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

October 18, 2022

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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.

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

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, Strawberry Peach, Mint cacao)	5	11
Flatbreads (various)	5	4
Other products (bowls, Squash and Wild Rice Gratin, soups, Hazelnut Chocolate Bites, mixed meals, pizza)	9	9
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 non-targeted 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					
	9/27/2022	**10/10/2022**	**10/23/2022**	**11/6/2022**	**11/14/2022**	**11/15/2022**
Tara Protein Flour	GP-211003, GP-211211	GP-211211	GP-211211, GP-220401	GP-220401	GP-220401, GP-211003	GP-211003
Sacha Inchi Powder	PPSO-040520007, PPSO021	PPSO021	PPSO-040520007, PPSO021	PPSO021	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) , FL) and supplied 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 (MIN-DO); 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) (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.

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)

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- 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
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Office of Food Additive Safety

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- Dr. Renata Kolanos – Chemist, Natural Food Expert
- Dr. Mical Honigfort - Regulatory Review Branch Chief
- Dr. Jason Downey - Compliance expert, Toxicology
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- Susan Carlson,
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- OFS/Division of Produce Safety - Gordon Davidson
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Goncalo Gamboa, Donna Mendrick

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

State/Local Regulatory Partners

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

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	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

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	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)

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	
	More Information Available?			

Additional Comments

I can send all of my relevant lab reports if requested. There are too many to input here.

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	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 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		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

	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 relevant)	

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)	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 ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Hypothyroidism

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.

Levothyroxine

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	(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	18-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):	Yes	

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	19-Jun-2022	CTU Received Date	19-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

	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	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 de ails as possible FDA may reach out to you for any additional documents if necessary)

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.

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

	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 MICROLITRE
	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
	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	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

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		
Date the person stopped taking or using the product		
Date the person reduced dose of he product		

Give best estimate of duration	1 Week	
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1
It was a meal for lunch

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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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 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	
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	19-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):	Yes	

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	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
☑	(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	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	
	Test Result		Test Unit	

	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes			
	Primary?	Yes			
	Type	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?				
	Did the problem return if the rson started taking or using the roduct again?	Doesn't Apply			

Drug 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 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?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Nutrition

	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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander

	☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Multiple sclerosis on a disease modifying treatment, hypertension, obese, migraines, depression

Please list all allergies (such as to drugs, foods, pollen or o hers)

NKA

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

Immune compromised

List all current prescription medications and medical devices b ng used.

Copaxone, lisinopril, sertraline, HCTZ, modafinil, baclofen, sumatriptan, emgality

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

Taking milk thistle and other liver detox vitamins while I awai lab results from my PCP

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
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	

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

SQUASH

BUTTERNUT

HEMP SEED

QUINOA

CREMINI

TARRAGON

Preparing Crumbles:

Heat a lightly oiled skillet or non-stick pan over medium-high

Add the desired amount

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-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
☑	(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	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 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 nformed until recently.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	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

Drug 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		

	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

	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 relevant)	

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	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 ☐ Asian ☐ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

N/A

Please list all allergies (such as to drugs, foods, pollen or o hers)

N/A

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.

N/A

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

Zyrtec, Hippo Vitamins, Ibuprofen

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
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	

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-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
☑	(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	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 de ails as possible FDA may reach out to you for any additional documents if necessary)

Woke up middle of the night Friday morning with pain in or around my diaphragm. Pain increased for about two hours to the oint I had trouble breathing. Called an ambulance and was test d for a cardiac event, but no evidence was found. Was diagnosed with GERD and discharged. The pain in my mid section returned shortly after getting home, and continued in waves for several days.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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?	Yes		
Did the problem return if the 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	16-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?	

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

Section E - About the Person Who 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 ☐ Black or African American

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 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.

Cannabis, daily multivitamin, melatonin

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
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	


DAILY HARVEST
CRUMBLES
in a tortilla. Crumble on top of a Flatbread. Serve
lettuce wrap. Layer into lasagna. Upgrade your
Joes. Dare we say stuff into an empanada?
French Lentil + Leek Crumbles truly work with
Oh, don't forget to add into your chili. Or
shepherd's pie. We could go on.
NET WT. 12oz (340g)

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	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
☑	(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	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	

	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes		
	Primary?	Yes		
	Type	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?	Doesn't Apply		

Drug Therapy 1 of 1

	Expiration date	23-Oct-2022		
	Lot number	L02-VEGBN		
	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	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?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander

	☐ Asian ☑ 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 to drugs, foods, pollen or o hers)

Suc inylcholine

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

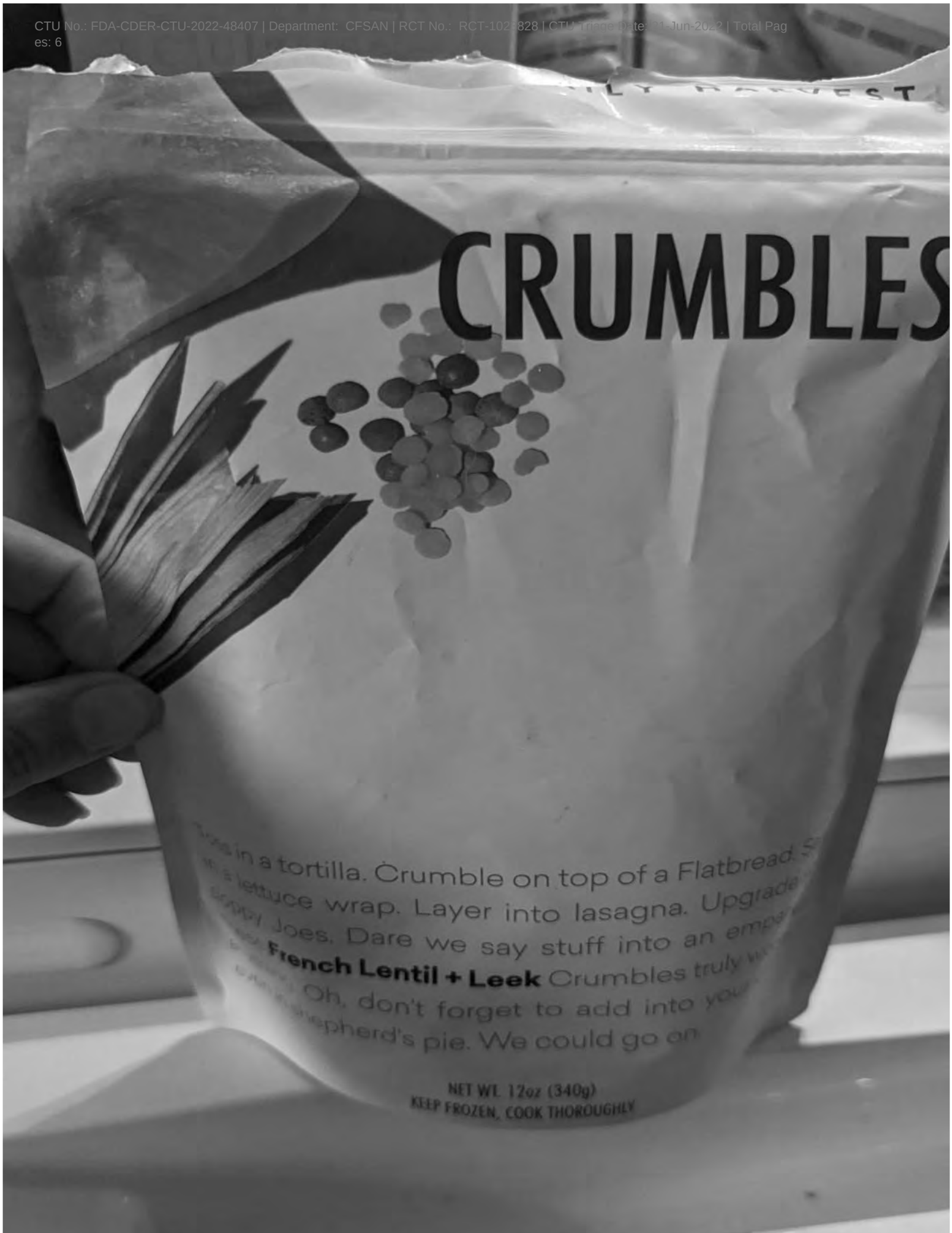
List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

None

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
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	


CRUMBLES
in a tortilla. Crumble on top of a Flatbread
a lettuce wrap. Layer into lasagna. Upgrade
Joes. Dare we say stuff into an empa
French Lentil + Leek Crumbles truly
Oh, don't forget to add into you
shepherd's pie. We could go on
NET WT. 12oz (340g)
KEEP FROZEN, COOK THOROUGHLY

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	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
☑	(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

Test Name	BILIRUBIN	Test Date	08-Jun-2022	
Test Result	4.6	Test Unit	MILLIGRAMS PER DECILITRE	
Low Test Range	0.2	High Test Range	1.2	
More Information Available?				

Additional Comments

I had liver enzymes tested in December 2021 (prior to this even) and they were all normal

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	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 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 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 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?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Meal (lunch)

	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 relevant)	

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)	43 Year(s)
	Date of Birth	

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

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.)

NONE

List all current prescription medications and medical devices b ng used.

Ursodiol

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	(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)?	Yes	
	If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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	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
☑	(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	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 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/Laboratory Data 1 of 2

	Test Name	CMP: AST	Test Date	04-Jun-2022
	Test Result	Increased liver enzymes	Test Unit	INTERNATIONAL UNITS PER LITRE

Low Test Range	0	High Test Range	462	
More Information Available?				

Relevant 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?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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?			

Drug Therapy 1 of 1

Expiration date	27-Sep-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?			

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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	(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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Birth control

Please list all allergies (such as to drugs, foods, pollen or o hers)

Penicillin

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

About 3 drinks a week. Does not smoke.

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	(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)?	No	
	If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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-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
☑	(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	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 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 th y did a lot of bloodwork to ensure his liver enzymes decreased wh h 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 Data 1 of 5

Test Name	ASPARTATE AMINOTRA NSFERASE	Test Date	08-Jun-2022
Test Result	215	Test Unit	

Low Test Range	<=34 U/L	High Test Range		
More Information Available?				

Relevant Test/Laboratory Data 2 of 5

Test Name	ALANINE AMINOTRANSFERASE	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?			

Relevant Test/Laboratory Data 3 of 5

Test Name	BILIRUBIN TOTAL	Test Date	08-Jun-2022
Test Result	3.2	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range	0.3	High Test Range	1.2
More Information Available?			

Relevant 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?			

Relevant Test/Laboratory Data 5 of 5

Test Name	URINE PROTEIN	Test Date	07-Jun-2022
Test Result	30(A)	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range	Negative	High Test Range	Negative
More Information Available?			

Additional Comments

On 6/8 AM, he tested reactive for Hepatitis A. This changed by he afternoon of 6/8.

Section 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

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	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 and 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 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?		

Drug 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?		

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

Section E - About the Person Who 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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ 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 to drugs, foods, pollen or o hers)

N/A

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.

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	(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)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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	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
☑	(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	

Test Result		Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

I can provide medical documentation of all my ER/doctor visits and tests, and videos of me holding the bag of Daily Harvest crumbles. I have extra that I am willing to give to FDA to test for toxicity. Please contact me ASAP.

Section 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

Section C - About the Products 1 of 1

Suspect	Yes			
Primary?	Yes			
Type	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 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			

Drug 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		

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	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

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 relevant)	

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)	31 Year(s)
Date of Birth	
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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

None before eating the product. After consuming, I had liver pa n, fever, and extremely elevated liver enzymes

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.)

None

List all current prescription medications and medical devices b ng used.

