Check	all that apply)	Used a product incorrectly w Noticed a problem with the q Had problems after switching	effect (including new or worsening symptor hich could have or led to a problem uality of the product g from one product maker to another maker		
1.00	C. 13(1)(0) (311)(1)	28-Jan-2022			
Serious		Yes			
	all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important med	Walter St.		
	erious/important medical (Please Describe Below)				
	hat happened and how onal documents if necess		as many details as possible FI	DA may reach out to you fo	
complai the dry	nt with company (through th	ere app) and received a r ent issues/delay and the	a, fever, body aches, dizzy) toward efund of the order. My hypothesis product thawed without our knowle	was (at the time) that maybe	

levant Test/Laboratory Data		1 of 1
Test Name	Test Date	
Test Result	Test Unit	

Generated by: SYSTEM Generated on: 06-Jul-2022 12:16:47 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-53143 | Department: CFSAN | RCT No.: RCT-1028361 | CTU Triage Date: 06-Jul-2022 | Total Pages: 8

	Low Test Range		I gh Test Range		
	More Information Availa?leq				
Ad	Iditional Comments				
Se	ection B - Product Availa?ility				
	Do you still have the product in case we need to evaluate itq	,е			
	Do you have a picture of the productq (checHyes if you are ncluding a picture)	,e			
Se	ection C - A?out the Products			k of k	
	Suspect	,e			
	Primaryq	,е			
	Туре	Drug/Biologi			
	This report is a?out	Food/Medical food			
	Name of the product as it appears on the ?ox' ?ottle' or pacHage (Thclude as many names as you see)	Daily I arvest (food order sh	nipment)		
	Name of the company that maH (or compounds) the roduct Product Type(checHall that apply)	Over-the-Counter Compounded ?y a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		7 Other		
	NDC num?er				
	Did the pro?lem stop after the rson reduced the dose or stopped taHng or using the roductq				
	Did the pro?lem return if the person started taHng or using the roduct againq				
Dr	ug Therapy			k of k	
	Expiration date				
	Lot num?er				
	Dosage Form				
	Quantity		7f Other		
	FreYuency		7f Other		
	I ow was it taHn or used		7f Other		
	Date the person first started taHng or using the product				

Generated ?y: S, STEM Generated on: 08-Jul-2022 k2:k8:16 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-53143 | Department: CFSAN | RCT No.: RCT-1028361 | CTU Triage Date: 06-Jul-2022 | Total Pages: 8

	Date the person stopped taHng or using the product				
	Date the person reduced dose of he product				
	Give ?est estimate of duration				
	7 therapy still on-goingq				
WI	hy was the person using the pr	roductq (such as what co	ndition was it supposed to trea	t) k of k	
	Returned to Manufacturer On				
Se	ection D - A?out the Medical De	evice			
	Name of medical device				
	Name of the company that maH the medical device				
	her identifying information (The	e model' catalog' lot' seri	al' or UD7num?er' and the exp	oiration date' if you can	
IOC	cate them)				
	Model Num?er				
	Catalog Num?er				
	Lot Num?er				
	Serial Num?er				
	UDD7Num?er				
	Expiration date				
	Was someone operating the medical device when the pro?lem oc urredq				
Fo	r implanted medical devices C	NL, (such as pacemaHe	rs' ?reast implants' etc.)		
Da	ate the implant was put in		Date the implant was taHen out (7 relevant)	f	
Se	ection E - A?out the Person Wh				
	Person 3 7 itials	(b) (6)			
	Sex				
] !	Sex	Female			
Ш	Gender	Female Cisgender woman/girl			
	Gender				
	Gender Please Specify Other Gender	Cisgender woman/girl			
	Gender Please Specify Other Gender Age (specify unit of time for age)	Cisgender woman/girl			
	Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth	Cisgender woman/girl 11 Month(s)			

Generated ?y: S, STEM Generated on: 08-Jul-2022 k2:k8:16 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-53143 | Department: CFSAN | RCT No.: RCT-1028361 | CTU Triage Date: 06-Jul-2022 | Total Pages: 8

		Asian	
		White	
		BlacHor African American	
Lis	st Hown medical conditions (S	uch as dia?etes' high ?lood pressure' cancer' heart disease' or others)	
ΡI	ease list all allergies (such as t	o drugs' foods' ollen or o hers)	
Lis	st any other important informati	on a?out the person (such as smoHng' pregnancy' alcohol use' etc.)	
l i	st all current prescription medic	ations and medical devices? ng used.	
	The same of the process process and the same	anono ana modical do neco : 1.9 doca.	
l i	l st all over-the-counter medicati	ons and any vitamins' minerals' supplements' and her?al remedies ?eing used.	
L-1\	of all over the oparitor medical	one and any vitamine minerale supplemente and not all remedies teming used.	
Se	ection F - A?out the Person Filli	ng Out This Form k of k	,
	Primaryq	,e	
	Reporter is Patientq		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Num?er/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(b) (6)	
	Country	UN7TED STATES	
	Z7P or Postal code	(b) (6)	
			1
	Telephone num?er	(b) (6)	

Generated ?y: S, STEM Generated on: 08-Jul-2022 k2:k8:16 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-53143 | Department: CFSAN | RCT No.: RCT-1028361 | CTU Triage Date: 06-Jul-2022 | Total Pages: 8

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today9 date	08-Jul-2022	
Did you report this pro?lem to the company that maH the product (the manufacturer/compounder)q		
If you do NOT want your dentity disclosed to the manufacturer' please marHthis ?ox (Confidentiality ReYuested):	No	

Generated ?y: S, STEM Generated on: 08-Jul-2022 k2:k8:16 Page 5 of 5

DAILY HARVEST

CAULIFLOWER* CARROT* KITCHARI* SPINACH *ORGANIC

Harvest Bowl

RED LENTIL + CUMIN

NET WT. 11.02oz (312g)

CTU No.: FDA-CDER-CTU-2022-53506 | Department: ISPSAN | RCT No.: RCT-1028725 | DTU Trage Date: 07-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details	2011	200 00000000000000000000000000000000000	12.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	07-Jul-2022	CTU Received Date	07-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	User	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
Ø	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem		
What kind of problem was it? (Check all that apply)	Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker	
Date the problem occurred	08-Jun-2022	
Serious	Yes	
Did any of the following happen? (Check all that apply)	Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I consumed Daily Harvest's French Lentil and Leek crumbles sometime after May 19th (that was the day they were delivered). The first week of June I noticed I had very dark urine and thought it was dehydration, so I started pounding electrolytes but it didn't clear up. Around June 13th I was applying eye makeup to go to work and noticed my eyes looked yellow. I made a doctor's appointment and they ran some tests. My liver enzymes were through the roof. They have done two additional sets of tests and my enzymes are still high and are going to schedule an MRI. They informed me that I might need a liver biopsy. I have kept a record of my orders with Daily Harvest and have my test results on My Chart for reference.

levant Test/Laboratory	Data		1 of 6
Test Name	ALT/SGPT (UWH)	Test Date	14-Jun-2022
Test Result	434	Test Unit	CELLS PER MICROLITR E
Low Test Range	0	High Test Range	55

Generated by: SYSTEM Generated on: 07-Jul-2022 11:46:28 Page 1 of 6

CTU No.: FDA-CDER-CTU-2022-53506 | Department: CFSAN | RCT No.: RCT-1028725 | CTU Triage Date: 07-Jul-2022 | Total Pages: 8

More Information Available?			
elevant Test/Laboratory D	ata		2 of 6
Test Name	AST/SGOT (UWH)	Test Date	14-Jun-2022
Test Result	199	Test Unit	CELLS PER MICROLITR E
Low Test Range	5	High Test Range	34
More Information Available?	,		
levant Test/Laboratory D	ata		3 of 6
Test Name	ALT/SGPT (UWH)	Test Date	21-Jun-2022
Test Result	477	Test Unit	CELLS PER MICROLITR E
Low Test Range	0	High Test Range	55
More Information Available?	,		
levant Test/Laboratory D	ata		4 of 6
Test Name	AST/SGOT (UWH)	Test Date	21-Jun-2022
Test Result	290	Test Unit	CELLS PER MICROLITR E
Low Test Range	5	High Test Range	34
More Information Available?	,		,
levant Test/Laboratory D	ata		5 of 6
Test Name	ALT/SGPT (UWH)	Test Date	01-Jul-2022
Test Result	125	Test Unit	CELLS PER MICROLITR
Low Test Range	0	High Test Range	55
More Information Available?	,		,
levant Test/Laboratory D			6 of 6
Test Name	AST/SGOT (UWH)	Test Date	01-Jul-2022
Test Result	53	Test Unit	CELLS PER MICROLITR
Low Test Range	5	High Test Range	34
More Information Available?	,		1
ditional Comments			
My levels are coming down,	but still over the high test range	э.	
ection B - Product Availab	ility		
Do you still have the produc	-		
ase we need to evaluate it?			

Generated by: SYSTEM Generated on: 07-Jul-2022 11:46:28 Page 2 of 6

CTU No.: FDA-CDER-CTU-2022-53506 | Department: CFSAN | RCT No.: RCT-1028725 | CTU Triage Date: 07-Jul-2022 | Total Pages: 8

	Do you have a picture of the roduct? (check yes if you are	Yes			
0 -	ncluding a picture)				
56	ection C - About the Products	V		1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest French Lentil	and Leek Crumbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No			
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			
Dr	ug Therapy			1 of 1	
	Expiration date	10-Oct-2022			
	Lot number	L5-A 08:15			
	Dosage Form				
	Quantity	Other	If Other	1 serving	
	Frequency	Other	If Other	1 meal	
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	01-Jun-2022			
	Date the person stopped taking or using the product	02-Jun-2022			
	Date the person reduced dose of he product				
	Give best estimate of duration				
	In the many atill are main and	Yes			
	Is therapy still on-going?				
W	hy was the person using the pr		ndition was it supposed to t	reat) 1 of 1	
W	,,,	oduct? (such as what co	ndition was it supposed to t	reat) 1 of 1	

Generated by: SYSTEM Generated on: 07-Jul-2022 11:46:28 Page 3 of 6

CTU No.: FDA-CDER-CTU-2022-53506 | Department: CFSAN | RCT No.: RCT-1028725 | CTU Triage Date: 07-Jul-2022 | Total Pages: 8

Se	ction D - About the Medical De	evice	
	Name of medical device		
	Name of the company that makes the medical device		
	her identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem		
	oc urred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast mplants, etc.)	
Da	ate the implant was put in	Date the implant was taken out (If relevant)	
10 -	-4: E Ab44b- D \A/b	and the Darkham	
Se	ction E - About the Person Wh		
Se	Person's Initials	(b) (6)	
Se	Person's Initials Sex	(b) (6) Female	
Se	Person's Initials Sex Gender	(b) (6)	
Se	Person's Initials Sex Gender Please Specify Other Gender	(b) (6) Female Decline to answer	
Se	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age)	(b) (6) Female	
Se	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth	Female Decline to answer 59 Year(s)	
Se	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight	Female Decline to answer 59 Year(s) 108 kg	
Se	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Female Decline to answer 59 Year(s)	
Se	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight	Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native	
Se	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	(b) (6) Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	
Se	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian	
Se	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one)	(b) (6) Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native Native Hawaiian or Other Pacific Islander	
	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Check all that apply)	Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Check all that apply)	Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White	
	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Check all that apply)	Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Check all that apply)	Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	
	Person's Initials Sex Gender Please Specify Other Gender Age (specify unit of time for age) Date of Birth Weight Ethnicity (Choose only one) Race (Check all that apply)	Female Decline to answer 59 Year(s) 108 kg Not Hispanic/Latino American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	

Generated by: SYSTEM Generated on: 07-Jul-2022 11:46:28 Page 4 of 6

CTU No.: FDA-CDER-CTU-2022-53506 | Department: CFSAN | RCT No.: RCT-1028725 | CTU Triage Date: 07-Jul-2022 | Total Pages: 8

	Sulfa	
Lis	t any other important information about the person (such as moking, pregnancy, alcohol use, etc.)	
	None	
Lis	t all current prescription medications and medical devices b ng used.	
	None	
Lis	t all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
Ĭ	Centrum Silver for Women	

tion F - About the Person Filli Primary?	ing Out This Form 1 of 1 Yes
Reporter is Patient?	
Title	
_ast name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
-ax	
Reporter Organization	
Department	
Reporter Speciality	
Γoday's date	07-Jul-2022
Did you report this problem to the company that makes the product the manufacturer/compounder)?	No
f you do NOT want your dentity disclosed to the	No

Generated by: SYSTEM Generated on: 07-Jul-2022 11:46:28 Page 5 of 6

CTU No.: FDA-CDER-CTU-2022-53506 | Department: CFSAN | RCT No.: RCT-1028725 | CTU Triage Date: 07-Jul-2022 | Total Pages: 8

manufacturer, please mark this box (Confidentiality Requested):

Generated by: SYSTEM Generated on: 07-Jul-2022 11:46:28 Page 6 of 6

DAILY HARVEST

BEST BY: 09/27/2022 15-A 13:53

BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI

Prepaing Crumbles:

O rest lightly oiled skillet or non-stick pan over medium-high heat

@ Mathedesired amount of frozen Crumbles to the pan, breaking up ay arge clusters.

O sing frequently, sauté until nicely browned and thoroughly cooked on nternal temperature of 165°F, about 5-6 minutes.

है अस्त्रात for 1-2 minutes. Enjoy on their own or add to your favorite dish.

সঙ্গন্তি STORE FROZEN. Do not thaw or refreeze. Cook thoroughly beritard amperature of 165°F. Fill level and cook time may vary.

Methor Fath Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290. Total ful 430 Stantad Fat 2g (10% DV), Trans Fat 0g, Cholesterol Omg (0% DV), Sodium 430mg (19% DV) Total Added Sugars ON DV, Total Sugars 3g (Includes Og Added Sugars ON DV), Total Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Total Sugars ON DV (Includes Og Added Sugars ON DV), Tota #Militan Dong (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (0% DV), Iron 4mg (20%

hysterian bitternit squash, organic hemp seeds, organic cauliflower rice, organic extra virgin cline of representation of squash, organic hemp seeds, organic cauliflower rice, organic extension organic large for the distribution of the control o sea organic red lentils, organic tri-colored quinoa, organic cremini mushrooms. Organic chia powder dia sea organic sacha number dia water, organic cassava root flour, organic flax seeds, organic sacha non powder number of course of the course of To provide himalayan sea salt, organic apple cider vinegar, organic onion powder number of provider number o

BEST BY: 10/10/2022 15-A 08:15

LENTIL BUTTERNUT SQUASH HEMP SEED QUINOA **CREMINI** TARA .

Preparing Crumbles:

- O Heat a lightly oiled skillet or non-stick pan over medium-high hea
- Add the desired amount of frozen Crumbles to the pan, breaking up any large clusters.
- Stirring frequently, sauté until nicely browned and thoroughly cooked to an internal temperature of 165°F, about 5-6 minutes.
- Let stand for 1-2 minutes. Enjoy on their own or add to your favorite dish

PERSHABLE. STORE FROZEN. Do not thaw or refreeze. Cook thoroughly maninternal temperature of 165°F. Fill level and cook time may vary.

Nutrition Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving Caloris II. how DV), Saturated Fat 2g (10% DV), Trans Fat 0g, Cholasterol Omg (0% DV), Sodium 430mg W Catalydrate 19g (7% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added Sugas 3) In 18th DV), Vitamin D Omcg (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium (4/11) May Value tells you how much a nutrient in a serving of food contributes to a daily diet 2000 for general nutrition advice.

Appelients organic butternut squash, organic hemp seeds, organic cauliflower rice, organic and organic red lentils, organic red lentils, organic tri-colored quinoa, organic cremini mushoomer The least organic parsley, water, organic cassava root flour, organic flax seeds, organic sate organic parsiey, water, organic cossera root root apple cidervinegar, organic onion post ogate gate powder, organic tomato powder, organic white pepper, organic conandar service organic tomato powder, organic white pepper, organic conandar service organic thyme.

MADE NAFROLITY THAT ALSO PROCESSES TREE NUTS, SOY, DAIRY, & SESAME OSTRBYDAILY HARVEST INC. NEW YORK, NY 10013

CTU No.: FDA-CDER-CTU-2022-53740 | Department: CFSAN | RCT No.: RCT-1028956 | CTU Triage Date: 08-Jul-2022 | Total Pages: 11

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details					
Company Unit	CDER-CTU	Originating Ac ount	FAERS		
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B		
Priority	Routine				
Override Auto Calculation Rule	No				
FDA Received Date	0J-f ul-2022	CTU Received Date	0J-f ul-2022		
CTU Triage Date		CTU Data Entry Date			
Report Type	Spontaneous	Report Classi/ication	Drug		
Assign To	User				
UservGroup					
Forward to Department					
Case Priority	Direct				
<u> </u>					

Contact						
Case Reporter	First Name	Last Name	Email Address	Phone		
\square	(b) (6)	(b) (6)	(b) (6)	(b) (6)		
Section A - A7out the Pro7lem						
	What b nd o/ pro7lem was itk (Checb all that apply) Were hurt or had a 7ad side e//ect (including new or worsening symptoms)					

outering the cat the morner		
What b nd o/ pro7lem was itk (Checb all that apply)	Were hurt or had a 7ad side e//ect (including new or worsening symptoms) Used a product incorrectly which could have or led to a pro7lem Noticed a pro7lem with the ?uality o/ the product q ad pro7lems a/ter switching /rom one product maber to another mab r	
Date the pro7lem oc urred	01-f un-2022	
Serious	He	
Did any o/ the /ollowing happenk (Checb all that apply)	qospitalization - admitted or stayed longer Re?uired help to prevent permanent harm Disa7ility or health pro7lem Birth de/ect Li/e-threatening Death Other seriouswmportant medical incident(Please Descri7e Below)	
Other serious wmportant medical ncident (Please Descri7e Below)		

6. Tell us what happened and how it happened (&clude as many details as possi7le FDA may reach out to you /or any additional documents i/ necessary)