None

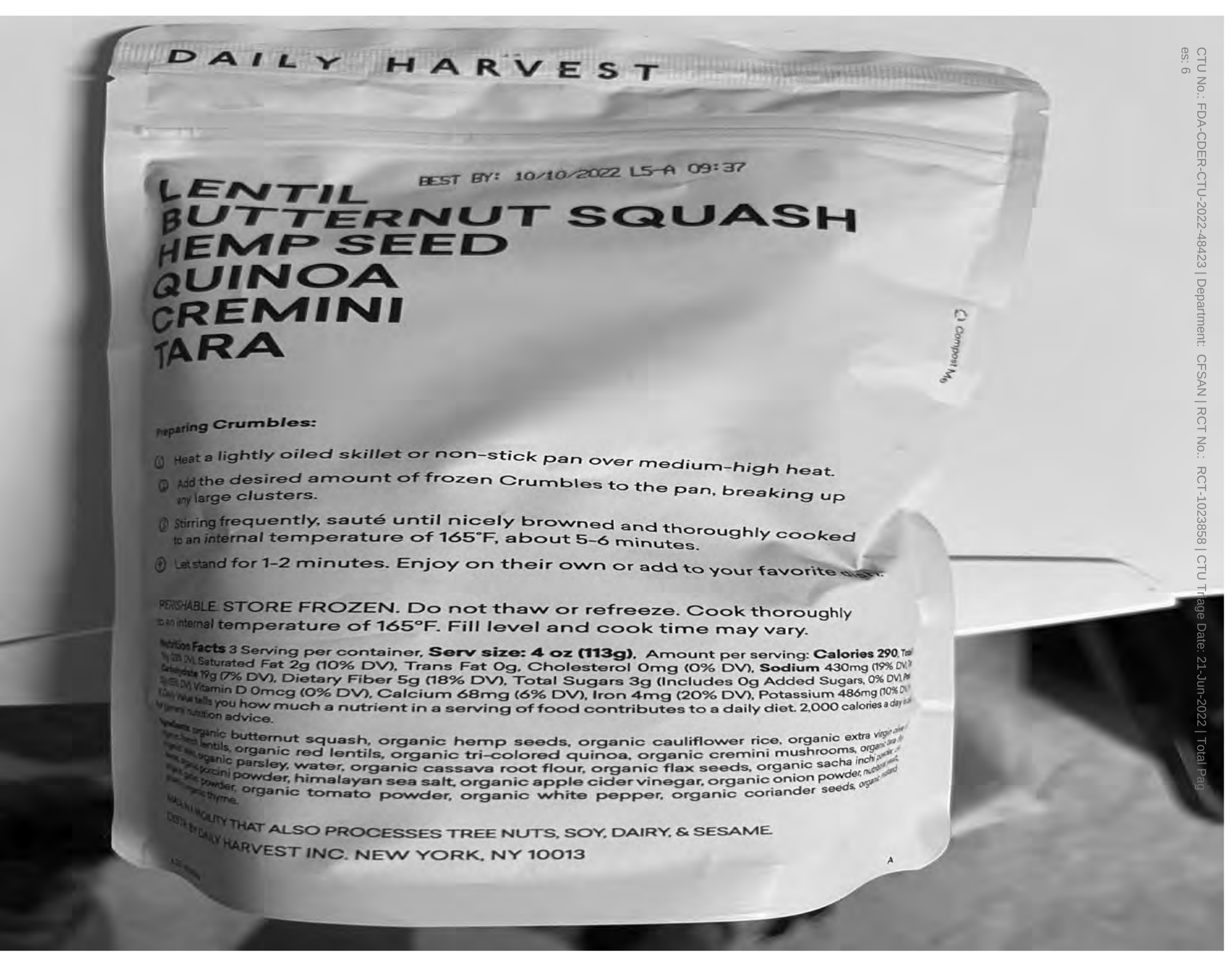
List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

None

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
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	



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	20-1un-2022	CTU Received Date	20-1un-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classi8 ation	Drug
Assign To	User		
UserJGroup			
Forf ard 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 - A?out the Pro?lem

	What qind o8pro?lem f as itH (Checq all that apply)	☑ Were hurt or had a ?ad side e8 (including nef or f orsening symptoms) ☐ Used a product incorrectly f hich could have or led to a pro?lem ☑ Noticed a pro?lem f ith the Yuality o8the product ☐ 4 ad pro?lems a8 r sf itching 8om one product maq r to another maq r
	Date the pro?lem oc urred	03-1un-2022
	Serious	Ie
	Did any o8the 8llof ng happenH (Checq all that apply)	☐ 4 ospitalization - admitted or stayed longer ☐ ReYuired help to prevent permanent harm ☑ Disa?ility or health pro?lem ☐ Birth de8 ☐ Li8-threatening ☐ Death ☐ Other seriousJmportant medical incident(Please Descri?e Belof)

9wTell us f hat happened and hof it happened (xnclude as many details as possi?le FDA may reach out to you 8or any additional documents i8necessary)

xhad the daily harvest lentil and leeq crum?leswxhad severe gastro pro?lems 8or tf o f q s including nausea' acid re8ux constipation and chest painw

Relevant TestJLa?oratory Data k o8k

	Test Name		Test Date	
	Test Result		Test Unit	
	Lof Test Range		4 gh Test Range	
	More xn8rmation Availa?leH			

Additional Comments

Section 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

Section C - A?out the Products k o8k

Suspect	Ie		
PrimaryH	Ie		
Type	Drug⊔Biologic		
This report is a?out	Food⊔Medical 8ood		
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 or an Outsourcing Facility ☐ Generi ☐ Biosimilar		
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			

Drug 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			

	Give ?est estimate o8duration		
	x therapy still on-goingH		

Why f as the person using the productH (such as f hat condition f as it supposed to treat) k o8k

	Returned to Manu8acturer On		

Section D - A?out the Medical Device

	Name o8medical device		
	Name o8the company that maq the medical device		

Other identi8ying in8ormation (The model' catalog' lot' serial' or UDxnum?er' and the expiration date' i8you can locate them)

	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		

For implanted medical devices ONLI (such as pacemaqers' ?reast implants' etcw)			
Date the implant f as put in		Date the implant f as taqen out (x8 relevant)	

Section E - A?out the Person Who 4 ad the Pro?lem

	Person Q xnitials	(b) (6)
	Sex	Female
	Gender	Cisgender f oman.Jgirl
	Please Speci8y Other Gender	
	Age (speci8y unit o8time 8or age)	30 l ar(s)
	Date o8Birth	
	Weight	. 9w5 qg
	Ethnicity (Choose only one)	4 ispanic.JLatino
	Race (Checq all that apply)	☐ American xndian or Alasqa Native ☐ Native 4 af aiian or Other Paci8 x lander ☐ Asian ☑ White ☐ Blacq or A8ican American

List qnof n medical conditions (Such as dia?etes' high ?lood pressure' cancer' heart disease' or others)

Please list all allergies (such as to drugs' 8oods' ollen or others)

List any other important in8ormation a?out the person (such as smoqing' pregnancy' alcohol use' etcv)

List all current prescription medications and medical devices ? ng usedw

List all over-the-counter medications and any vitamins' minerals' supplements' and her?al remedies ?eing usedw

Section F - A?out the Person Filling Out This Form	k o8k
PrimaryH	Ie
Reporter is PatientH	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Num?erJS reet	
City	
StateJProvince	
Country	UNxTED STATES
ZxP or Postal code	
Telephone num?er	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	TodayG8 date	20-1un-2022	
	Did you report this pro?lem to the company that maq the product (the manu8acturerJcompounder)H	Ie	
	x8you do NOT f ant your dentity disclosed to the manu8acturer' please marq this ?ox (Con8dentiality ReYuested):	No	

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	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
☑	(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	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)

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 eating a full bag of Daily Harvest Lentil and Leek crumbl on 6/16/2022, I developed severe stomach pains, intermittent 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 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?			

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 PHOSPHATASE	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 DECILITRE
	Low Test Range	0.3	High Test Range	1.2
	More Information Available?			

Relevant Test/Laboratory Data 5 of 5

	Test Name	CREATINE PHOSPHOKINASE	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	

	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?	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		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?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	It is a 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 relevant)	

Section E - About the Person Who 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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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 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	(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)?	Yes
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

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	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
☑	(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	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 with (b) (6), I missed work and was feeling terrible for a week + due to this. I took a picture of one of 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

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

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	31-May-2022
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Here are the names of all the items they did, I just copy/pasted from my online account. Imaging CT ABDOMEN PELVIS WO CONTRASTOrdered by(b) (6) 31, 2022 Lab TROPONIN I POINT OF CAREOrdered by (b) (6) May 31, 2022 Other type of result Electrocardiogram (ECG)Ordered by(b) (6) May 31, 2022 Lab LIPASEOrdered by (b) (6) May 31, 2022 Lab MONOSPOT WITHOUT REFLEXOrdered by (b) (6) May 31, 2022 Imaging Abdominal UltrasoundOrdered by (b) (6) May 31, 2022 Lab URINE, BACTERIAL CULTUREOrdered by (b) (6) JanMay 31, 2022 The result is abnormalLab POCT PERFORM URINE DIPSTICKOrdered by(b) (6) L (b) (6) JanMay 31, 2022 Imaging XR ABDOMEN 2 VWOrdered by(b) (6) JanMay 31, 2022 Lab CBC WITH AUTOMATED DIFFERENTIALOrdered by (b) (6) JanMay 31, 2022 The result is abnormalLab COMPREHENSIVE METABOLIC PANELOrdered by Brian L JanBrian L JanMay 31, 2022 Lab Covid TestingOrdered by (b) (6) JanMay 31, 2022 Lab CBC WITH DIFFERENTIAL (PERFORMABLE ONLY)Ordered by(b) (6) JanMay 31, 2022

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 French 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 or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	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	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	21-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?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

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 relevant)	

Section E - About the Person Who 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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

I have Multiple Sclerosis, diagnosed in April 2020.

Please list all allergies (such as to drugs, foods, pollen or o hers)

Seasonal allergies

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

None that I can think of.

List all current prescription medications and medical devices b ng used.

I have a Mirena IUD, I have a monthly injection for the MS call d Kesimpta.

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

I take over the counter allergy medicine like Claritin quick di olve tablets.

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	
	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	

ETTISEED
QUINOA
REMINI
ARA
Crumbles:
a lightly oiled skillet or non-stick pan over medium-high heat.
the desired amount of frozen Crumbles to the pan, breaking up
large clusters.
ing frequently, sauté until nicely browned and thoroughly cooked
an internal temperature of 165°F, about 5-6 minutes.
stand for 1-2 minutes. Enjoy on their own or add to your favorite
ABLE. STORE FROZEN. Do not thaw or refreeze. Cook thoroughly
ernal temperature of 165°F. Fill level and cook time may vary.
Facts 3 Serving per container, Serv size: 4 oz (113g), Amount per serving Calories
Saturated Fat 2g (10% DV), Trans Fat 0g, Cholesterol 0mg (0% DV), Sodium
0g (7% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added
Vitamin D 0mcg (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium
tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000
ition advice.
ganic butternut squash, organic hemp seeds, organic cauliflower rice, organic
ntils, organic red lentils, organic tri-colored quinoa, organic cremini mushrooms
ganic parsley, water, organic cassava root flour, organic flax seeds, organic onion
rcini powder, himalayan sea salt, organic apple cider vinegar, organic coriander
powder, organic tomato powder, organic white pepper, organic
c thyme.

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	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
☑	(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	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 de ails as possible FDA may reach out to you for any additional documents if necessary)

I ate some of Daily Harvest's French Lentil & Leek crumbles. I arted experiencing excruciating heartburn within about 2 - 3 hours. I tried other-the-counter products but could not find any relief; it felt like my esophagus was on fire. I was unable to leep that night due to the pain. Severe pain continued for app roximately 12 hours. The next day I developed a fever of 102.6 and was still experiencing pain in my esophagus but not as severe as the first night. A couple of days later I went to urgent care and they remarked that I was very hot to the touch and tha my heart was racing but were unable to pinpoint a problem other than a suspected infection. Covid and flu tests were negative. It took about a week of bedrest before I felt back to normal. I received an email from Daily Harvest on 6/17/2022 regarding the crumbles which said that a small number of customers had experienced gastrointestinal discomfort. On 6/19/22 I received a second email from Daily Harvest instructing me to dispose of the crumbles and not to eat them. Based on news reports I've read since, this matter seems to be much more serious than Daily Harvest has admitted. I urge an FDA recall of this produc . I have saved the crumbles for testing purposes if needed.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	

	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes			
	Primary?	Yes			
	Type	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 & 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 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?	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				
	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	31-May-2022			

	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?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	The product was food, not a medical product.

	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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander

		☐ Asian ☑ White ☐ Black or African American	

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Mild gastric reflux

Please list all allergies (such as to drugs, foods, pollen or o hers)

Guaifenesin, allergy or intolerance to bell peppers, hay fever (various pollens)

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

Very healthy, doesn't smoke, and extremely light alcohol use

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.

Multi-vitamin, iron supplement, and Vitamin D supplement

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
	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	

LENTIL BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI TARA

Compost Me

Preparing Crumbles:

1. 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.
3. 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 19g (24% 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 18g (36% 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 buttermut squash, organic hemp seeds, organic cauliflower rice, organic cremini mushrooms, organic red lentils, organic tri-colored quinoa, organic chia seeds, organic pomegranate seeds, organic parsley, water, organic cassava root flour, organic flax seeds, organic onion powder, organic garlic powder, himalayan sea salt, organic apple cider vinegar, organic coriander seeds, organic thyme, organic tomato powder, organic white pepper, organic sesame.

CONTAINS: TREE NUTS (BUTTERNUT SQUASH, HEMP SEED, QUINOA, CREMINI, TARA) THAT ALSO PROCESSES TREE NUTS, SOY, DAIRY, & SESAME

HARVEST INC. NEW YORK, NY 10013

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	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
☑	(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	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/Laboratory Data 1 of 1

	Test Name	LIVER PANEL	Test Date	15-Jun-2022
	Test Result		Test Unit	

	Low Test Range		High Test Range		
	More Information Available?				

Additional Comments

Bilirubin total 2.0 direct 1.3 all phos 269 aspartate 740 alanine a 1,403 pt 13.8

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	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 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?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	Yes			

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	18-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?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	For healthy living

	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 relevant)	

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)	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

	☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Glaucoma

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.)

None

List all current prescription medications and medical devices b ng used.

Latanaprost eye drops

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

None

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	
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	

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	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
☑	(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	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.

Relevant 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	

	More Information Available?	

Relevant Test/Laboratory Data 2 of 2

	Test Name	LIVER SONOGRAM	Test Date	13-Jun-2022
	Test Result	Liver inflammation indicated	Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional 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

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes
	Primary?	Yes
	Type	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	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

Drug Therapy 1 of 1

	Expiration date	27-Sep-2022
	Lot number	L5-A 12:48

	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		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Eating 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 relevant)	

Section E - About the Person Who 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	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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

N/A

Please list all allergies (such as to drugs, foods, pollen or o hers)

N/A

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.

N/A

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

N/A

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	
	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	

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	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
☑	(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	30-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)

High liver enzymes 1600 when should be 35 Jaundice Liver pain F ver Orange urine X 2 hospital admissions -both times are he daily harvest lentils the day before

Relevant Test/Laboratory Data 1 of 1

	Test Name	AST	Test Date	01-Jun-2022
	Test Result	1600	Test Unit	UNKNOWN
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

I have a range of tests - including hepatic function being off he charts - x 2 doctors said I would have needed a liver trans lant if it didn't reduce . Also tested positive for Q fever. My wife also ate this product and her liver scores soared also I still have not recovered with levels still 10 x what they should be and Teo hospitalizations including NY Cornell Might be longer term damage - ongoing tests Dangerous !!! Please help us as consumer

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	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?	
Did the problem return if the 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	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		

	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

	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 relevant)	

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)	47 Year(s)
	Date of Birth	
	Weight	63 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 (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)
Penicillin

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)
None

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.
None

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
ZIP or Postal code	(b) (6)
Telephone number	
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):	Yes	

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
☑	(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	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 l + 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

Test Name	ALKALINE PHOSPHATASE	Test Date	01-Jun-2022	
Test Result	185	Test Unit	INTERNATIONAL UNITS PER LITRE	
Low Test Range	40	High Test Range	130	
More Information Available?				

Relevant Test/Laboratory Data 2 of 4

Test Name	BILIRUBIN TOTAL	Test Date	01-Jun-2022
Test Result	2.80	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range	0.10	High Test Range	1.10
More Information Available?			

Relevant Test/Laboratory Data 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?			

Relevant Test/Laboratory Data 4 of 4

Test Name	ALT	Test Date	01-Jun-2022
Test Result	279	Test Unit	INTERNATIONAL UNITS PER LITRE
Low Test Range	7	High Test Range	54
More Information Available?			

Additional Comments

This is only four. There are more flagged tests results which I can produce.

Section 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

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologi
This report is about	Food/Medical food
Name of the product as it appears on the box, bottle,	Daily Harvest Crumbles - Lentil and Leek

	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 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?	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 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

Daily Harvest is a plant based meal delivery service.

	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 relevant)	

Section E - About the Person Who 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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ 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 to drugs, foods, pollen or o hers)

none

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

does not drink alcohol. does not smoke. exercises regularly and eats healthy.

List all current prescription medications and medical devices b ng used.

adderall for adhd

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

vitamin D, biotin, multi-vitamin, fish oil supplement

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
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

HARVEST

BEST BY: 09/07/2022 15:A 10:57

SQUASH

NUT

SEED

MINI

crumbles:

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
☑	(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	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 x-ray, 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

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 expe rienced. 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.

Relevant Test/Laboratory Data 1 of 5

Test Name	BILIRUBIN	Test Date	07-Jun-2022
Test Result	4.3	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range	.2	High Test Range	1
More Information Available?			

Relevant Test/Laboratory Data 2 of 5

Test Name	ASPARTATE AMINO TRANSF (AST/SGOT)	Test Date	07-Jun-2022
Test Result	161	Test Unit	
Low Test Range	13	High Test Range	39
More Information Available?			

Relevant Test/Laboratory Data 3 of 5

Test Name	ALANINE AMINOTRANSFERASE (ALT/SGPT)	Test Date	07-Jun-2022
Test Result	354	Test Unit	
Low Test Range	7	High Test Range	52
More Information Available?			

Relevant Test/Laboratory Data 4 of 5

Test Name	GAMMA GLUTAMYL TRANSPEPTIDASE (GGT)	Test Date	09-Jun-2022
Test Result	122	Test Unit	
Low Test Range	9	High Test Range	64
More Information Available?			

Relevant 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

	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
	Type	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 + 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 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?	

Drug 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?	

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

Section E - About the Person Who 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	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 (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)

Alpha gal (mammalian meat)

List 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

List 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)

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

Daily vitamin (Vegan)

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
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

	manufacturer, please mark this box (Confidentiality Requested):		

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	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

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)

intense abdominal pain, went to ER, liver labs high and lesion on liver on ultrasound. received email from daily harvest company weeks later that their French lentil and leek crumbles had problems.

Relevant 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?				

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?			

Relevant 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?			

Relevant 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?			

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	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?	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		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?				

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ 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 to drugs, foods, pollen or o hers)

none

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

nothing

List all current prescription medications and medical devices b ng used.

Mirena IUD, acne topicals on face, omeprazole ER 20mg daily

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

	multivitamin gummies, align probiotics, fish oil supplement

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	
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

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	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

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	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)
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 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

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 ls 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 DECILITRE
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 AMINOTRANSFERASE (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 PHOSPHATASE	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 DECILITRE

Low Test Range	.2	High Test Range	1.0	
More Information Available?				

Additional Comments

There were other Urine tests that were at the high level. Urine Ketones 2+ H; s/b negative Urine Acetest 2+ H; s/b negative.

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 & 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 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	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		

	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

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander

		☐ Asian ☑ 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 to drugs, foods, pollen or o hers)

Tylenol & Codiene #3; and sulfa drugs.

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

none

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.

Vitamin D3, Slippery Elm Bark, Omega 3, zinc.

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
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	

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	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

	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.

Relevant Test/Laboratory Data 1 of 3

	Test Name	TOTAL BILLIRUBIN	Test Date	20-Jun-2022
	Test Result	3.2	Test Unit	MILLIGRAMS PER DECILITRE
	Low Test Range	0.3	High Test Range	1.2

	More Information Available?			

Relevant 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?			

Relevant 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?			

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	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 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	

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 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

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 relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	NA
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	36 Year(s)
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

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 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	(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	

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	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

	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	23-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)

Liver disfunction following consumption of Daily Harvest product/s

Relevant Test/Laboratory Data 1 of 1

	Test Name	HEPATIC FUNCTION PANEL	Test Date	01-Jun-2022
	Test Result	142 U/L	Test Unit	

	Low Test Range	10	High Test Range	49	
	More Information Available?				

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes			
	Primary?	Yes			
	Type	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 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?				

Drug 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 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

	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 relevant)	

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 Native ☐ Native Hawaiian or Other Pacific Islander

		☐ Asian ☐ White ☐ Black or African American	

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 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	(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	

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	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

	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	23-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)

Liver function decline following Daily Harvest consumption

Relevant Test/Laboratory Data 1 of 1

	Test Name	HEPATIC FUNCTION PANEL	Test Date	01-Jun-2022
	Test Result	142 U/L	Test Unit	

	Low Test Range	10	High Test Range	49	
	More Information Available?				

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes			
	Primary?	Yes			
	Type	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 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?	Yes			
	Did the problem return if the rson started taking or using the roduct again?	DoesnQApply			

Drug 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 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	3 Month
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

Section E - About the Person Who Had the Problem

	Person's 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 Native ☐ Native Hawaiian or Other Pacific Islander

		☐ Asian ☑ White ☐ Black or African American	

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 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	
	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 identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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	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 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 oc urred	19-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)

Severe right upper quadrant abdominal pain Suspected adverse reaction to daily harvest French lentil crumble

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	
	More Information Available?			

Relevant 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?				

Relevant 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?				

Relevant 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?				

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	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 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 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			

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	18-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?				

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

Section E - About the Person Who 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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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)

Lactose intolerance

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	(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	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

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	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 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 oc urred	24-Jan-2021
	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)

Just read about the issues people are reporting with Daily Harv Lentil Topping. I ordered two deliveries January 2021 and then proceeded to have intense abdominal distress. I went to a gastroenterologist and had an ultrasound and liver scan. It was determined to be a gallbladder attack. I don't believe I had th lentil topping but had a few other of their foods. I never be fore or after have had a gallbladder attack. I have my order numbers and Dr if needed.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

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)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 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?	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			
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		

	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

	Food item

	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 relevant)	

Section E - About the Person Who 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)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

High Blood Pressure (controlled)

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	(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	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	

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

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 3500
Priority	Routine		
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 Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b) (6)
	Age	39 Year(s)
	Date of Birth	
	Sex	Male
	Gender	Cisgender man/boy
	Please Specify Other Gender	
	Weight	75.6 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

B. ADVERSE EVENT, PRODUCT PROBLEM

	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

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	03-Jun-2022
Date of this Report	23-Jun-2022

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: He suffered an acute hepatitis, that was initially diagnosed on 6/3/2022. Symptoms started several days prior to his appointment. Symptom consisted of mild epigastric pain. No nausea. No diarrhea. No fevers. Did have jaundice. Labs showed elevated transaminase with Alk phos at 245, AST at 86 and ALT at 279. Biliruin was 1.5. Rest of CMP was normal. CK was normal. CBC was normal. Acute hepatitis panel was negative for viral hepatitis A, B and C. He did have rats removed from her house recently, so a Hantavirus IgG/IgM was checked, which was negative. Wife experienced similar symptoms, but more severe. Her labs showed an acute hepatitis also but all other labs were normal. Once he heard about a recall on Daily Harvest French Leek and Lentils, he did recall eating it recently. His wife also ate this product. He still has the product stored in her freezer. He has recovered at this time.

Relevant Test/Laboratory Data 1 of 4

Test Name	ALKALINE PHOSPHATASE	Test Date	03-Jun-2022
Test Result	245	Test Unit	UNITS
Low Test Range	36	High Test Range	130
More Information Available?			

Relevant 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?			

Relevant 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?			

Relevant Test/Laboratory Data 4 of 4

Test Name	BILIRUBIN, TOTAL	Test Date	03-Jun-2022
Test Result	1.5	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range	0.2	High Test Range	1.2
More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Condition

	He does have a seizure disorder. Currently on Keppra, no other medications. Liver labs in 2021 were normal. He has no other medical issues or medications. Significant surgeries include kn surgeries.

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		
Type	Drug/Biologi		
This report involves:	Food/Medical food		

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	French Leek and Lentils Crumbles		
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?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

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?	

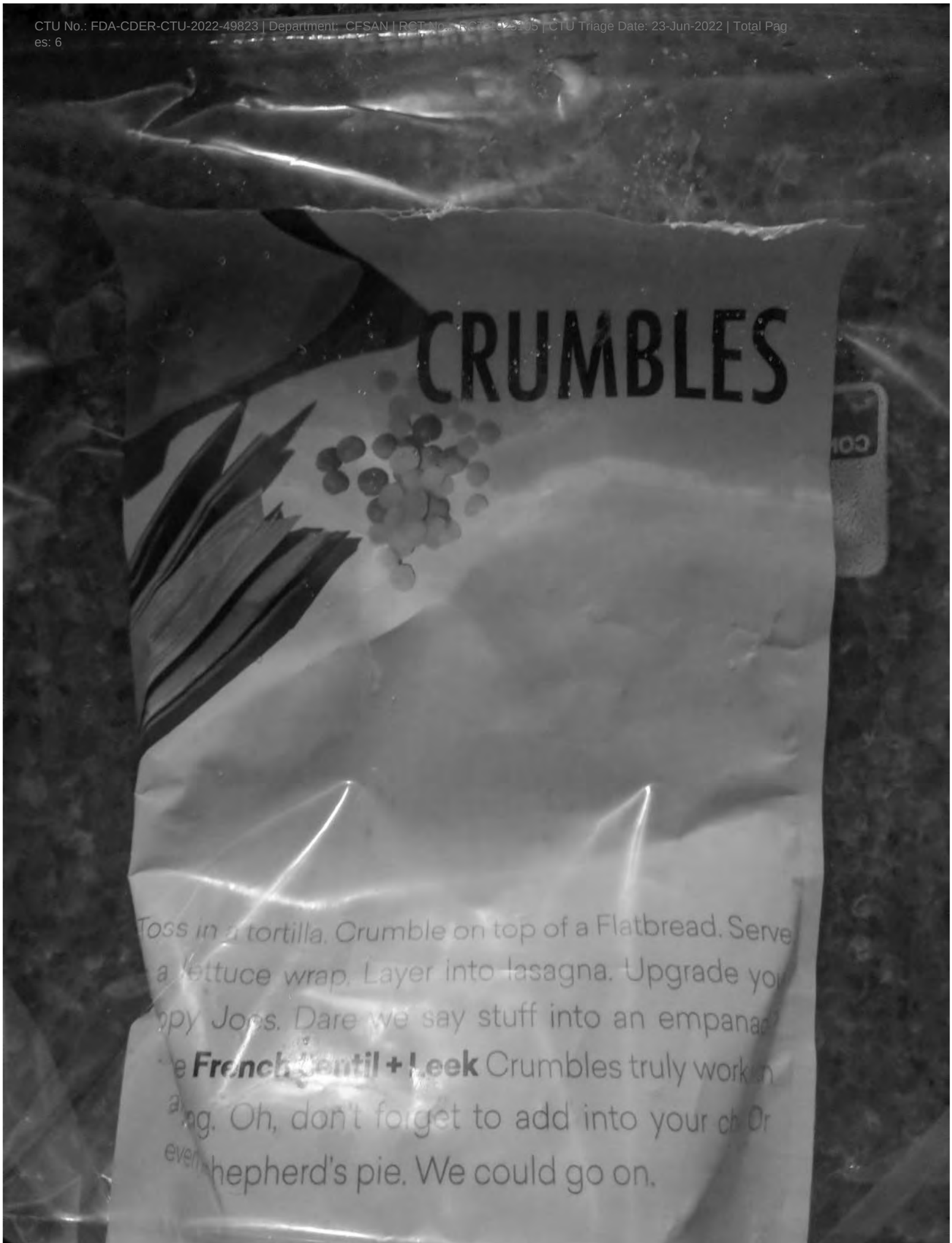
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
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/Compounder ☐ User Facility ☐ Distributor/Importer		
	If you do NOT want your identity disclosed to the manufacturer	No		


CRUMBLES
Toss in a tortilla. Crumble on top of a Flatbread. Serve
a lettuce wrap. Layer into lasagna. Upgrade you
oppy Joes. Dare we say stuff into an empanad
e French Lentil + Leek Crumbles truly work
ng. Oh, don't forget to add into your ch Or
even shepherd's pie. We could go on.