On May 2Yth 8had one serving o/ Daily q arvest4French Lentil I Leeb Crum7les. During Memorial Day Weebend my daughter4 who is a nurse4noticed a slight yellowing in my eyes. 8also was e, periencing slight /atigue and slight headaches. Thought it was xust 7ecause o/ 7eing too 7usy. f une 1420224had a 2 routine Cat scans o/ chest and a7domen and /ollowed up with 7lood worb on same day. Three liver enzymes were elevated on the comp meta7olic panel. Albaline Phosphatase was 111 (range is 36-123)4AST was Y6 (range 13-35) and ALT was 56 (range J-31). Doctor said to retabe 7loodworb a weeb later. Retoob 7lood worb on YMYM2 and Albaline Phosphatase was 15J4AST 5Y and ALT 35. Retoob 7lood worb again on YM60M2 and Albaline Phosphatase was 1364AST 65 and ALT 22. Bacb on 5M6M248had the same 7loodworb and this was 7e/ore 8ate the French Lentil4Leeb Crum7les. Albaline Phosphatase was J04AST was 23 and ALT was 14which were all normal range. On f une 1 Jth422nd and 2Jth 8received emails /rom Daily q arvest a7out a voluntary recall o/ this /ood and to throw it away. 8 was causing some gastro intestinal discom/ort a/ter consuming the French Lentil I Leeb Crum7les. On f une 30th 8decided to google the Daily q arvest French Lentil and Leeb Crum7les and ran across a post with comments. People were commenting how their liver enzymes were elevated and some had gall7ladder removed. 8immediately got suspicious that perhaps that is the reason my liver enzymes were elevated. On Friday4f uly 1st48read some more articles and contacted an attorney handling the class action suit. 8will have another 7lood test ne, t weeb

Generated 7y: SHSTEM G nerated on: 0J-f ul-2022 23:1Y:25 Page 1 o/ Y

Re	levant Testwa7oratory Data			1 o/ 1
	Test Name	AL&AL&NE Pq OSPq ATAS E	Test Date	01-f un-2022
	Test Result	1 11	Test Unit	CELLS PER M&CROL8TR E
	Low Test Range	36	q gh Test Range	123
	More & formation Availa7lek			
Re	levant Testwa7oratory Data			2 o/ 1
	Test Name	AST	Test Date	01-f un-2022
	Test Result	Y6	Test Unit	CELLS PER M&CROL8TR E
	Low Test Range	13	q gh Test Range	35
	More & formation Availa7lek			
Re	levant Testwa7oratory Data			3 o/ 1
	Test Name	ALT	Test Date	01-f un-2022
	Test Result	56	Test Unit	CELLS PER M&CROL8TR E
	Low Test Range	J	q gh Test Range	31
	More 8n/ormation Availa7lek			
Re	levant Testwa7oratory Data			6 o/ 1
	Test Name	AL&AL8NE Pq OSPq ATAS E	Test Date	1 Y-f un-2022
	Test Result	15J	Test Unit	CELLS PER M&CROL8TR E
	Low Test Range	36	q gh Test Range	123
	More &n/ormation Availa7lek			
Re	levant Testwa7oratory Data			5 o/ 1
	Test Name	AST	Test Date	1 Y-f un-2022
	Test Result	5Y	Test Unit	
	Low Test Range	13	q gh Test Range	35
	More 8n/ormation Availa7lek			
Re	levant Test⊮a7oratory Data			Y o/ 1
	Test Name	ALT	Test Date	1 Y-f un-2022
	Test Result	35	Test Unit	CELLS PER M&CROL8TR E
	Low Test Range	J	q gh Test Range	31
	More 8n/ormation Availa7lek			
Re	levant Testwa7oratory Data			J o/ 1
	Test Name	AL&AL8NE Pq OSPq ATAS	Test Date	30-f un-2022

Generated 7y: SHSTEM G nerated on: 0J-f ul-2022 23:1 Y:25 Page 2 o/ Y

	Test Result	136	Test Unit	CELLS PER M&CROL8TR E
	Low Test Range	36	q gh Test Range	123
	More & formation Availa7lek			
Re	elevant Testwa7oratory Data			1 o/ 1
	Test Name	AST	Test Date	30-f un-2022
	Test Result	65	Test Unit	CELLS PER M&CROL8TR E
	Low Test Range	13	q gh Test Range	35
	More &n/ormation Availa7lek			
Ac	Iditional Comments			
	AST on Yw30w22 was 22 in normal	range.		
Se	ection B - Product Availa7ility			
	Do you still have the product in case we need to evaluate itk	No		
	Do you have a picture o/ the productk (checb yes i/ you are	Не		
	ncluding a picture)			
Se	ection C - A7out the Products			1 o/ 1
Se		He		1 o/ 1
Se	ection C - A7out the Products	He He		1 0/1
Se	ection C - A7out the Products Suspect			1 o/ 1
Se	Suspect Primaryk	Не		1 0/1
Se	Suspect Primaryk Type	He DrugvBiologi	I Leeb Crum7les	1 0/1
Se	Primaryk Type This report is a7out Name o/ the product as it appears on the 7o, 47ottle4 or pacbage (&ction C - A7out the Product as many	He DrugvBiologi FoodvMedical /ood	I Leeb Crum7les	1 0/1
Se	Suspect Primaryk Type This report is a7out Name o/ the product as it appears on the 7o, 47ottle4 or pacbage (&clude as many names as you see) Name o/ the company that mab (or compounds) the	He DrugvBiologi FoodvMedical /ood Daily q arvest French Lentil		1 0/1
Se	Suspect Primaryk Type This report is a7out Name o/ the product as it appears on the 7o, 47ottle4 or pacbage (&clude as many names as you see) Name o/ the company that mab (or compounds) the roduct Product Type(checb all that	He DrugvBiologi FoodvMedical /ood Daily q arvest French Lentil Daily q arvest Over-the-Counter Compounded 7y a Pharmacy of Generi		1 0/1
Se	Suspect Primaryk Type This report is a7out Name o/ the product as it appears on the 7o, 47ottle4 or pacbage (&clude as many names as you see) Name o/ the company that mab (or compounds) the roduct Product Type(checb all that apply)	He DrugvBiologi FoodvMedical /ood Daily q arvest French Lentil Daily q arvest Over-the-Counter Compounded 7y a Pharmacy of Generi	or an Outsourcing Facility	1 0/1
Se	Suspect Primaryk Type This report is a7out Name o/ the product as it appears on the 7o, 47ottle4 or pacbage (&clude as many names as you see) Name o/ the company that mab (or compounds) the roduct Product Type(checb all that apply) Strength	He DrugvBiologi FoodvMedical /ood Daily q arvest French Lentil Daily q arvest Over-the-Counter Compounded 7y a Pharmacy of Generi	or an Outsourcing Facility	1 0/1

Generated 7y: SHSTEM G nerated on: 0J-f ul-2022 23:1 Y:25 Page 3 o/ Y

Drug	Therapy			1 o/ 1	
E	, ration date				
Lo	ot num7er				
D	osage Form				
Q	uantity		8 Other		
Fı	re?uency		8 Other		
q	ow was it tab n or used		8 Other		
	ate the person /irst started b ng or using the product	2Y-May-2022			
	ate the person stopped tab ng rusing the product	2Y-May-2022			
	ate the person reduced dose o/ e product				
G	ive 7est estimate o/ duration				
8	therapy still on-goingk				
Why	was the person using the pr	oductk (such as what cor	ndition was it supposed to tr	reat) 1 o/1	
R	eturned to Manu/acturer On				
Secti	on D - A7out the Medical De	evice			
	ame o/ medical device				
	ame o/ the company that				
Othe	r identi/ying in/ormation (The	e model4catalog4lot4seria	al4or UD8num7er4and the	e, piration date4i/ you can	
locate	e them)				
М	lodel Num7er				
С	atalog Num7er				
Lo	ot Num7er				
S	erial Num7er				
U	DD8Num7er			-	
E	, ration date				
m	/as someone operating the ledical device when the pro7lem courredk				
	nplanted medical devices O the implant was put in	NLH (such as pacemabe	rs47reast implants4etc.) Date the implant was taben our relevant)	ut (8	
Secti	on E - A7out the Person Wh	no g ad the Pro7lem			
	erson's & itials	(b) (6)			

Generated 7y: SHSTEM G nerated on: 0J-f ul-2022 23:1 Y:25 Page 6 o/ Y

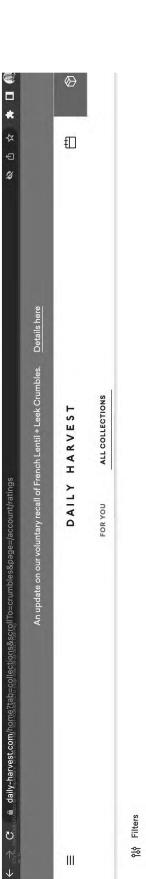
CTU No.: FDA-CDER-CTU-2022-53740 | Department: CFSAN | RCT No.: RCT-1028956 | CTU Triage Date: 08-Jul-2022 | Total Pag es: 11

	Se,	Female	
	Gender	Cisgender womanwgirl	
	Please Speci/y Other Gender		
	Age (speci/y unit o/ time /or age)	Y2 H ar(s)	
	Date o/ Birth		
	Weight	61. Y bg	
	Ethnicity (Choose only one)	Not q anicwLatino	
	Race (Checb all that apply)	American & dian or Alasba Native	
		Native q awaiian or Other Paci/ic 8lander	
		Asian	
		White	
		Blacb or A/rican American	
Lis	st bnown medical conditions (S	Such as dia7etes4high 7lood pressure4cancer4heart disease4or others)	
	cancer		П
Ple	ease list all allergies (such as t	to drugs4/oods4pollen or others)	
	azithromycin4and hydrocodone4a		Т
	-		
ll is	et any other important in/ormat	ion a7out the person (such as mob ing4pregnancy4alcohol use4etc.)	
LIS	st arry other important in/ormati	ion arout the person (such as mobiling-pregnancy-acconditional ase-etc.)	
		-Managand madical decises 7 may read	<u>_</u>
LIS	st all current prescription medic	cations and medical devices 7 ng used.	
Lis		ions and any vitamins4minerals4supplements4and her7al remedies 7eing used.	
	magnesium glycinate4polyresvera urbey tail4reishi4	atrol-sr 4curcumin4ashwagandha4vit d34multivitamin4calcium4vit B4Pro7iotic4zinc4vit c4	
Se	ection F - A7out the Person Fill	ing Out This Form 1 o/1	
	Primaryk	He	
	Reporter is Patientk		+
_	Title		-
	Last name	(b) (6)	+
i	LUSTIBLIC		1

Generated 7y: SHSTEM G nerated on: 0J-f ul-2022 23:1 Y:25 Page 5 o/ Y

Middle Name	
First name	(b) (6)
Num7erv6treet	(b) (6)
City	(b) (6)
StatevProvince	(b) (6)
Country	UN8TED STATES
Z8P or Postal code	(b) (6)
Telephone num7er	(b) (6)
Email address	(b) (6)
Fa,	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	0J-f ul-2022
Did you report this pro7lem to the company that mab the product (the manu/acturervcompounder)k	
8 you do NOT want your dentity disclosed to the manu/acturer4please marb this 7o, (Con/identiality Re?uested):	He

Generated 7y: SHSTEM G nerated on: 0J-f ul-2022 23:1 Y:25 Page Y o/ Y





Harvest Bowls

Smoothies

Back in Stock Gotta Haves

Harvest Bakes

Flatbreads Crumbles



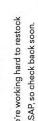
Walnut + Thyme Crumbles

discontinued. Please dispose of this item and do not eat it. This item is temporarily

Details here.