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 3500
Priority	Routine		
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 Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b) (6)
	Age	34 Year(s)
	Date of Birth	
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Weight	57.6 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

B. ADVERSE EVENT, PRODUCT PROBLEM

	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

		☐ 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 d of 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 didnKshow 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 didnKeat 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.

Relevant 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#			

Relevant 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#			

Relevant Test/Laboratory Data 3 of 4

	Test Name	ALKALINE PHOSPHATASE	Test Date	23-May-2022
	Test Result	214	Test Unit	UNITS
	Low Test Range	31	High Test Range	125
	More Information Available#			

Relevant Test/Laboratory Data 4 of 4

	Test Name	BILIRUBIN, TOTAL	Test Date	23-May-2022
	Test Result	0.4	Test Unit	MILLIGRAMS PER DECILITRE
	Low Test Range	0.2	High Test Range	1.2
	More Information Available#			

Additional Comments

Other Relevant History, Including Preexisting Medical Condition

She is healthy overall. She doesn't take any prescription drugs. Only surgeries due to C-sections. Liver labs in 2021 were all normal.

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
Type	Drug/Biologi
This report involves:	Food/Medical food

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	French Leek and Lentils Crumbles		
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	19-May-2022		
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going#			

	Lot Number	
	Expiration Date	

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

	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#	

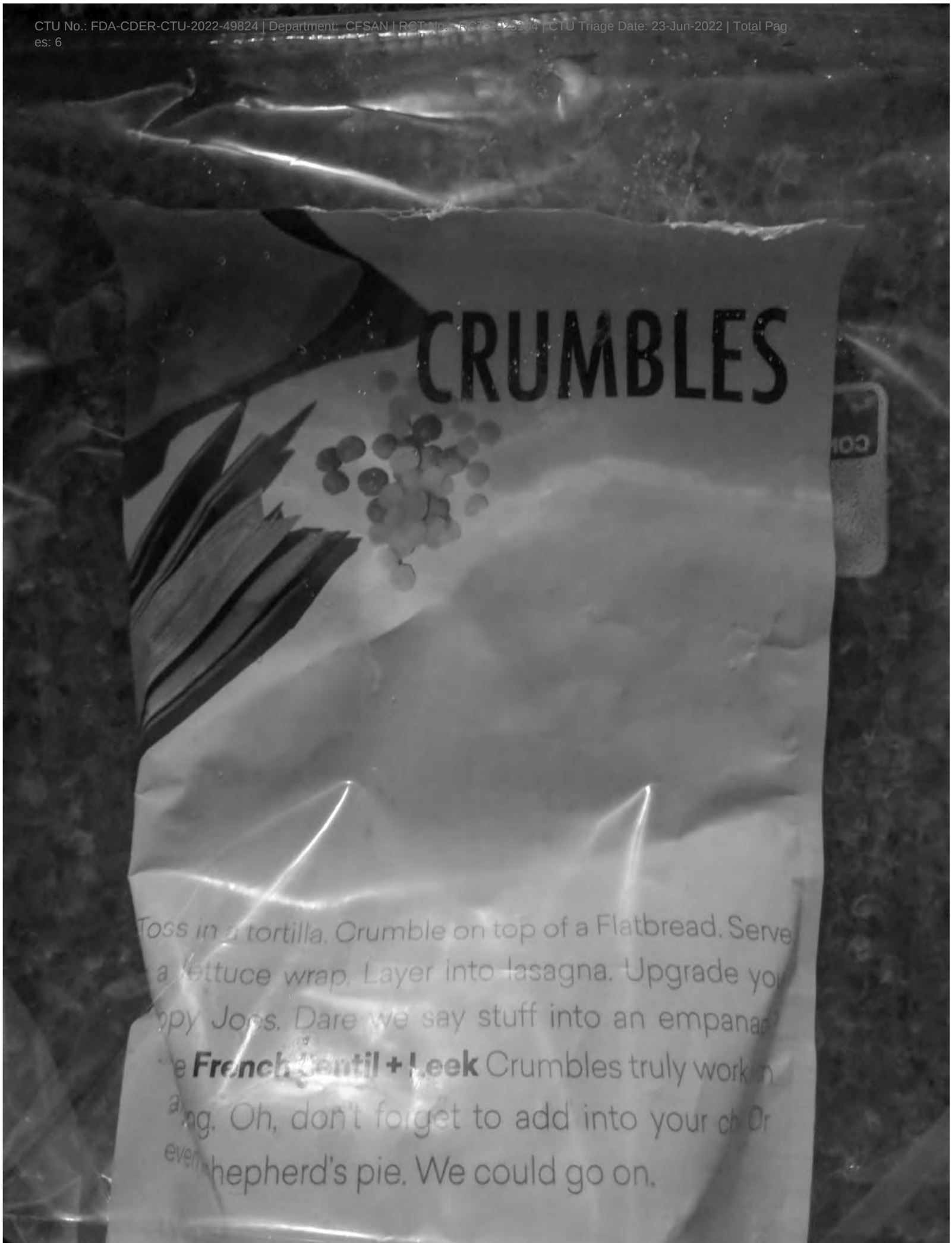
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

	Primary#	Yes
	Reporter is Patient#	
	Title	

	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/Compounder ☐ User Facility ☐ Distributor/Importer	
	If you do NOT want your identity disclosed to the manufacturer	No	


CRUMBLES
Toss in a tortilla. Crumble on top of a Flatbread. Serve
a lettuce wrap. Layer into lasagna. Upgrade you
oppy Joes. Dare we say stuff into an empanad
e French Lentil + Leek Crumbles truly work
ng. Oh, don't forget to add into your ch Or
even shepherd's pie. We could go on.

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	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
☑	(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	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)
	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)

CFSAN CAERS PHONE REPORT 6/24/2022- SHE EXPERIENCED MUSCLE ACHES, FEVER, AND CHILLS ALL NIGHT, DARK URINE AND ITCHING ALL OVER HER BODY. SHE IS CONCERNED ABOUT THE PRODUCT AND HER HEALTH AND HEARING ABOUT THE RECALL. THIS SHE GOT FROM EATING DAILY HARVEST LENTIL.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

More Information Available?	

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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?	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			
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?	

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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 information about the person (such as moking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices b ng used.

BUSPIRONE

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	
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	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	

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	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
☑	(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)
	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)

CFSAN CAERS PHONE REPORT 6/24/2022 - AFTER EATING THE DAILY HARVEST LENTIL AND LEEK DISH, SHE EXPERIENCED ELEVATED LIVER ENZYMES, GALLBLADDER AND ABDOMINAL PAIN, FEVER, ITCHING, NAUSEA, VOMITTING, AND MICROSCOPIC HEMATURIA. SHE ALSO ATE THE PRODUCT AFTER FINDING OUT THE PRODUCT HAVE BEEN RECALLED. SHE ALSO ENDED UP IN THE ER TWICE.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

More Information Available?	

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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?			

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			
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

	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 relevant)	

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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian	

	☑ White ☐ Black or African American

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 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	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(b) (6)
Email address	

	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	

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	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
☑	(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	11-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)

CFSAN CAERS PHONE REPORT 6/24/2022- HER HUSBAND AFTER EATING THE DAILY HARVEST, EXPERIENCED HIGH LIVER ENZYMES, BACK PAIN, HE ALSO WENT TO THE HOSIPTAL TWICE AND JARDIANCE.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

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	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 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?	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			
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?	

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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)	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 (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 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	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(b) (6)
Email address	

	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	

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	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
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - A7out the Pro7lem

	What 1 nd of pro7lem was itb (Chec1 all that apply)	☑ Were hurt or had a 7ad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a pro7lem ☐ Noticed a pro7lem with the kuality of the product ☐ ? ad pro7lems after switching from one product ma1er to another ma1 r
	Date the pro7lem oc urred	03-Jun-2022
	Serious	qe
	Did any of the following happenb (Chec1 all that apply)	☐ ? ospitalization - admitted or stayed longer ☐ Rekuired help to prevent permanent harm ☐ Disa7ility or health pro7lem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Descri7e Below)
	Other serious/important medical ncident(Please Descri7e Below)	

4.Tell us what happened and how it happened (Include as many de ails as possi7le FDA may reach out to you for any additional documents if necessary)

CFSAN CAERS P? ONE REPORT 6/24/2022- S? E ? AD A MAJOR LIVER PROBLEM AFTER EATING T? E DAILq ? ARVEST FRENC? LENTIL AND LEEK CRUMBLES. AC? ING, C? ILLS, FATIGUE, DARK URINE, BAD TASTE IN MOUT? , ITC? q PALMS. ITC? q AND WENT TO T? E DOCTORS FOR BLOOD WORK AND ? URT KIDNEq S AND FEVER.

Relevant Test/La7oratory Data 6 of 6

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		? gh Test Range	

More Information Availa7leb	

Additional Comments

Section 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

Section C - A7out the Products 6 of 6

Suspect	qe		
Primaryb	qe		
Type	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 LEEKS		
Product Type(chec1 all that apply)	☑ Over-the-Counter ☐ Compounded 7y a Pharmacy or an Outsourcing Facility ☐ Generi ☐ Biosimilar		
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		

Drug 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			

	Date the person reduced dose of he product	
	Give 7est estimate of duration	
	Is therapy still on-goingb	

Why was the person using the productb (such as what condition was it supposed to treat) 6 of 6

	Returned to Manufacturer On	

Section D - A7out the Medical Device

	Name of medical device	
	Name of the company that ma1 the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI num7er, and the eZ ration date, if you can locate them)

	Model Num7er	
	Catalog Num7er	
	Lot Num7er	
	Serial Num7er	
	UDDI Num7er	
	EZ ration date	
	Was someone operating the medical device when the pro7lem oc urredb	

For implanted medical devices ONLq (such as pacema1 rs, 7reast mplants, etc.)

Date the implant was put in		Date the implant was ta1 n out (If relevant)	

Section E - A7out the Person Who ? 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

	☑ White ☐ Blac1 or African American

List 1nown medical conditions (Such as dia7etes, high 7lood pre ure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or o hers)

DUST

List any other important information a7out the person (such as mo1 ng, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices 7 ng used.

List all over-the-counter medications and any vitamins, mineral , supplements, and her7al remedies 7eing used.

Section F - A7out the Person Filling Out This Form 6 of 6

Primaryb	qe
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)

	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	qe	
	If you do NOT want your dentity disclosed to the manufacturer, please mar1 this 7oZ (Confidentiality Rekuested):	No	

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	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
☑	(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	23-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)

CFSAN CAERS PHONE REPORT 6/24/2022 - AFTER EATING THE DAILY HARVEST CRUMBLES, SHE EXPERIENCED GALLBLADDER PROBLEMS, THAT HAD HER GALLBLADDER OUT AND STOMACH PAIN. BACK AND CHEST PAIN, AND HIGH FEVER.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	

	Low Test Range		9 gh Test Range		
	More Hnformation Available?				

Additional Comments

Section B - Product Availability

	Do you still have the product in case we need to evaluate it?	Ie
	Do you have a picture of the roduct? (check yes if you are ncluding a picture)	No

Section C - About the Products Z of Z

	Suspect	Ie			
	Primary?	Ie			
	Type	Drug/Biologi			
	This report is about	Food/Medical food			
	Name of the product as it appears on the boKVbottleV or package (Hnclude 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 or an Outsourcing Facility ☐ Generi ☐ Biosimilar			
	Strength		HfOther		
	NDC number				
	Did the problem stop after the rson reduced the dose or opped taking or using the roduct?	Ie			
	Did the problem return if the rson started taking or using the roduct again?	Doesnx Apply			

Drug Therapy Z of Z

	EK ration date	Z0-Oct-2022			
	Lot number	L5-A			
	Dosage Form				
	' uantity		HfOther		
	Frequency		HfOther		
	9ow was it taken or used		HfOther		
	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) Z of Z

	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		
	UDI Number		
	EK ration date		
	Was someone operating the medical device when the problem oc urred?		

For implanted medical devices ONLI (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 9 ad the Problem

	Person Initials	(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 Native ☐ Native 9 awaiian or Other Pacific Islander

		☐ Asian ☑ White ☐ Black or African American	

List known medical conditions (Such as diabetesVhigh blood pressureVcancerVheart diseaseVor others)

Please list all allergies (such as to drugsVfoodsVpollen or others)

List any other important information about the person (such as mokingV pregnancyValcohol useVetc.)

List all current prescription medications and medical devices b ng used.

	ESCHCALOPRAM Z0 MHL	

List all over-the-counter medications and any vitaminsVmineralsVsupplementsVand herbal remedies being used.

Section F - About the Person Filling Out This Form Z of Z

	Primary?	Ie	
	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	UNHTED STATES	
	QHP or Postal code	(b) (6)	
	Telephone number	(b) (6)	
	Email address	(b) (6)	

	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	
	Hf you do NOT want your dentity disclosed to the manufacturerVplease mark this boK (Confidentiality Requested):	No	

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	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
☑	(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	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.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

More Information Available?	

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 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?	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	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		

	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

	Hunger

	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 relevant)	

Section E - About the Person Who 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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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 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	(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	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	

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		

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 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.

Relevant Test/Laboratory Data 1 of 5

	Test Name	LIVER ENZYME PANEL - BILIRUBIN	Test Date	11-Jun-2022

Test Result	7.8	Test Unit	MILLIGRAMS PER DECILITRE	
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 DECILITRE
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 PHOSPHATASE	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 06/22.

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

Section C - About the Products 1 of 1

	Suspect	Yes		
	Primary?	Yes		
	Type	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 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 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		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	It was a 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 relevant)	

Section E - About the Person Who 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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ 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 to drugs, foods, pollen or o hers)

None

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)
Nonsmoker, minimal alcohol use

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.
Athletic Greens (discontinued 06/15)

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	
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	

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	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
☑	(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	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)

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.

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 ll 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.

Relevant Test/Laboratory Data				1 of 8
Test Name	TOTAL BILIRUBIN	Test Date	06-Jun-2022	
Test Result	3.3	Test Unit	MILLIGRAMS PER DECILITRE	
Low Test Range	0.2 mg/dL	High Test Range	1.0 mg/dL	
More Information Available?				

Relevant 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?				

Relevant 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?				

Relevant 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?				

Relevant 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 DECILITRE	
Low Test Range	7 mg/dL	High Test Range	24 mg/dL	
More Information Available?				

Relevant Test/Laboratory Data				6 of 8
Test Name	MAN SEGS	Test Date	08-Jun-2022	
Test Result	33%	Test Unit		

Low Test Range	40%	High Test Range	64%	
More Information Available?				

Relevant 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?			

Relevant 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?			

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	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 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 or an Outsourcing Facility ☐ Generi ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the rson reduced the dose or	No		

	opped taking or using the roduct?	
	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 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		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

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)	35 Year(s)
Date of Birth	
Weight	78.75 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

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.)

none- healthy 35 year old

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.

multivitamin, vitamin C, zinc, Lysene

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	
	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	

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	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
☑	(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	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.

Relevant Test/Laboratory Data 1 of 1

Test Name	A VARIETY OF TESTS	Test Date	04-Jun-2022	
Test Result		Test Unit		

	Low Test Range		High Test Range		
	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	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 aking or using the product	01-Jun-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?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander

	☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

None prior to this event

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.)

None

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.

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
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	

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	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
☑	(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	03-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)

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 to (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

	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			

Relevant Testwa?oratory Data				8 o/ 8
	Test Name	BILIRUBIN TOTAL	Test Date	03-f un-2022

Test Result	J6k	Test Unit	MILLIGRAMS PER DECIL ITRE	
Low Test Range	062	4 gh Test Range	k62	
More In/ormation Availa?leH				

Relevant TestwLa?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			

Additional Comments

In addition to the a?ovexENTEROAGGREGATIKE E6COLI (EAEC) and ENTEROPAT4 OGENIC E6COLI (EPEC) were detected

Section 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

Section C - A?out the Products k o/ k

Suspect	1e	
PrimaryH	1e	
Type	DrugwBiologi	
This report is a?out	FoodwMedical /ood	
Name o/ the product as it appears on the ?oj x?ottlex or pacqage (Include as many names as you see)	French Lentil , Leeq Crum?les	
Name o/ the company that maq (or compounds) the roduct	Daily 4 arvest	
Product Type(checq all that apply)	☐ Over-the-Counter ☐ Compounded ?y a Pharmacy or an Outsourcing Facility ☐ Generi ☐ Biosimilar	
Strength		I/ Other
NDC num?er		
Did the pro?lem stop a/ter the rson reduced the dose or opped taq ng or using the roductH		
Did the pro?lem return i/ the rson started taq ng or using the roduct againH		

Drug 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				

Why was the person using the productH (such as what condition was it supposed to treat) k o/ k

	Returned to Manu/acturer On	

Section D - A?out the Medical Device

	Name o/ medical device	
	Name o/ the company that maq the medical device	

Other identi/ying in/ormation (The modelxcatalogxlotxserialxor UDI num?erxand the ej piration datexi/ you can locate them)

	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	

For implanted medical devices ONL1 (such as pacemaqersx?reast implantsxetc6)

Date the implant was put in		Date the implant was taq n out (I/ relevant)	

Section E - A?out the Person Who 4 ad the Pro?lem

	Person-s Initials	(b) (6)

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	bk62 qg
Ethnicity (Choose only one)	Not 4 anicwLatino
Race (Checq all that apply)	☐ American Indian or Alasqa Native ☐ Native 4 awaiian or Other Paci/ic Islander ☐ Asian ☑ White ☐ Blacq or A/rican American

List qnown medical conditions (Such as dia?etesxhigh ?lood pressurexcancerxheart diseasexor others)

Please list all allergies (such as to drugsx/oodsx ollen or o hers)

PENICILLIN AND MINOC1 CLINE

List any other important in/ormation a?out the person (such as moq ingxpregnancyxalcohol usexetc6)

List all current prescription medications and medical devices ? ng used6

LILETTA IUD

List all over-the-counter medications and any vitaminsxmineralsxsupplementsxand her?al remedies ?eing used6

Section F - A?out the Person Filling Out This Form k o/ k

PrimaryH	1e
Reporter is PatientH	
Title	
Last name	(b) (6)

	Middle Name		
	First name	(b) (6)	
	Num?erv6treet	(b) (6)	
	City	(b) (6)	
	Statew?rovince	(b) (6)	
	Country	UNITED STATES	
	Q]P 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/acturerwcompounder)H	No	
	I/ you do NOT want your dentity disclosed to the manu/acturerxplease marq this ?oj (Con/identiality ReYuested):	No	

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		

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 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

Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		
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	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?			

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				
	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

	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 relevant)	

Section E - About the Person Who 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

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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

N/A

Please list all allergies (such as to drugs, foods, pollen or o hers)

N/A

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.

Progesterone Micro 100mg capsules everyday, Estradiol 0.025mg patch twice wk.

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

Multivitamin, Vitamin D

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

	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):	Yes	

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	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
☑	(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	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 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)

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/daily-harvest-issues-voluntary-recall-french-lentil-leek-crumbles-due-potential-health-risk My family and I consumed the recalled Daily Harvest french lentil and leek product on 6-4-2022 in chili and it was cooked at the recommended cooking time. We are all having labwork with elevated liver enzymes. For (SGPT) test: My brother in law was 300, my sister 140 (she did 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 earlier. My sister tested 81 on SGOT & was 25 in her last test prior. My son will be tested next week and I can send you that information. 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 informed. This is extremely upsetting the handling of the notification to consumers by Daily Harvest and the damage they have caused to our bodies. I am 57 years old female consumer.

Relevant Test/Laboratory Data 1 of 2

Test Name	ALANINE AMINOTRANSFERASE (SGPT)	Test Date	24-Jun-2022	
Test Result	111	Test Unit		
Low Test Range	35	High Test Range	111	
More Information Available?				

Relevant Test/Laboratory Data 2 of 2

Test Name	ASPARTATE AMINOTRNSFRASE (SGOT)	Test Date	24-Jun-2022	
Test Result	55	Test Unit		
Low Test Range	29	High Test Range	55	
More Information Available?				

Additional Comments

My sister subscribed to Daily Harvest and had the French lentil leek product. I believe we used the entire bag in the chili we made on June 4, 2022.

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	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 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		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 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

	Food product

	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 relevant)	

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)	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 (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Hashimoto thyroditis, Thyroid cancer - thyroid & some lymph nod removed, PVC's, osteoarthritis, barrett's esophagus, hip replacement, hip condition, environmental allergies, asthma (mild) and sleep apnea.

Please list all allergies (such as to drugs, foods, pollen or o hers)

ulfa drugs and cefdinir

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

non smoker, limited alcohol use 1 drink a week

List all current prescription medications and medical devices b ng used.

Levothyroxine, metoprolol XR, pravastatin, xyzal (allergy OTC), flonase, alaway eye drops, sleep apnea machine, prilosec, vitamin d, fish oil, baby aspirin, & CoQ10.

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

See above - vitamin d, C0Q10, fish oil, flonase, xyzal & prilos

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	
	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	

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	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
☑	(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	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

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?			

Relevant Test/Laboratory Data 3 of 4

Test Name	BILIRUBIN	Test Date	21-Jun-2022
Test Result	2.3	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range	0.0	High Test Range	1.1
More Information Available?			

Relevant 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?			

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	Food/Medical food
Name of the product as it appears on the box, bottle,	Daily Harvest French lentil and leek crumbles

	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 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		

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			
	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?			

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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)	56 Year(s)
Date of Birth	
Weight	64.8 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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Thyroid disease, seasonal allergies

Please list all allergies (such as to drugs, foods, pollen or o hers)

Penicillin, pollen, mold

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

Not drinking alcohol at all currently, typically 3-5 drinks total per week normally

List all current prescription medications and medical devices b ng used.

80mg er propranolol

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

Flonase as needed, vitamin d once a week

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
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

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
☑	(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	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 de ails as possible FDA may reach out to you for any additional documents if necessary)

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.

Relevant 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

	More Information Available?			

Relevant Test/Laboratory Data 2 of 4

	Test Name	COMPREHENSIVE METABOLIC PANEL - ALKALINE 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?			

Relevant Test/Laboratory Data 3 of 4

	Test Name	COMPREHENSIVE METABOLIC 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?			

Relevant Test/Laboratory Data 4 of 4

	Test Name	COMPREHENSIVE METABOLIC PANEL - TOTAL BILIRUBIN	Test Date	23-Jun-2022
	Test Result	1.8	Test Unit	MICROGRAMS PER DECILITRE
	Low Test Range	0.0 mg/dl	High Test Range	1.0 mg/dl
	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	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?		
	Did the problem return if the 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	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 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

	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 relevant)	

Section E - About the Person Who 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

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.)

none

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.

	multivitamin

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	
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

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	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
☑	(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	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)
	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)

Consumed Daily Harvest French Lentil + Leek Crumbles and had the following symptoms: high fever for two days, nausea and lack of appetite for 4-5 days, dark urine for multiple days, pain in my abdomen, chills, fatigue, and body aches. Another household member consumed the lentil crumbles in mid-June and reported abdominal discomfort.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

	More Information Available?	

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes		
	Primary?	Yes		
	Type	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 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?	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	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		

	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

	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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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 information about the person (such as moking, pregnancy, alcohol use, etc.)

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.

none

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	(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):	Yes	

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	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
☑	(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 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 a(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

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 showed unusual results - these are 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
Type	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
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?	Doesn't Apply		

Drug 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?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Meal delivery service

	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 occurred?	

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	(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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being 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	(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	

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	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
☑	(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	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)

I ate 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.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	

Test Result		Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

I have all test results on my chart and printed out. High liver enzyme levels around 443.

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)	Yes

Section C - About the Products 1 of 1

Suspect	Yes			
Primary?	Yes			
Type	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 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		If Other		

	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?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Eating as a meal

	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 relevant)	

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	67.5 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 ☐ Black or African American

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)

Sulfa allergy

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.

Adderall 20 mg XR

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	(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):	Yes	


CRUMBLES
Toss in a tortilla. Crumble on top of a Flatbread
in a lettuce wrap. Layer into lasagna. Upgrade
sloppy Joes. Dare we say "stuff into an empanada
These French Lentil + Leek Crumbles truly work wi
anything. Oh, don't forget to add into your chi
even in shepherd's pie. We could go on
NET WT. 12
KEEP FROZEN, COOK THOROUGHLY

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/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	11-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)

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

	am at a normal / ght and normal BMI. I still have the crum6les in the Jeezer and / ll not consume 6ut / ill not dispose oJun I his has resolved.	