We're working hard to restock ASAP, so check back soon.





Soups

Lattes

Bites

MAIL

CTU No.: FDA-CDER-CTU-2022-53967 | Department: CFSAN | RCT No.: RCT 4029328 | CTU Triage Date: 11-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details		200000000000000000000000000000000000000	12.22
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine	-	
Override Auto Calculation Rule	No		
FDA Received Date	08-Jul-2022	CTU Received Date	08-Jul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User	-6	
User/Group			
Forward to Department			
Case Priority	Direct		

Contact	- T-	40.00	100000000000000000000000000000000000000		
Case Reporter	First Name	Last Name	Email Address	Phone	
	(b) (6)	(b) (b)	(b) (6)	(b) (6)	
Section A	- About the Problem				
	nd of problem was it? all that apply)	Used a product incorrectly was Noticed a problem with the o	effect (including new or worsening sympto which could have or led to a problem quality of the product g from one product maker to another make		
Date the	e problem occurred	26-Jun-2022			
Serious		Yes			
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent per Disability or health problem Birth defect Life-threatening Death Other serious/important med	rmanent harm		
4.Tell us w any additio	hat happened and hove	v it happened (Include a ssary)	as many details as possible F	DA may reach out to you for	
	d Daily Harvest French Le ests confirmed liver damag		d having symptoms consistent wit	h liver damage 2-3 weeks later.	

evant Test/Laboratory	Data		1 of 4
Test Name	TOTAL BILIRUBIN	Test Date	01-Jul-2022
Test Result	7.7 mg/dL	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	0.2 mg/dL	High Test Range	1.2 mg/dL

Generated by: SYSTEM Generated on: 08-Jul-2022 20:46:22 Page 1 of 5

Mana 14/2002 45 22 Ave 12 Ole O			
More Information Availa6le8 Relevant Testwa6oratory Data			2 o/ 9
Test Name	AL' ALHNE P? OSP? ATAS E	Test Date	04-f ul-2022
Test Result	235 UVL	Test Unit	CELLS PER MICROLITR E
Low Test Range	35 UvL	? gh Test Range	499 Uvk
More Ht/ormation Availa6le8			
Relevant Testwa6oratory Data			3 o/ 9
Test Name	ASTv6GOT	Test Date	04-f ul-2022
Test Result	4x2 Uvk	Test Unit	CELLS PER MICROLITR E
Low Test Range	40 Uvk	? gh Test Range	35 Uvk
More Hil/ormation Availa6le8			
Relevant Testwa6oratory Data			9 o/ 9
Test Name	ALT (SGPT)	Test Date	04-f ul-2022
Test Result	9J9 UVL	Test Unit	CELLS PER MICROLITR
Low Test Range	1 Uvk	? gh Test Range	97 Uvk
More Hil/ormation Availa6le8			
Section B - Product Availa6ility			
Do you still have the product in case we need to evaluate it8	qe		
Do you have a picture o/ the product8 (checb yes i/ you are ncluding a picture)	No		
Section C - A6out the Products			4 o/ 4
Suspect	qe		
Primary8	qe		
Туре	DrugvBiologi		
This report is a6out			
Name o/ the product as it appears on the 6oK+6ottle+ or pacbage (Hiclude as many names as you see)	Daily ? arvest French Lentil	Y Leeb Crum6les	
Name o/ the company that mab (or compounds) the roduct	Daily ? arvest		

Generated 6y: SqSTEM G nerated on: 0J-f ul-2022 20:97:22 Page 2 o/ 5

CTU No.: FDA-CDER-CTU-2022-53967 | Department: CFSAN | RCT No.: RCT-1029328 | CTU Triage Date: 11-Jul-2022 | Total Pag es: 5

	Product Type(checb all that apply)	Generi	Compounded 6y a Pharmacy or an Outsourcing Facility Generi					
	Strength	Biosimilar	H Other					
	NDC num6er		1/1 0 (110)					
	Did the pro6lem stop a/ter the rson reduced the dose or opped tab ng or using the roduct8	No						
	Did the pro6lem return i/ the rson started tab ng or using the roduct again8	Doesn K Apply						
Dr	ug Therapy			4 o/ 4				
	EK ration date							
	Lot num6er							
	Dosage Form							
	Quantity		H Other					
	Frekuency		H Other					
	? ow was it tab n or used		H Other					
	Date the person /irst started ab ng or using the product	0x-f un-2022						
	Date the person stopped tab ng or using the product	0J-f un-2022						
	Date the person reduced dose o/ he product							
	Give 6est estimate o/ duration		_					
	Hs therapy still on-going8	qe						
WI	ny was the person using the pr	oduct8 (such as what co	ndition was it supposed to	treat) 4 o/ 4				
	Returned to Manu/acturer On							
Se	ection D - A6out the Medical De	evice						
	Name o/ medical device							
	Name o/ the company that mab the medical device							
	her identi/ying in/ormation (The cate them)	e model+catalog+lot+seri	ial+or UDHhum6er+and the	e eKpiration date+i/ you can				
	Model Num6er							
	Catalog Num6er							
	Lot Num6er							

Generated 6y: SqSTEM G nerated on: 0J-f ul-2022 20:97:22 Page 3 o/ 5

CTU No.: FDA-CDER-CTU-2022-53967 | Department: CFSAN | RCT No.: RCT-1029328 | CTU Triage Date: 11-Jul-2022 | Total Pag es: 5

	Serial Num6er				
	UDDHNum6er				
	EK ration date				
	Was someone operating the medical device when the pro6lem oc urred8				
Fo	r implanted medical devices C	NLq (such as pacemaber	rs+6reast implants+etcl)		
Da	ate the implant was put in		Date the implant was tab n out (H/ relevant)		
Se	ction E - A6out the Person Wh	no ? ad the Pro6lem			
	Personks Hitials	(b) (6)			
	SeK	Male			
	Gender	Cisgender manv6oy			
	Please Speci/y Other Gender				
	Age (speci/y unit o/ time /or age)	53 q ar(s)			
	Date o/ Birth	,			
	Weight	Jxlx5 bg			
	Ethnicity (Choose only one)	Not ? anicwLatino			
	Race (Checb all that apply)	American Hidian or Alasba Nati Native ? awaiian or Other Paci/ Asian White Blacb or A/rican American			
LIS	<u>`</u>		od pressure+cancer+heart diseas	se+or otners)	
	slightly high cholesterol+history o	cardiomyopauty			
PΙ	ease list all allergies (such as t	o drugs+/oods+pollen or o	others)		
	contrast				
Lis	t any other important in/ormat	ion a6out the person (suc	h as mob ing+pregnancy+alcoho	l use+etcl)	
Lis	t all current prescription medic		es 6 ng usedl		
	Ramipril+Rosuvastatin+Carvedilo	I			

Generated 6y: SqSTEM G nerated on: 0J-f ul-2022 20:97:22 Page 9 o/ 5

CTU No.: FDA-CDER-CTU-2022-53967 | Department: CFSAN | RCT No.: RCT-1029328 | CTU Triage Date: 11-Jul-2022 | Total Pages: 5

Li	List all over-the-counter medications and any vitamins+minerals+supplements+and her6al remedies 6eing usedl						
	Xyzal Allergy						

tion F - A6out the Person Fil	ling Out This Form 4 o/ 4
Primary8	qe
Reporter is Patient8	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Num6erv6treet	(b) (6)
City	(b) (6)
StatevProvince	(b) (6)
Country	UNITED STATES
ZHP or Postal code	(b) (6)
Telephone num6er	(b) (6)
Email address	(b) (6)
FaK	
Reporter Organization	
Department	
Reporter Speciality	
Todayks date	0J-f ul-2022
Did you report this pro6lem to the company that mab the product (the manu/acturerwompounder)8	
Hyou do NOT want your dentity disclosed to the manu/acturer+please marb this 6oK (Con/identiality Rekuested):	No

CTU No.: FDA-CDER-CTU-2022-53929 | Department: CFSAN | RCT No.: RCT-1029211 | CTU Triage Date: 11-Jul-2022 | Total Pag