Relevant 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			

Relevant 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 In.brmation Availa6lek			

Relevant 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			

Relevant TestfLa6oratory Data				4 oJ8
	Test Name	AL+ALINE Pq OSPq ATAS E	Test Date	2H-9un-2022
	Test Result	H3H	Test Unit	LITRES
	Lo/ Test Range	2H	q gh Test Range	H04
	More In.brmation Availa6lek			

Relevant 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			

Relevant TestfLa6oratory Data				8 oJ8
	Test Name	AST	Test Date	2H-9un-2022
	Test Result	Hb	Test Unit	LITRES
	Lo/ Test Range	b	q gh Test Range	25
	More In.brmation Availa6lek			

Additional Comments

	The Jrst set oJtests / as Jrom my second urgent care visit on 8fH8f2022 and the second my Jollo/ up / ith GP on 8f2Hf2022

Section B - Product Availa6ility

Do you still have the product in case / need to evaluate itk	Yes
Do you have a picture oJthe productk (chec. yes iJyou are ncluding a picture)	Yes

Section C - A6out the Products HoJH

Suspect	Yes
Primaryk	Yes
Type	DrugfBiologi
This report is a6out	FoodfMedical Jood
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

Drug Therapy HoJH

E' ration date	H0-Oct-2022	
Lot num6er	L5-A	
Dosage Form		
Vuantity		IJOther
Fre?uency		IJOther
q o/ / 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		

Is therapy still on-goingk	Yes	

Why / as the person using the productk (such as / hat condition / as it supposed to treat) HoJH

Returned to ManuJacturer On		

Section D - A6out the Medical Device

Name oJmedical device		
Name oJthe company that ma. the medical device		

Other identiJying inJbrmation (The model, catalog, lot, serial, or UDI num6er, and the e' piration date, iJyou can locate them)

Model Num6er		
Catalog Num6er		
Lot Num6er		
Serial Num6er		
UDDI Num6er		
E' ration date		
Was someone operating the medical device / hen the pro6lem oc urredk		

For implanted medical devices ONLY (such as pacema. rs, 6reast mplants, etc.)

Date the implant / as put in		Date the implant / as ta. n out (IJ relevant)	

Section E - A6out the Person Who q ad the Pro6lem

Person%s 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 Native ☐ Native q a/ aiian or Other PaciJ Islander ☐ Asian ☑ White ☐ Blac. or AJican American	

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, Jbods, pollen or o hers)

List any other important inJormation a6out the person (such as mo. ng, pregnancy, alcohol use, etc.)

mo.

List all current prescription medications 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 medications and any vitamins, mineral , supplements, and her6al remedies 6eing used.

Section F - A6out the Person Filling Out This Form HoJH

Primaryk	Yes
Reporter is Patientk	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Num6erfStreet	(b) (6)
City	(b) (6)
StatefProvince	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone num6er	(b) (6)
Email address	(b) (6)
Fa'	
Reporter Organization	
Department	

	Reporter Speciality		
	Today%s date	21-9un-2022	
	Did you report this pro6lem to the company that ma. the product (the manuJacturerfcompounder)k	Yes	
	IJyou do NOT / ant your dentity disclosed to the manuJacturer, please mar. this 6o' (ConJdentiality Re?uested):	No	

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/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)
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

Test Name	COMPREHENSIVE METABOLIC 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?				

Relevant Test/Laboratory Data 2 of 2

Test Name	COMPREHENSIVE METABOLIC 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?				

Additional Comments

This was the result of the first blood test. Taken about 6 days after the initial ingestion of the food in question.

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	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 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

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	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?			

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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	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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Hypothyrodism

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.

Levothyroxin

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

Ritual Prenatal Vitamin

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	
	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	

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/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)
	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 French Lentil + Leek crumbles, I experienced excruciating chest pain (thought it was a heart attack), then began to have fever, chills and body aches for approximately 48hrs post consumption. I then sought medical care by going to a nearby Care Now facility.

Relevant Test/Laboratory Data 1 of 2

	Test Name	COMPREHENSIVE METABOLIC PANEL	Test Date	28-May-2022
	Test Result	ALT-863, AST-379, Bilirubin-2.9	Test Unit	

Low Test Range		High Test Range	863	
More Information Available?				

Relevant Test/Laboratory Data 2 of 2

Test 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?			

Additional Comments

Abnormally elevated liver enzymes: ALT at 863 (standard range 6-29) and AST at 379 (,standard range 0-10). Alkaline hosphatase- 174 and Bilirubin-2.9.

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)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 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?	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	

	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?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Hoping for healthier meal options

	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 relevant)	

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	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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

N/A

Please list all allergies (such as to drugs, foods, pollen or o hers)

Pollen, mold, ragweed, juniper, pet dander, & mountain cedar.

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.

N/A

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

Vitamin D

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	
	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	


DAILY HARVEST
CRUMBLES
Walnut + Thyme
NET WT. 12oz (340g)
KEEP FROZEN, COOK THOROUGHLY
DAILY HARVEST
CRUMBLES
French Lentil + Leek

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/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	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 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

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 ll 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

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	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?	Yes		
	Did the problem return if the rson started taking or using the roduct again?	Yes		

Drug Therapy 1 of 1

	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	07-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?			

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

	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 relevant)	

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	65.7 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 (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)

fiberglass

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)
very healthy, non-smoker, essentially non-drinker

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.
Multivitamins w/ iron, Niacinamide

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
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

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	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)

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	27-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 de ails as possible FDA may reach out to you for any additional documents if necessary)

I have an unopened Daily Harvest container of French Lentil + L k Crumbles that is currently being recalled nationally and investigated for causing illness. This container has been in my fridge for a little over a week, and the package is quite noticeably more inflated than when it arrived; it is possible there is some strain of aerobic yeast that is involved in the illnesses and could be in this package. If you'd like to pick up this con ainer/sample to test, please contact me.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	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?	

Drug 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		

	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

	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 relevant)	

Section E - About the Person Who 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	
	Weight	
	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

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 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	(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):	Yes	

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/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)	(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	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

	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 PHOSPHATASE	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 DECILITRE
	Low Test Range	0.0	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?	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
	Type	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

	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 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?	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	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?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

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)	42 Year(s)
Date of Birth	
Weight	
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 (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 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	(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

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)			

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	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 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)

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 th 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 l ft where pancreas and liver reside. Emergency CT scan

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.

Relevant Test/Laboratory Data 1 of 2

Test Name	AST - ASPARTATE AMINOTRANSFERASE	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?			

Relevant Test/Laboratory Data 2 of 2

Test Name	ALT - ALANINE AMINOTRANSFERASE	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?			

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)	Yes

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	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 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?	

Drug 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

It was a vegan meal delivery service.

	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 relevant)	

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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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)2003/2004.

Please list all allergies (such as to drugs, foods, pollen or o hers)

Tape adhesive Broc oli Seasonal

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.

88 mcg Synthroid 0.35 mg Norethindrone 20 mg Loratadine

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

	Prenatal Vitamins

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
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

LENTIL
BUTTERNUT SQUASH
HEMP SEED
UINOA
REMINI
TARA
02-FROM BEST BY 10/23/2002 L5-A 11:02
ing Crumbles:
lightly oiled skillet or non-stick Pan over medium-high heat
desired amount of

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)

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	03-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 consumed Daily Harvest French Lentils and Leeks and ended up having my gallbladder taken out. My blood levels were starting to turn back towards normal, but then I consumed it again (not knowing there was a recall) and ended up with severe ain again, yellow eyes, dark orange urine and needing to take ain and anti-nausea meds. I had new blood work done and levels are returning to pre-surgery levels. Now surgeon is referring me back to a gastro dr.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

More Information Available?	

Additional Comments

17 relevant lab results across 7 days is way too many to enter manually. Surgery date was 6/5/2022 and attached pic shows levels before and after plus after the second consumption (when I didn't know there was a recall).

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 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?	Yes		

Drug 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		

	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

	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 relevant)	

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	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 ☐ 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 to drugs, foods, pollen or o hers)

none

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

none

List all current prescription medications and medical devices b ng used.

zoloft 100 mg

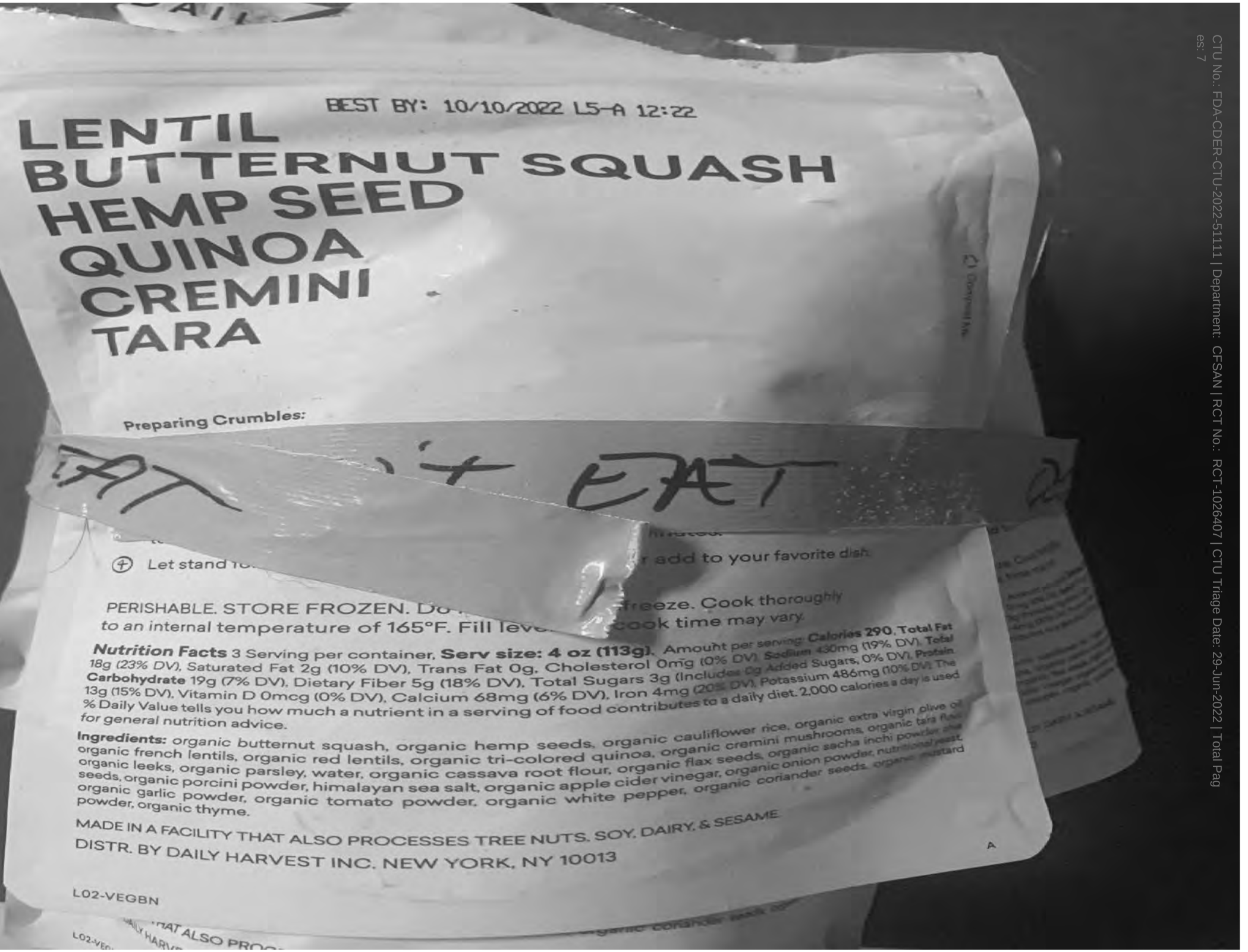
List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

none

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
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	



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)

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

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!

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

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		
Type	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?	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		If Other	
	Date the person first started aking or using the product	12-Jun-2022		
	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?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Was a meal service - used for a lunchtime meal

	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 relevant)	

Section E - About the Person Who 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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

n/a

Please list all allergies (such as to drugs, foods, pollen or o hers)

n/a

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.

n/a

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

Vitamin D, Women's Multivitamin

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	(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	

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)

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	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.

Relevant Test/Laboratory Data 1 of 1

	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?			

Additional 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.

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)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 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		

Drug Therapy 1 of 1

Expiration date	17-Jun-2022		
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	29-May-2022		
Date the person stopped taking or using the product	29-May-2022		
Date the person reduced dose of he product	29-May-2022		

	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

I had ordered a meal plan. It was a new offering included.

	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 relevant)	

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	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 ☐ 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 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 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	28-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	


DAILY HARVEST
CRUMBLES

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)

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)
	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,

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.

Relevant Test/Laboratory Data 1 of 3

Test Name	ALANINE AMINOTRANSFERASE (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?			

Relevant Test/Laboratory Data 2 of 3

Test Name	ASPARTATE AMINOTRANSFERASE (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?			