All dates displa	yed in the report are in EST(G	MT-05	i:00) time zone			
Basic Deta	ils					
Company U	nit	CDI	ER-CTU	Origi	nating Ac ount	FAERS
Source Med	lium	MW	/O (Drug)	Sour	ce Form Type	E2B XML 3500B
Priority		Rou	ıtine			
Override Au	to Calculation Rule	No				
FDA Receiv	red Date	08-	Jul-2022	CTU	Received Date	08-Jul-2022
CTU Triage	Date			CTU	Data Entry Date	
Report Type	9	Spc	ontaneous	Repo	ort Classification	Drug
Assign To		Use	er			
User/Group						
Forward to	Department	$\overline{\mathbf{Z}}$	1			
Case Priorit	у	Dire				
	-					
Contact						
Case Reporter	First Name		Last Name		Email Address	Phone
	(b) (6)		(b) (6)		(b) (6)	(b) (6)
Section A -	About the Problem					
What kind of problem was it? (Check all that apply) Date the problem oc urred Serious Did any of the following happen?			Were hurt or had a bad side effect (including new or worsening symptoms) Used a product incorrectly which could have or led to a problem Noticed a problem with the quality of the product Had problems after switching from one product maker to another maker 20-May-2022 Yes Hospitalization - admitted or stayed longer			
(Check all that apply)		Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)				
ncidento	rious/important medical Please Describe Below) hat happened and how nal documents if nece	w it h	nappened (Include as y)	many	/ de ails as possible FDA	may reach out to you for
After consuming Daily Harvest French Lentil Crumbles for dinner I began suffered from extremely serious gastrointestinal ain and breathing problems early the following morning. I was aken to the ER but the treating clinician was unable to identify he cause of my problems. The GI pain, which was extremely severe, continued for 3 days. The breathing problems still continue to this day. When I received notice from Daily Harvest to dispose of the Lentil Crumbles because other consumers had reported issues I realized that I too was a victim. My Fitness Pal calorie tracker confirmed that I consumed the lentils the day before I was in the ER and I never consumed the crumbles again and also have not had a recurrence of the GI pain.						
Relevant T	est/Laboratory Data					1 of 1
Test Na				Test	Date	
Test Re	sult			Test	Unit	
Low Tes	t Range			High	Test Range	

Generated by: SYSTEM Generated on: 08-Jul-2022 15:46:33 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-53929 | Department: CFSAN | RCT No.: RCT-1029211 | CTU Triage Date: 11-Jul-2022 | Total Pages: 5

	More Information Available?				
Ad	lditional Comments				
Se	ection B - Product Availability				
	Do you still have the product in case we need to evaluate it?	No			
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No			
Se	ection C - About the Products			1 of 1	
	Suspect	Yes			
	Primary?	Yes			
	Туре	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil & Leek Crumb	oles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number			<u> </u>	
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?				
Dr	ug Therapy			1 of 1	
	Expiration date				
	Lot number				
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used		If Other		
	Date the person first started aking or using the product	19-May-2022			
	Date the person stopped taking	19-May-2022			

Generated by: SYSTEM Generated on: 08-Jul-2022 15:46:33 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-53929 | Department: CFSAN | RCT No.: RCT-1029211 | CTU Triage Date: 11-Jul-2022 | Total Pages: 5

	Date the person reduced dose of he product				
_	Give best estimate of duration				
	Is therapy still on-going?				
W		roduct? (such as what cor	ndition was it supposed to treat)	1 of 1	
	Meal	(
_					
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				
	Name of the company that				
	makes the medical device				
Ot	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the expira	tion date, if you can	
100					
	Model Number	<u></u>			
	Catalog Number				
	Lot Number				
	Serial Number				
	UDDI Number				
	Expiration date				
	Was someone operating the medical device when the problem				
	oc urred?				
Fc	or implanted medical devices O	NLY (such as pacemake	rs. breast mplants, etc.)		
_	ate the implant was put in		Date the implant was taken out (If		
			relevant)		
Se	ection E - About the Person Wh	no Had the Problem			
	Person's Initials	(b) (6)			
	Sex	Female			
	Gender	Cisgender woman/girl			
	Please Specify Other Gender		-		
	Age (specify unit of time for age)				
	Date of Birth	(b) (6)			
	Weight	49.95 kg			
	Ethnicity (Choose only one)	Not Hispanic/Latino			
	Race (Check all that apply)				
	,	American Indian or Alaska Nati			
		Asian	iio isialluci		
ı	I.				

Generated by: SYSTEM Generated on: 08-Jul-2022 15:46:33 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-53929 | Department: CFSAN | RCT No.: RCT-1029211 | CTU Triage Date: 11-Jul-2022 | Total Pages: 5

		White Black or African American							
l is	List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)								
LIO	Hashimoto's	don as diabetes, mgm blood pre-dre, carteer, meant disease, or ethors)							
PΙε	ease list all allergies (such as t	o drugs, foods, pollen or o hers)							
	N/A								
Lis		on about the person (such as moking, pregnancy, alcohol use, etc.)							
	Healthly, non-smoker, non-drinke								
Lis		cations and medical devices b ng used.							
	Levothyroxine								
Lis	t all over-the-counter medicati	ons and any vitamins, mineral , supplements, and herbal remedies being used.							
	N/A								
Se	ction F - About the Person Fill								
	Primary?	Yes	-						
	Reporter is Patient? Title		\vdash						
	Last name	(b) (6)	-						
	Middle Name								
	First name	(b) (6)							
	Number/Street	(b) (6)							
	City	(b) (6)							
	State/Province	(b) (c)							
	Country	UNITED STATES							
	ZIP or Postal code	(b) (6)							
	Telephone number	(b) (6)	+						
	Email address	(b) (6)							

Generated by: SYSTEM Generated on: 08-Jul-2022 15:46:33 Page 4 of 5

Fax		
Reporter Organization		
Department		
Reporter Speciality		
Today's date	08-Jul-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 08-Jul-2022 15:46:33 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-53920 | Department: CFSAN | RCT No.: RCT-1029177 | CTU Triage Date: 11-Jul-2022 | Total Pag

II dates displa	yed in the report are in EST(G	MT-05	:00) time zone			
Basic Deta	ils					
Company U	Init	CDI	ER-CTU	Origin	nating Ac ount	FAERS
Source Med	dium	MW	O (Drug)	Sourc	e Form Type	E2B XML 3500B
Priority		Rou	tine			
Override Au	ito Calculation Rule	No				
FDA Receiv	ved Date	08-	Jul-2022	CTU	Received Date	08-Jul-2022
CTU Triage	Date			CTU	Data Entry Date	
Report Type	9	Spo	ntaneous	Repo	rt Classification	Drug
Assign To		Use	r	l		
Jser/Group						
orward to	Department					
Case Priorit	tv	Dire	-			
	• 9					
Contact						
Case	First Name		Last Name		Email Address	Phone
Reporter						
\checkmark	(b) (6)		(b) (6)		(b) (6)	(b) (6)
ection A -	- About the Problem					
			Used a product incorrectly whith working a problem with the qualities and problems after switching for the control of the cont	ality of the	•	
Date the	problem oc urred	03-Jun-2022 Yes				
Serious						
Did any of the following happen? (Check all that apply)		Hospitalization - admitted or stayed longer Required help to prevent permanent harm Disability or health problem Birth defect Life-threatening Death Other serious/important medical incident(Please Describe Below)				
ıny additio	nal documents if nece	essar	y)		de ails as possible FDA	
chills, na hours, m was di of viral s	ausea, gastrointestinal illn ny husband took me to the scovered that my liver en	ess, se eme e eme zymes r that,	stomach, abdominal pa ergency room and I was s were quite high and th my skin was jaundiced	n, paint admit a my r as wer	ek Crumbles. Within 16 - 18 out and swollen joints, and few did there for treatment. After sa nagnesium was low. I was re the corners of my eyes and and lethargy.	er. After seven or eight aline and then bloodwork, leased with the diagnosis
elevant T	est/Laboratory Data					1 of 1
				T- (Data	
Test Na	me			Test	Jate	03-Jun-2022
Test Res	sult			Test	Jnit	

Test Name	Test Date	03-Jun-2022	
Test Result	Test Unit		
Low Test Range	High Test Range		
More Information Available?			