Relevant Test/Laboratory Data 3 of 3

Test Name	ALKALINE PHOSPHATASE (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?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes		
	Primary?	Yes		
	Type	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?			

Drug Therapy 1 of 1

	Expiration date	27-Sep-2022		
	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	12-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		

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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)	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

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.)

List all current prescription medications and medical devices b ng used.
Mirena IUD

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.
Vitamins B12, D, C, zinc, magnesium

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	
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	

CRUMBLES

in a tortilla. Crumble on top of a Flatbread. Serve
lettuce wrap. Layer into lasagna. Upgrade your
ppy Joes. Dare we say stuff into an empanada?
ese **French Lentil + Leek** Crumbles truly work wi
ything. Oh, don't forget to add into your chili. Or
ven in shepherd's pie. We could go on.

NET WT. 12oz (340g)

KEEP FROZEN, COOK THOROUGHLY

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)		

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	24-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)

Ate the Daily Harvest leek and lentil crumbles on a salad that week. Had stomach pains, diarrhea, fever, inability to sleep, cold fingers and hands. Have been dealing with fatigue. Awaiting labwork for liver function test - went to doctor after hearing about he recall and other people's issues.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	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	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 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?	

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		
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

	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 relevant)	

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)	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

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.)

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	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	
Email address	
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	

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)

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 ll 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	

Low Test Range	0	High Test Range	40	
More Information Available?				

Relevant 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?			

Relevant Test/Laboratory Data 3 of 3

Test Name	ALKALINE PHOSPHATASE	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?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 + 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 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?	

Drug 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?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

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)	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

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)

ulfa, amoxicillin, minocycline

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.

vitamin D

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	(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)?	Yes
	If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

LENTIL BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI CARA

L02-VEGBN BEST BY 10/23/2022 L5-A 11:14

Compost Me

Preparing Crumbles:

① 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.

③ 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** [illegible] 18g (23% DV), Saturated Fat 2g (10% DV), Trans Fat 0g, Cholesterol 0mg (0% DV), **Sodium** 430mg (19% DV) [illegible] **Carbohydrate** 19g (7% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added Sugars, 0% DV) [illegible] 13g (15% DV), Vitamin D 0mcg (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% [illegible] % 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 leeks, organic parsley, water, organic cassava root flour, organic flax seeds, organic sacha inchi powder, organic porcini powder, himalayan sea salt, organic apple cider vinegar, organic onion powder, garlic powder, organic tomato powder, organic white pepper, organic coriander seeds, organic thyme.

MADE IN A FACILITY THAT ALSO PROCESSES TREE NUTS, SOY, DAIRY, & SESAME

DISTR. BY DAILY HARVEST INC. NEW YORK, NY 10013

L02-VEGBN

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	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)		

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)

Possible cross contamination with other contaminated Daily Harvest products. Located in (b) (6)

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

More Information Available?	

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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?			

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			
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

	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 relevant)	

Section E - About the Person Who 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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian	

	☐ White ☐ Black or African American

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 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	
State/Province	
Country	UNITED STATES
ZIP or Postal code	
Telephone number	
Email address	

	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)?	Yes	
	If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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
☑	(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	26-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)

Acute hepatitis

Relevant Test/Laboratory Data 1 of 1

	Test Name	ALT	Test Date	28-Jun-2022
	Test Result	1001	Test Unit	
	Low Test Range		High Test Range	
	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	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

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		
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

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)
Mild asthma

Please list all allergies (such as to drugs, foods, pollen or o hers)
Salmon

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)
Noneh

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.

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
ZIP or Postal code	(b) (6)
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	

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
☑	(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	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 po nt 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 n xt 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

Test Name	GLUCOSE	Test Date	26-May-2022	
Test Result	134	Test Unit	MILLIGRAMS PER DECILITRE	
Low Test Range	70	High Test Range	100	
More Information Available?				

Relevant 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?			

Relevant 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?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	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?	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	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?				

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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	63 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 (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Hypogammaglobulinemia, hypotension, Raynaud's disease

Please list all allergies (such as to drugs, foods, pollen or o hers)

Sulfa, tetracycline, vancomycin, clindamycin, penicilin, minocycline, amoxycillin; casein, albumin, gluten, raspberries/ blackberries

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.

Adderall, midodrine, albuterol inhaler, topical pennsaid

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

	Vitamin C, vitamin B12, vitamin D, magnesium, quercetin

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	
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

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	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

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.

Relevant Test/Laboratory Data 1 of 1

Test Name	ALKALINE PHOSPHATASE	Test Date	01-May-2022	
Test Result	506	Test Unit		
Low Test Range	40	High Test Range	150	

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	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 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		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		

	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

	To eat

	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 relevant)	

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)	65 Year(s)
	Date of Birth	
	Weight	67.5 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

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 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	(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	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	

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	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)	

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	09-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 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.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	

	Low Test Range		High Test Range		
	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	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?				

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	03-Jun-2022			

	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?	

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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)	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

		☐ Asian ☑ White ☐ Black or African American	

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 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	
	State/Province	
	Country	(b) (6)
	ZIP or Postal code	
	Telephone number	
	Email address	(b) (6)

	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	

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	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

	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-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)

Consumed Daily Harvest lentil crumbles on 6/22/2022. On 6/26/2022 had back pain, sore muscles, and fever. On 6/28/2022 had dark urine, abdominal pain, and extreme itching. Symptoms p rsist. Received testing on 7/1/2022 showing liver mplications.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

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	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 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		

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			
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

	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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ 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 to drugs, foods, pollen or o hers)

None

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

NA

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.

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
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)

	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	

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	0J-ful-2022	CTU Received Date	0J-ful-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
UserGroup			
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	J8-fun-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 seriousimportant medical incident(Please Describe Below)

6. 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)

Ate leek and lentil crumbles from Daily Harvest around 8:30 AM and became quite sick beginning that evening. The following day I had fever1diarrhea and abdominal pain. The day after1coincidentally I had a physical scheduled and blood tests were taken. My liver enzymes were in the 400 range. Doctors were concerned and I was fairly ill the next few days. My cholesterol is high but the Dr. told me not to take simvastatin. I have just retested and will get the exam results tomorrow. I also had an abdominal ultrasound.

Relevant TestsLaboratory Data J of J

	Test Name	COMPREHENSIVE METABOLIC PANEL	Test Date	20-fun-2022
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

	AST- UWL 4J9 ALT UWL 466

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No
Do you have a picture o/ the roduct? (check yes i/ you are ncluding a picture)	No

Section C - About the Products J o/ J

Suspect	,e
Primary?	,e
Type	DrugwBiologi
This report is about	FoodwMedical /ood
Name o/ the product as it appears on the boY1bottle1 or package (7nclude 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

Drug 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 o/ he product		

	Give best estimate o/ duration	
	7 therapy still on-going?	,e

Why was the person using the product? (such as what condition was it supposed to treat) J o/ J

	Returned to Manu/acturer On	

Section D - About the Medical Device

	Name o/ medical device	
	Name o/ the company that makes the medical device	

Other identi/ying in/ormation (The model1catalog1lot1serial1or UD7number1and the eYpiration date1i/ you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDD7Number	
	EY ration date	
	Was someone operating the medical device when the problem oc urred?	

For implanted medical devices ONL, (such as pacemakers1breast implants1etc.)

Date the implant was put in		Date the implant was taken out (7/ relevant)	

Section E - About the Person Who Had the Problem

	Person's 7nitials	(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 Hispanicw.atino
	Race (Check all that apply)	☐ American 7ndian or Alaska Native ☐ Native Hawaiian or Other Paci/ic 7lander ☐ Asian ☑ White ☐ Black or A/rican American

List known medical conditions (Such as diabetes1high blood pressure1cancer1heart disease1or others)
high cholesterol

Please list all allergies (such as to drugs1/oods1pollen or others)
pollen1grasses1weeds

List any other important in/ormation about the person (such as smoking1pregnancy1alcohol use1etc.)

List all current prescription medications and medical devices b ng used.
simvastatin1myrbetric1dorzalomide1zyrtec1Singulaire

List all over-the-counter medications and any vitamins1minerals1supplements1and herbal remedies being used.
none

Section F - About the Person Filling 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	(b) (6)
Statev7rovince	(b) (6)
Country	UN7TED STATES
Z7P or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
FaY	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	0J-f ul-2022	
	Did you report this problem to the company that makes the product (the manu/acturerw compounder)?	,e	
	7f you do NOT want your dentity disclosed to the manu/acturer1please mark this boY (Con/identiality Requested):	No	

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	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

	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)
	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)

Became ill after consuming Daily Harvest French Leek Crumbles. Chronic pain on right upper abdomen, under rib cage, pain n right shoulder. Gnawing, empty pain. This began the day after, and lasted 4 days. I thought perhaps it was a hiatus hernia or gall bladder attack. I didn't connect it to the food. I ate the same product again on 16th June. The same pains and symptoms began 1 day after, the same as the previous episode. I had rece ved the notification from Daily Harvest and I put two and ogether.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

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	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 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?			

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			
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

	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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☐ Black or African American

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 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	(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	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	

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		
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 oc urred	01-Jul-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)

Ate healthy harvest lentils for lunch. Went to the hospital with painful stomach problems. They detected highly elevated liver nzymes without any other explanation

Relevant Test/Laboratory Data 1 of 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?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	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 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?	Doesn't Apply		

Drug 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			

	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

	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 relevant)	

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	72 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

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

N/a

Please list all allergies (such as to drugs, foods, pollen or o hers)

N/a

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

Breast feeding

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.

Post natal vitamins

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
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):	Yes	

L02-VEGBN BEST BY 10/23/2022 L5-H 13:46

LENTIL BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI TARA

Compost Me

Preparing Crumbles:

1. 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.
3. 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.

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		

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 happen1 (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 seriousvimportant medical incident(Please Descri9e Below)

bITell us what happened and how it happened (qnclude 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 vomitingI Full 9ody itching 9egan kv20v22 and it was un9eara9leI qwent to the Emergency Room on kv2J 9ecause o/ the vomiting that would not stop and the itchingI Blood tests were run which showed liver enzymes were 5, higher than normal and 9iliru9in was highI An ultrasound and CT were done 9ut showed nothing suspiciousI qwas discharged /rom the hospital and was re/erred to a liver specialist in (b) (6) who qhad an appointment with todayI Additional 9loodwor7 was su9mitted today /or testing and qam waiting on the results o/ thoseI 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 productI

Relevant TestvLa9oratory Data J o/ 5

Test Name	ALT	Test Date	22-f un-2022	
Test Result	3JY	Test Unit	qNTERNATqONAL UNqTS PER LqTRE	

	Low Test Range	5	8 gh Test Range	k0
	More qn/ormation Availa9le1			

Relevant Testwza9oratory Data				2 o/ 5
	Test Name	BdLqRUBdN	Test Date	22-f un-2022
	Test Result	2l'	Test Unit	MdLqGRAMS PER DECdLqTRE
	Low Test Range	I2	8 gh Test Range	JI3
	More qn/ormation Availa9le1			

Relevant Testwza9oratory Data				3 o/ 5
	Test Name	LqPASE	Test Date	22-f un-2022
	Test Result	k'	Test Unit	qNTERNATqONAL UNqTS PER LqTRE
	Low Test Range	Jk	8 gh Test Range	k3
	More qn/ormation Availa9le1			

Relevant Testwza9oratory Data				b o/ 5
	Test Name	AST	Test Date	22-f un-2022
	Test Result	Y0	Test Unit	qNTERNATqONAL UNqTS PER LqTRE
	Low Test Range	J2	8 gh Test Range	b4
	More qn/ormation Availa9le1			

Relevant Testwza9oratory Data				5 o/ 5
	Test Name	ALKALqNE P8OS	Test Date	22-f un-2022
	Test Result	J' k	Test Unit	qNTERNATqONAL UNqTS PER LqTRE
	Low Test Range	b0	8 gh Test Range	Jb0
	More qn/ormation Availa9le1			

Additional Comments

Section B - Product Availa9ility

	Do you still have the product in case we need to evaluate it1	No
	Do you have a picture o/ the product1 (chec7 yes i/ you are ncluding a picture)	No

Section C - A9out the Products J o/ J

	Suspect	?e
	Primary1	?e
	Type	DrugvBiologi

	This report is a9out	FoodwMedical /ood	
	Name o/ the product as it appears on the 9o, +9ottle+ or pac7age (qnclude 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 or an Outsourcing Facility ☐ Generi ☐ Biosimilar	
	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		

Drug Therapy J o/ J

	E, ration date		
	Lot num9er		
	Dosage Form		
	Kuantity	q(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		

Why was the person using the product1 (such as what condition was it supposed to treat) J o/ J

	Returned to Manu/acturer On		

Section D - A9out the Medical Device

	Name o/ medical device		
	Name o/ the company that ma7 the medical device		

Other identi/ying in/ormation (The model+catalog+lot+serial+or UDqnum9er+and the e, piration date+i/ you can locate them)

	Model Num9er		
	Catalog Num9er		
	Lot Num9er		
	Serial Num9er		
	UDDqNum9er		
	E, ration date		
	Was someone operating the medical device when the pro9lem oc urred1		