Generated by: SYSTEM Generated on: 08-Jul-2022 14:46:25 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-53920 | Department: CFSAN | RCT No.: RCT-1029177 | CTU Triage Date: 11-Jul-2022 | Total Pages: 5

A	dditional Comments					
Se	ection B - Product Availability					
	Do you still have the product in case we need to evaluate it?	No				
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No				
Se	ection C - About the Products			1 of 1		
	Suspect	Yes				
	Primary?	Yes				
	Туре	Drug/Biologi				
	This report is about	Food/Medical food				
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Daily Harvest Crumbles F	Daily Harvest Crumbles French Lentil & Leek			
	Name of the company that makes (or compounds) the roduct	Daily Harvest				
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy Generi Biosimilar	Compounded by a Pharmacy or an Outsourcing Facility Generi			
	Strength		If Other			
	NDC number		,			
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	No				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply				
Dı	rug Therapy			1 of 1		
	Expiration date					
	Lot number					
	Dosage Form					
	Quantity		If Other			
	Frequency		If Other			
	How was it taken or used		If Other			
	Date the person first started aking or using the product	02-Jun-2022				
	Date the person stopped taking or using the product	02-Jun-2022				
	Date the person reduced dose of he product					

Generated by: SYSTEM Generated on: 08-Jul-2022 14:46:25 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-53920 | Department: CFSAN | RCT No.: RCT-1029177 | CTU Triage Date: 11-Jul-2022 | Total Pag es: 5

	Give best estimate of duration		
	Is therapy still on-going?		
Wł	ny was the person using the pr	oduct? (such as what condition was it supposed to treat) 1 of 1	
	his is a food product		
	Returned to Manufacturer On		
Se	ction D - About the Medical De	evice	
	Name of medical device		
01	Name of the company that makes the medical device		
	ner identifying information (The ate them)	e model, catalog, lot, serial, or UDI number, and the expiration date, if you can	
	,		
	Model Number		
	Catalog Number		
	Lot Number		
	Serial Number		
	UDDI Number		
	Expiration date		
	Was someone operating the medical device when the problem oc urred?		
Fo	r implanted medical devices O	NLY (such as pacemakers, breast mplants, etc.)	
	ate the implant was put in	Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o Had the Problem	
	Person's Initials	(b) (6)	
	Sex	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	
	Weight	46.35 kg	
	Ethnicity (Choose only one)	Not Hispanic/Latino	
	Race (Check all that apply)	American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Asian White Black or African American	

Generated by: SYSTEM Generated on: 08-Jul-2022 14:46:25 Page 3 of 5

Lis	st known medical conditions (Such as diabetes, high blood pre_ure, cancer, heart disease, or others)	
PΙε	ease list all allergies (such as to drugs, foods, pollen or o hers)	
	dust, mildew/mold	
Lis	st any other important information about the person (such as moking, pregnancy, alcohol use, etc.)	
Lis	et all current prescription medications and medical devices b ng used.	
Lis	st all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
	entrum womens +50, fish oil, citracal,	
Se	ction F - About the Person Filling Out This Form 1 of 1	

ction F - About the Perso	Filling Out This Form	1 of 1
Primary?	Yes	
Reporter is Patient?		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Number/Street	(b) (6)	
City	(b) (6)	
State/Province		
Country	UNITED STATES	
ZIP or Postal code	(b) (6)	
Telephone number	(b) (6)	
Email address	(b) (6)	
Fax		
Reporter Organization		

Generated by: SYSTEM Generated on: 08-Jul-2022 14:46:25 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-53920 | Department: CFSAN | RCT No.: RCT-1029177 | CTU Triage Date: 11-Jul-2022 | Total Pages: 5

Department		
Reporter Speciality		
Today's date	08-Jul-2022	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?		
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Generated by: SYSTEM Generated on: 08-Jul-2022 14:46:25 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-54027 | Department: IRPSAN | RCT-No.: RCT-1029405 | ICTU Trage Date: 11-Jul-2022 | Total Pag

Company l Source Me	Jnit	CDER-CTU	THE A THE ACT OF THE			
******		GDEIX-CTO	Originating Account	FAERS		
=	dium	MWO (Drug)	Source Form Type	E2B XML 3500		
Priority		Routine				
Override A	uto Calculation Rule	No				
FDA Recei	ved Date	10-Jul-2022	CTU Received Date	10-Jul-2022		
CTU Triage	Date		CTU Data Entry Date			
Report Typ	е	Spontaneous	Report Classification	Drug		
Assign To		User				
User/Group						
Forward to	Department					
Case Priori	ty	Direct				
		1				
ontact			To your	7.00		
Case Reporter	First Name	Last Name	Email Address	Phone		
Z	(b) (6)	(b) (0)	(b) (6)			
Z J						
. PATIEN	IT INFORMATION	_				
Patient	Identifier (In Confidence)	OB nurse SJH				
Age		34 Year(s) Undifferentiated Other Gender category non-binary 63 kg				
Date of	Birth					
Sex						
Gender						
Please	Specify Other Gender					
Weight						
Ethnicity (Check single best answer)		Not Hispanic/Latino				
Race (C	Check all that apply)	Asian American Indian or Alasi Black or African America White Native Hawaiian or Othe	าก			
. ADVER	SE EVENT, PRODUC	T PROBLEM				
	Report (check all that	Adverse Event				

Generated by: SYSTEM Generated on: 10-Jul-2022 00:46:22 Page 1 of 5

CTU No.: FDA-CDER-CTU-2022-54027 | Department: CFSAN | RCT No.: RCT-1029405 | CTU Triage Date: 11-Jul-2022 | Total Pages: 5

		Congenital Anomaly/Birth Defe			
	Date of Death	Required Intervention to Preve	nt Permanent Impairment/Damage		_
	Date of Event	09-Jul-2022			
	Date of this Report	10-Jul-2022			
	· · · · · · · · · · · · · · · · · · ·				
De	escribe Event, Problem or Prod		11 66 30 13 1	F 11 (101 1	
	Crumbles. intractable vomiting	uct Use Error: Hyperbilirubine	em a and hepatitis with daily harvest	French Lentil & Leek	
	· ·				
Re	levant Test/Laboratory Data			1 of 2	
	Test Name	TBILI	Test Date	09-Jul-2022	
	Test Result	6.4	Test Unit	MILLIGRAMS PER DECIL	
	Low Test Range		High Test Range		
	More Information Available?				
Re	elevant Test/Laboratory Data			2 of 2	
1 (0	Test Name	ALT	Test Date	09-Jul-2022	
	Test Result		Test Unit		
		0.336		UNITS PER MILLILITRE	
	Low Test Range		High Test Range		
	More Information Available?				
Ad	ditional Comments				
Ot	her Relevant History, Including	Preexisting Medical Con	dition		
C.	PRODUCT AVAILABILITY				
	Product Available for Evaluation? (Do not send product to FDA)	Yes			
	Returned to Manufacturer on				
	Do you have a picture of the	No			
	roduct? (check yes if you are ncluding a picture)				
D.	PRODUCT(S)			1 of 1	
	Suspect	Yes			
	Primary?	Yes			

Generated by: SYSTEM Generated on: 10-Jul-2022 00:46:22 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-54027 | Department: CFSAN | RCT No.: RCT-1029405 | CTU Triage Date: 11-Jul-2022 | Total Pag es: 5

Туре	Drug/Biologi			
This report involves:	Food/Medical food			
me,Strength,Manufacturer/Co	mpounder (from product	label)		
Product Name	French Lentil & Leek Cruml	bles dailey harvest		
Strength		If Other		
Manufacturer/Compounder				
NDC# or Unique ID				
Product Type(check all that apply)	OTC Compounded Generi Biosimilar			
Event Abated After Use Stopped or Dose Reduced?				
Event Reappeared after Reintroduction ?				
			1 of 1	
Frequency		If Other		
Route		If Other		
Dosage Form				
Start	01-Jul-2022			
Stop				
Dose Reduced				
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Expiration Date				
agnosis for Use (indication)			1 of 1	
SUSPECT MEDICAL DEVICE				
Brand Name				
Common Device Name				
Procode				
Manufacturer Name				
City				
State		-		
Model #				
Lot#				
Catalog #			-	
Expiration Date				
Serial #				
	This report involves: Ime,Strength,Manufacturer/Co Product Name Strength Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? ug Therapy Dose or Amount Frequency Route Dosage Form Start Stop Dose Reduced Therapy Duration Is therapy still on-going? Lot Number Expiration Date agnosis for Use (indication) SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date	This report involves: Food/Medical food me,Strength,Manufacturer/Compounder (from product Product Name French Lentil & Leek Crumi Strength French Lentil & Leek Crumi Strength French Lentil & Leek Crumi Strength French Lentil & Leek Crumi Strength French Lentil & Leek Crumi Strength French Lentil & Leek Crumi Description French Lentil & Leek Crumi Description French Lentil & Leek Crumi Description French Lentil & Leek Crumi Description French Lentil & Leek Crumi Description Lentil & Leek Crumi Description Description French Lentil & Leek Crumi Description Description Product Description Product Description Product P	This report involves: Food/Medical food me_Strength_Manufacturer/Compounder (from product label) Product Name French Lentil & Leek Crumbles dailey harvest Strength If Other Manufacturer/Compounder NDC# or Unique ID Product Type(check all that apply) Product Type(check all that apply) Product Type(check all that apply) Event Abated After Use Stopped or Dose Reduced? Event Reappeared after Reintroduction? Up Therapy Dose or Amount If Other Frequency If Other Frequency If Other Start O1-Jul-2022 Stop Dose Reduced Therapy Duration If Other Is therapy still on-going? Lot Number Expiration Date SUSPECT MEDICAL DEVICE Brand Name Common Device Name Procode Manufacturer Name City State Model # Lot # Catalog # Expiration Date Expiration Date Expiration Date Catalog # Expiration Date Expiration Date Catalog # Expiration Date Expiration Date Date If Other If Other	This report involves: Food/Medical food French Its/Manufacturer/Compounder (from product labe) French Lentil & Leek Crumbles dailey harvest French Leek Crumbles dailey harvest French Lentil & Leek Crumbles dailey harvest French Lentil & Leek Crumbles dailey harvest French Leek Crumbles dailey harvest French Leek Crumbles dailey harvest French Leek Crumbles dailey harvest French Leek Crumbles dailey harvest French Leek Crumbles dailey harvest French Leek Crumbles dailey harvest French Leek Crumbles dailey harve

Generated by: SYSTEM Generated on: 10-Jul-2022 00:46:22 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-54027 | Department: CFSAN | RCT No.: RCT-1029405 | CTU Triage Date: 11-Jul-2022 | Total Pag es: 5

	Unique Identifier (UDI)#		
	Operator of Device	Health Professional	
		Patient/Consumer	
		Other	
	Other		
	If Implanted, Give Date		
	If Explanted, Give Date		
	Is this a single-use device that was reprocessed and reused on a patient?		
	If Yes for the above field, Enter Name and Address of Reprocessor		
	Was this device serviced by a hird party?		
F.	OTHER (CONCOMITANT) ME		
	CONCOMITANT MEDICAL PRODU	UCT DESCRIPTION	
G.	REPORTER	1 of 1	
	Primary?	Yes	
	Reporter is Patient?		
	Title	(EV CO)	
	Last Name	(b) (6)	
	Middle Name	(EV/CV	
	First Name	(b) (6)	
	Address		
	City		
	State/Province/Region		
	Country	UNITED STATES If Other	
	ZIP/Postal Code		
	Phone		
	Email	(b) (6)	
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Health Professional?	Yes	
	Oc upation	Physician If Other	
	Also Reported to	Manufacturer/Compounder	

Generated by: SYSTEM Generated on: 10-Jul-2022 00:46:22 Page 4 of 5

CTU No.: FDA-CDER-CTU-2022-54027 | Department: CFSAN | RCT No.: RCT-1029405 | CTU Triage Date: 11-Jul-2022 | Total Pages: 5

If you do NOT want your identity disclosed to the manufacturer	No No	
--	-------	--

Generated by: SYSTEM Generated on: 10-Jul-2022 00:46:22 Page 5 of 5

CTU No.: FDA-CDER-CTU-2022-54755 | Department: CFSAN | RCT No.: RCT-1029998 | CTU Triage Date: 12-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

All dates display Basic Detai	red in the report are in EST(G	M I -05	(UU) time zone				
		CD	D CTU	0-1	nating Ap audi	FAFDS	
Company U			R-CTU		nating Ac ount	FAERS	_
Source Med	lum		O (Drug)	Sourc	ce Form Type	E2B XML 3500B	\dashv
Priority		Rou	tine				_
Override Auto Calculation Rule FDA Received Date CTU Triage Date Report Type Assign To User/Group Forward to Department		No					
CTU Triage Date		12-			Received Date	12-Jul-2022	
Report Type			CTU Data Entry Date				
		<u> </u>	ntaneous	Repo	rt Classification	Drug	
	Report Type Assign To User/Group Forward to Department Case Priority Contact		<u>r</u>			_	
Forward to [Department	\checkmark					
Case Priorit	y	Dire	ct				
Contact							
Case	First Name		Last Name		Email Address	Phone	
	(h) (6)		(h) (6)		(b) (6)	(b) (6)	_
$\mathbf{\Delta}$	(6) (6)		(6) (6)		(6) (6)	(6) (6)	
Section A -	About the Problem						
		\square	Vere hurt or had a bad side eff	ect (incli	uding new or worsening symptoms)		
(Crieck a	ш шасарріу)		Jsed a product incorrectly which	ch could	have or led to a problem		
			Noticed a problem with the qua	th the quality of the product			
			· · · · · · · · · · · · · · · · · · ·	om one	product maker to another maker		
	problem oc urred						
Serious		Yes					
		\square	Hospitalization - admitted or sta	ayed long	ger		
(Crieck a	ш шасарріу)	<u> </u>	Required help to prevent perma	anent ha	rm		
		∐ˈ	Disability or health problem				
		╽╠┇	Birth defect				
		╎╠╵	ife-threatening				
			Death				
A Tall wa wi			<u> </u>		t(Please Describe Below)	and was about to you for	
		14 1.			. da aila aa waaaibla CDA wa		
any additio	nat happened and how nal documents if nece	w it h	appened (Include as y)	many	de ails as possible FDA m	lay reach out to you for	
any addition	porter						
I ate Dail vere ab	nal documents if nece y Harvest French Lentil a dominal pain. On June 1	essar and Le 6 the	eek Crumbles multiple til pain got worse and was	mes be	etween June 6- June 15. In that npanied by headache and naus	week I experienced sea. I called a nurse	
I ate Dail vere ab hotline the	y Harvest French Lentil a dominal pain. On June 10 lat recommended I go to be bloodwork tested as we	essar and Le 6 the p urger ell as u	eek Crumbles multiple ti pain got worse and was it care. Urgent care sent ultrasound, x-ray, and C	mes be ac or me to	etween June 6- June 15. In that	week I experienced sea. I called a nurse n the hospital. I had	
I ate Dail vere ab hotline the	nal documents if nece y Harvest French Lentil a dominal pain. On June 1 nat recommended I go to	essar and Le 6 the p urger ell as u	eek Crumbles multiple ti pain got worse and was it care. Urgent care sent ultrasound, x-ray, and C	mes be ac or me to	etween June 6- June 15. In that npanied by headache and naus the ER and I stayed the night i	week I experienced sea. I called a nurse n the hospital. I had	

Relevant Test/Lal	ooratory Data		1 of 5
Test Name	COMPREHENSIVE META BOLIC PANEL	A Test Date	16-Jun-2022
Test Result	Bilirubin=2.5mg/dl alkaline hosphate=175units/L	Test Unit	
Low Test Range	bilirubin=.2 alkaline phosp hate= 45	High Test Range	bilirubin=1 alkaline phosp hate=117

Generated by: SYSTEM Generated on: 12-Jul-2022 12:16:23 Page 1 of 5

More Information Available?			
elevant Test/Laboratory Data			2 of 5
Test Name	TCO2 POINT OF CARE	Test Date	16-Jun-2022
Test Result	26	Test Unit	MILLIMOLES PER LITRE
Low Test Range	19	High Test Range	24
More Information Available?			
elevant Test/Laboratory Data			3 of 5
Test Name	BILIRUBIN TOTAL	Test Date	17-Jun-2022
Test Result	3.4	Test Unit	MILLIGRAMS PER DECIL
Low Test Range	.2	High Test Range	1.0
More Information Available?			
elevant Test/Laboratory Data			4 of 5
Test Name	BILIRUBIN DIRECT	Test Date	17-Jun-2022
Test Result	1.5	Test Unit	MILLIGRAMS PER DECII
Low Test Range	0	High Test Range	.2
More Information Available?			J
elevant Test/Laboratory Data			5 of 5
Test Name	ALKALINE PHOSEPHATE	Test Date	17-Jun-2022
Test Result	194	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	45	High Test Range	117
More Information Available?			,
ditional Comments			
ection B - Product Availability			
Do you still have the product in case we need to evaluate it?	Yes		
Do you have a picture of the roduct? (check yes if you are ncluding a picture)	Yes		
ection C - About the Products			1 of 1
Suspect	Yes		
Primary?	Yes		
Туре	Drug/Biologi		
This report is about	Food/Medical food		

Generated by: SYSTEM Generated on: 12-Jul-2022 12:16:23 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-54755 | Department: CFSAN | RCT No.: RCT-1029998 | CTU Triage Date: 12-Jul-2022 | Total Pages: 7

	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Lentil and Leek Crui	mbles		
	Name of the company that makes (or compounds) the roduct	Daily Harvest			
	Product Type(check all that apply)	Over-the-Counter Compounded by a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		If Other		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Yes			
Dr	ug Therapy			1 of 1	
	Expiration date	23-Oct-2022			
	Lot number	L02 L5-A 15:32			
	Dosage Form				
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started aking or using the product	06-Jun-2022			
	Date the person stopped taking or using the product	15-Jun-2022			
	Date the person reduced dose of he product			_	
	Give best estimate of duration				
	Is therapy still on-going?	Yes			
WI	hy was the person using the pr	oduct? (such as what cor	ndition was it supposed to t	reat) 1 of 1	
	Returned to Manufacturer On				
Se	ection D - About the Medical De	evice			
	Name of medical device				П
	Name of the company that makes the medical device				
	her identifying information (The cate them)	e model, catalog, lot, seria	al, or UDI number, and the	expiration date, if you can	

Generated by: SYSTEM Generated on: 12-Jul-2022 12:16:23 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-54755 | Department: CFSAN | RCT No.: RCT-1029998 | CTU Triage Date: 12-Jul-2022 | Total Pag es: 7

	Model Number			\vdash
	Catalog Number			\vdash
	Lot Number			
	Serial Number			\vdash
	UDDI Number			
	Expiration date			
	Was someone operating the medical device when the problem oc urred?			
Fo	r implanted medical devices O	NLY (such as pacemaker	rs, breast mplants, etc.)	
Da	ate the implant was put in		Date the implant was taken out (If relevant)	
Se	ction E - About the Person Wh	o Had the Problem		
	Person's Initials	(b) (6)		
	Sex	Female		
	Gender	Cisgender woman/girl		
	Please Specify Other Gender			
	Age (specify unit of time for age)			
	Date of Birth	(b) (6)		
	Weight	62.1 kg		
	Ethnicity (Choose only one)	Not Hispanic/Latino		
	Race (Check all that apply)	American Indian or Alaska Nati Native Hawaiian or Other Pacif Asian White Black or African American		
Lis	t known medical conditions (S	uch as diabetes, high blo	od pre ure, cancer, heart disease, or others)	
	The second containers (C	and the transfered, ingit old	The production of the control of the	
PΙε	ease list all allergies (such as t	o drugs, foods, pollen or o	o hers)	
	mold			
Lic	t any other important informati	on about the person (suc	h as moking, pregnancy, alcohol use, etc.)	

12-Jul-2022 12:16:23

Page 4 of 5

Generated on:

Generated by: SYSTEM

CTU No.: FDA-CDER-CTU-2022-54755 | Department: CFSAN | RCT No.: RCT-1029998 | CTU Triage Date: 12-Jul-2022 | Total Pages: 7

Lis	t all current prescription medications and medical devices b ng used.	
	atrovent	
Lis	t all over-the-counter medications and any vitamins, mineral, supplements, and herbal remedies being used.	
	ostnatal vitamins	

tion F - About the Person Fill	ing Out This Form 1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	12-Jul-2022
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

Generated by: SYSTEM Generated on: 12-Jul-2022 12:16:23 Page 5 of 5

LENTIL LOZ-VEGEN BEST BY 10/23/2022 L5-A 15/32 BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI TARA

Compost Me

Preparing Crumbles:

- Heat a lightly oiled skillet or non-stick pan over medium-high heat.
- Add the desired amount of frozen Crumbles to the pan, breaking up any large clusters.
- Stirring frequently, sauté until nicely browned and thoroughly cooked to an internal temperature of 165°F, about 5-6 minutes.
- ① Let stand for 1-2 minutes. Enjoy on their own or add to your favorite dish.

PERISHABLE, STORE FROZEN. Do not thaw or refreeze. Cook thoroughly to an internal temperature of 165°F. Fill level and cook time may vary.

Nutrition Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving: Calories 290, Total Fat 18g (23% DV), Saturated Fat 2g (10% DV), Trans Fat 0g, Cholesterol 0mg (0% DV), Sodium 430mg (19% DV), Total 18g (23% DV), Sodium 430mg (19% DV), Protein Carbohydrate 19g (7% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added Sugars, 0% DV), Protein 13g (15% DV), Vitamin D 0mcg (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% DV). The 13g (15% DV), Vitamin D 0mcg (0% DV). Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% DV), Vitamin D 0mcg (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Ocalcium 68mg (10% DV), Iron 4mg (20% DV), Potassium 486mg (10% DV

Ingredients: organic butternut squash, organic hemp seeds, organic cauliflower rice, organic extra virgin olive oil, organic french lentils, organic red lentils, organic tri-colored quinoa, organic cremini mushrooms, organic tara flour, organic leeks, organic parsley, water, organic cassava root flour, organic flax seeds, organic sacha inchi powder, chi organic porcini powder, himalayan sea salt, organic apple cider vinegar, organic onion powder, nutritional yeast, organic garlic powder, organic tornato powder, organic white pepper, organic coriander seeds, organic mustard powder, organic thyme.

MADE IN A FACILITY THAT ALSO PROCESSES TREE NUTS, SOY, DAIRY, & SESAME.

DISTR. BY DAILY HARVEST INC. NEW YORK, NY 10013

CTU No.: FDA-CDER-CTU-2022-55042 | Department: CFSAN | RCT-No. RCT-1030277 | CTU Trage Date: 13-Jul-2022 | Total Pag

All dates displayed in the report are in EST(GMT-05:00) time zone

Relevant Test/Laboratory Data

Test Name

Test Result

Basic Details		200 (200) 200 (200)		
Company Unit	CDER-CTU	Originating Account	FAERS	
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B	
Priority	Routine			
Override Auto Calculation Rule	No			
FDA Received Date	12-Jul-2022	CTU Received Date	12-Jul-2022	
CTU Triage Date		CTU Data Entry Date		
Report Type	Spontaneous	Report Classification	Drug	
Assign To	User	1		
User/Group				
Forward to Department				
Case Priority	Direct	Direct		

Contact	and the same		(m) (m)	B
Case Reporter	First Name	Last Name	Email Address	Phone
	(b) (6)	(b) (6)	(b) (6)	(b) (6)
Section A	- About the Problem		10	
What k	ind of problem was it? all that apply)	Used a product incorrectly was Noticed a problem with the o	effect (including new or worsening symptor which could have or led to a problem quality of the product g from one product maker to another maker	
Date th	e problem occurred	09-Jun-2022	g iron one product manes to anomia maker	
Serious	1	Yes		
	of the following happen? all that apply)	Hospitalization - admitted or Required help to prevent pe Disability or health problem Birth defect Life-threatening Death	rmanent harm	
	serious/important medical t(Please Describe Below)			
4.Tell us v any additi	what happened and how onal documents if nece	vit happened (Include a ssary)	as many details as possible FI	DA may reach out to you for
	e Daily Harvest French Ler e. I continue to experience		nad severe illness including extrem ter.	e pain, fever, nausea and liver

Generated by: SYSTEM Generated on: 12-Jul-2022 21:46:38 Page 1 of 5

Test Date

Test Unit

CTU No.: FDA-CDER-CTU-2022-55042 | Department: CFSAN | RCT No.: RCT-1030277 | CTU Triage Date: 13-Jul-2022 | Total Pages: 5

	Low Test Range		High Test Range		
	More xnformation AvailagleY				
Ad	ditional Comments				
Se	ction B - Product Availaqility				
	Do you still have the product in case we need to evaluate itY	,e			
	Do you have a picture of the productY (checHyes if you are ncluding a picture)	No			
Se	ction C - Aqout the Products			4 of 4	
	Suspect	,е			
	PrimaryY	,е			
	Туре	Drug/Biologi			
	This report is aqout	Food/Medical food			
	Name of the product as it appears on the qo' VqottleV or pacHage (xnclude as many names as you see)	Paily Harvest French Lentil QLeeHCrumqles			
	Name of the company that maH (or compounds) the roduct	Daily H arvest			
	Product Type(checHall that apply)	Over-the-Counter Compounded qy a Pharmacy of Generi Biosimilar	or an Outsourcing Facility		
	Strength		xf Other		
	NDC numqer				
	Did the proqlem stop after the rson reduced the dose or stopped taHng or using the roductY				
	Did the proqlem return if the person started taHng or using the roduct againY				
Dru	ug Therapy			4 of 4	
	E' ration date	23-Oct-2022			
	Lot numqer	L02-VEGBN			
	Dosage Form				
	Quantity		xf Other		
	Frel uency		xf Other		
	How was it taHn or used	Oral	xf Other		
	Date the person first started taHng or using the product				

Generated qy: S, STEM G nerated on: 42-Jul-2022 24:bk:31 Page 2 of 5

CTU No.: FDA-CDER-CTU-2022-55042 | Department: CFSAN | RCT No.: RCT-1030277 | CTU Triage Date: 13-Jul-2022 | Total Pag es: 5

	Date the person stopped taHng or using the product	01-Jun-2022	
	Date the person reduced dose of he product		
	Give qest estimate of duration		
	x therapy still on-goingY		
W	hy was the person using the pr	oductY (such as what condition was it supposed to treat) 4 of 4	
	Returned to Manufacturer On		
Se	ection D - Aqout the Medical De	evice	
	Name of medical device		
	Name of the company that maH the medical device		
	her identifying information (The	e modelVcatalogMotVserialVor UDxnumqerVand the e' piration dateVif you can	
100	cate them)		
	Model Numqer		
	Catalog Numqer		
	Lot Numqer		
	Serial Numqer		
	UDDxNumqer		
	E' ration date		
	Was someone operating the medical device when the proqlem oc urredY		
Fc	or implanted medical devices O	NL, (such as pacemalersVqreast implantsVetc.)	
D	ate the implant was put in	Date the implant was taHen out (xf relevant)	
Se	ection E - Aqout the Person Wh	no Had the Proqlem	
	Person® xnitials	(b) (6)	
	Se'	Female	
	Gender	Cisgender woman/girl	
	Please Specify Other Gender		
	Age (specify unit of time for age)		
	Date of Birth	(b) (6)	
	Weight		
	Ethnicity (Choose only one)		
	Race (ChecHall that apply)	American xndian or AlasHa Native Native Hawaiian or Other Pacific xlander	

Generated qy: S, STEM G nerated on: 42-Jul-2022 24:bk:31 Page 3 of 5

CTU No.: FDA-CDER-CTU-2022-55042 | Department: CFSAN | RCT No.: RCT-1030277 | CTU Triage Date: 13-Jul-2022 | Total Pag

		Asian White BlacHor African American	
Lis	t Hown medical conditions (S	uch as diaqetesVhigh qlood pressureVcancerVheart diseaseVor others)	
PΙ	ease list all allergies (such as t	o drugsVfoodsVpollen or others)	
Lis	t any other important informat	on aqout the person (such as smoHngVpregnancyValcohol useVetc.)	
Lis	t all current prescription medic	cations and medical devices q ng used.	
Lis	t all over-the-counter medicati	ons and any vitaminsVmineralsVsupplementsVand herqal remedies qeing used.	
Se	ction F - Aqout the Person Fill	ing Out This Form 4 of 4	
	PrimaryY	,e	
	Reporter is PatientY		
	Title		
	Last name	(b) (6)	
	Middle Name		
	First name	(b) (6)	
	Numqer/Street	(b) (6)	
	City	(b) (6)	
	State/Province	(6) (6)	
	Country	UNXTED STATES	
	ZxP or Postal code	(b) (6)	
	Telephone numqer	(b) (6) (b) (6)	
	Email address	(1)1 (0)	1

Generated qy: S, STEM G nerated on: 42-Jul-2022 24:bk:31 Page b of 5

CTU No.: FDA-CDER-CTU-2022-55042 | Department: CFSAN | RCT No.: RCT-1030277 | CTU Triage Date: 13-Jul-2022 | Total Pag es: 5

Fa'		
Reporter Organization		
Department		
Reporter Speciality		
Today6 date	42-Jul-2022	
Did you report this proglem to the company that maH the product (the manufacturer/compounder)Y	,e	
xf you do NOT want your dentity disclosed to the manufacturerVplease marHthis qo' (Confidentiality Rel uested):	No	

Generated qy: S, STEM G nerated on: 42-Jul-2022 24:bk:31 Page 5 of 5