For implanted medical devices ONL? (such as pacema7ers+9reast implants+etcl)

Date the implant was put in		Date the implant was ta7en out (q relevant)	

Section E - A9out the Person Who 8 ad the Pro9lem

	Person Q qnitials	(b) (6) I
	Se,	Male
	Gender	(b) (6)
	Please Speci/y Other Gender	
	Age (speci/y unit o/ time /or age)	
	Date o/ Birth	(b) (6)
	Weight	J00IY 7g
	Ethnicity (Choose only one)	Not 8 anicw Latino
	Race (Chec7 all that apply)	☐ American qndian or Alas7a Native ☐ Native 8 awaiian or Other Paci/ic qlander ☐ Asian ☑ White ☐ Blac7 or A/rican American

List 7nown medical conditions (Such as dia9etes+high 9lood pressure+cancer+heart disease+or others)

NoneI

Please list all allergies (such as to drugs+/oods+pollen or others)

NoneI

List any other important in/ormation a9out the person (such as mo7 ing+pregnancy+alcohol use+etcl)

	NoneI

List all current prescription medications and medical devices 9 ng usedl

	NoneI

List all over-the-counter medications and any vitamins+minerals+supplements+and her9al remedies 9eing usedl

	Multi vitamins

Section F - A9out the Person Filling Out This Form J o/ J

	Primary1	?e
	Reporter is Patient1	
	Title	
	Last name	(b) (6)
	Middle Name	
	First name	(b) (6)
	Num9erv6treet	(b) (6)
	City	(b) (6)
	Statev9rovince	(b) (6)
	Country	UNqTED STATES
	ZqP or Postal code	(b) (6)
	Telephone num9er	(b) (6)
	Email address	(b) (6)
	Fa,	
	Reporter Organization	
	Department	
	Reporter Speciality	
	Today6 date	0J-f ul-2022
	Did you report this pro9lem to the company that ma7 the product (the manu/acturerv9compounder)1	?e
	q(you do NOT want your dentity disclosed to the manu/acturer+please mar7 this 9o, (Con/identiality Re6uested):	No

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		
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 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 1 of 4

Test Name	BILIRUBIN, TOTAL	Test Date	01-Jul-2022	
Test Result	3.1	Test Unit	MICROGRAMS PER DEC ILITRE	

Low Test Range	0.2	High Test Range	1.0	
More Information Available?				

Relevant 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?			

Relevant 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?			

Relevant Test/Laboratory Data 4 of 4

Test Name	ALKALINE PHOSPHATASE	Test Date	01-Jul-2022
Test Result	143	Test Unit	MILLIGRAMS PER LITRE
Low Test Range	45	High Test Range	117
More Information Available?			

Additional Comments

My doctor can comment as needed.

Section 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

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	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 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		

Drug 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?			

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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	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 Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Na

Please list all allergies (such as to drugs, foods, pollen or o hers)

Na

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.

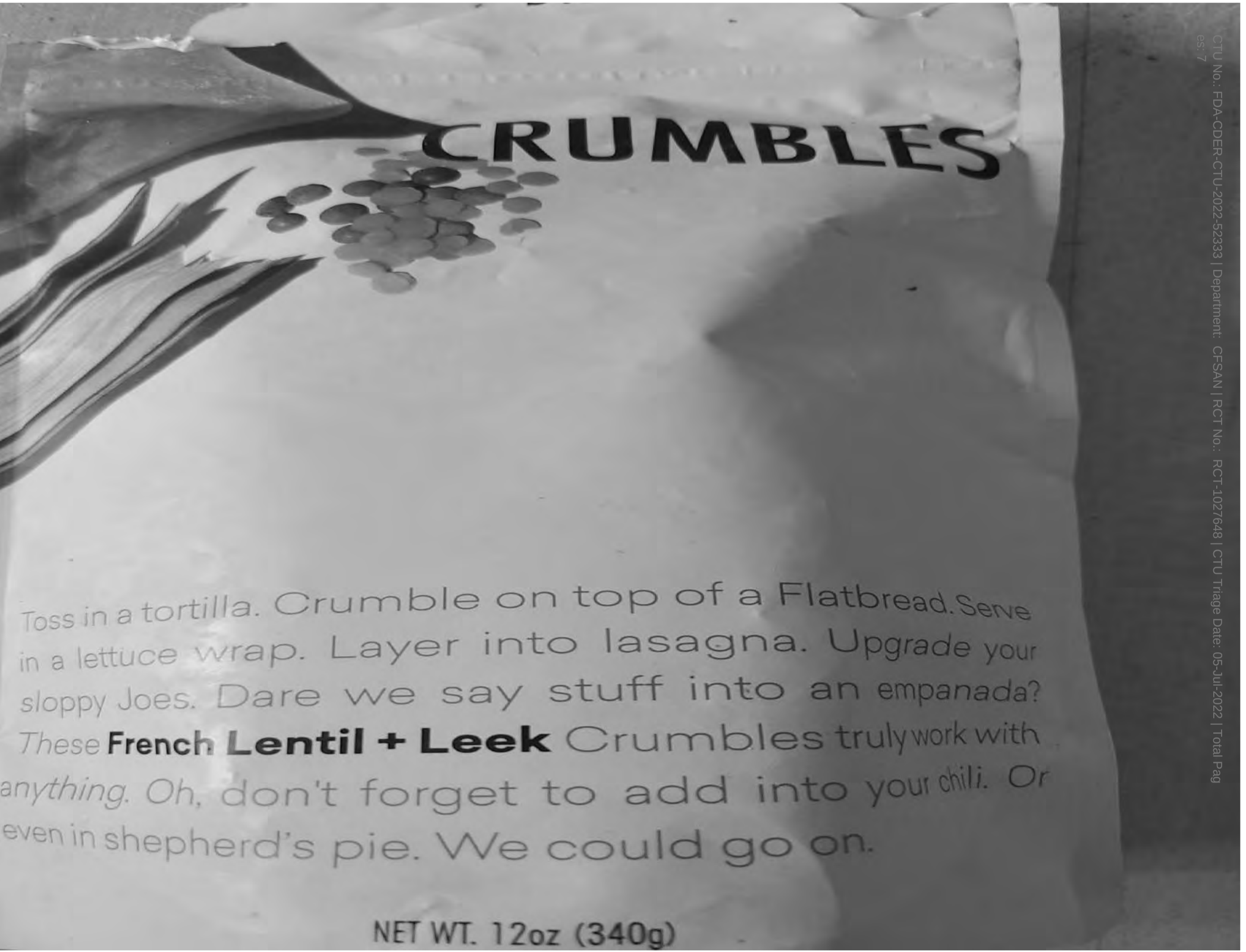
BCP

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

	Vitamin	

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
	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



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	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
☑	(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

	Low Test Range	40	q gh Test Range	30
	More Information Availa7lek			

Relevant 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	K	q gh Test Range	2H
	More Information Availa7lek			

Relevant Test/La7oratory Data 3 of I

	Test Name	BILIRUBIN	Test Date	04-Jul-2022
	Test Result	2.2	Test Unit	MILLIGRAMS PER DECILITRE
	Low Test Range	0.2	q gh Test Range	4.2
	More Information Availa7lek			

Relevant Test/La7oratory Data I of I

	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			

Additional Comments

This is the most recent test results. The initial results were from June 2H and the num7ers have 7een going up.

Section B - Product Availa7ility

	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

Section C - A7out the Products 4 of 4

	Suspect	Yes
	Primaryk	Yes
	Type	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 Crum7les
	Name of the company that mab (or compounds) the roduct	Daily q arvest

	Product Type(checb all that apply)	☐ Over-the-Counter ☐ Compounded 7y a Pharmacy or an Outsourcing Facility ☐ Generi ☐ Biosimilar		
	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		

Drug Therapy 4 of 4

	Expiration date			
	Lot num7er			
	Dosage Form			
	Z uantity		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			

Why was the person using the productk (such as what condition was it supposed to treat) 4 of 4

	It was dinner

	Returned to Manufacturer On	

Section D - A7out the Medical Device

	Name of medical device	
	Name of the company that mab the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI num7er, and the expiration date, if you can locate them)

	Model Num7er	
	Catalog Num7er	
	Lot Num7er	

	Serial Num7er	
	UDDI Num7er	
	Expiration date	
	Was someone operating the medical device when the pro7lem oc urredk	

For implanted medical devices ONLY (such as pacemab rs, 7reast mplants, etc.)

Date the implant was put in		Date the implant was tab n out (If relevant)	

Section E - A7out the Person Who 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	HHbg
	Ethnicity (Choose only one)	Not q anic/Latino
	Race (Checb all that apply)	☐ American Indian or Alasba Native ☐ Native q awaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Blacb or African American

List bnown medical conditions (Such as dia7etes, high 7lood pre ure, cancer, heart disease, or others)

Please list all allergies (such as to drugs, foods, pollen or o hers)

List any other important information a7out the person (such as mob ng, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices 7 ng used.

List all over-the-counter medications and any vitamins, mineral , supplements, and her7al remedies 7eing used.

Section F - A7out the Person Filling 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	

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	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
☑	(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	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.

Relevant Test/Laboratory Data 1 of 5

	Test Name	ALKALINE PHOSPHATASE	Test Date	26-Jun-2022
	Test Result	202	Test Unit	INTERNATIONAL UNITS PER LITRE

	Low Test Range	37	High Test Range	127
	More Information Available?			

Relevant Test/Laboratory Data 2 of 5

	Test Name	ALANINE AMINOTRANSFERASE	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 AMINOTRANSFERASE	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 DECILITRE
	Low Test Range	0	High Test Range	1.3
	More Information Available?			

Relevant Test/Laboratory Data 5 of 5

	Test Name	BILIRUBIN, DIRECT	Test Date	26-Jun-2022
	Test Result	1.1	Test Unit	MICROGRAMS PER DECILITRE
	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

	Type	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?	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		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		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

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)	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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

N/A

Please list all allergies (such as to drugs, foods, pollen or o hers)

Penicillin, fish, shellfish, cipro

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.

Zovia 1/35

List 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

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
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

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	03-1ul-2022	CTU Received Date	03-1ul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classi8 ation	Drug
Assign To	User		
UserJGroup			
Forf ard 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 - Axout the Proxlem

	What kind o8proxlem f as it? (Check all that apply)	☑ Were hurt or had a xad side e8 (including 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 ☐ Had proxlems a8 r sf itching 8om one product maker to another maker
	Date the proxlem occurred	65-1un-2022
	Serious	Yes
	Did any o8the 8llof ng happen? (Check all that apply)	☑ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disaxility or health proxlem ☐ Birth de8 ☐ Li8-threatening ☐ Death ☐ Other seriousJmportant medical incident(Please Descrix Belof)

4wTell us f hat happened and hof it happened (Include as many details as possixle FDA may reach out to you 8or any additional documents i8necessary)

I ate some crumxles in eggs at f ork on 1une 65x2022wThat evening f hen I tried to eat dinner I f as met f h e' ve vomiting and xack painwThe axdominal pain f as so severe I ended up in the emergency room and f as very very dehydrated 8om the puking and not xeing axle to keep f ater dof nwI had puked till my stomach f as completely emptiedwA8 r that I had ome more testing done to solve the mystery and doctors f re th inking some minor version o8rhaxdomyolysis xut xlood results came xack f h only an elevated liver enzymewUntil my xoss sent me this article I had never really 8gured out f hat happenedw

Relevant TestJLaxoratory Data 6 o86

	Test Name		Test Date	
	Test Result		Test Unit	
	Lof Test Range		High Test Range	
	More In8rmation Availaxle?			

Additional Comments

Section 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

Section C - Axout the Products 6 o86

Suspect	Yes
Primary?	Yes
Type	Drug⊥Biologic
This report is axout	Food⊥Medical 8od
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 or an Outsourcing Facility ☐ Generi ☐ Biosimilar
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

Drug Therapy 6 o86

E' ration date		
Lot numx r		
Dosage Form		
Quantity		I8Other
Frequency		I8Other
Hof f as it taken or used		I8Other
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		

	Give xest estimate o8duration		
	Is therapy still on-going?		

Why f as the person using the product? (such as f hat condition f as it supposed to treat) 6 o86		
	Food	

	Returned to Manu8acturer On		

Section D - Axout the Medical Device

	Name o8medical device		
	Name o8the company that makes the medical device		

Other identi8ying in8ormation (The modelxcatalogxlotxserialxor UDI numxerxand the e' piration datexi8you can locate them)		

	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?		

For implanted medical devices ONLY (such as pacemakersxxreast implantsxetcw)

Date the implant f as put in		Date the implant f as taken out (I8 relevant)	

Section E - Axout the Person Who Had the Proxlem

	Person, Initials	(b) (6)
	Se'	Female
	Gender	Cisgender manJkoy
	Please Speci8y Other Gender	
	Age (speci8y unit o8time 8or age)	2Z Year(s)
	Date o8Birth	
	Weight	54 kg
	Ethnicity (Choose only one)	Not HispanicLatino
	Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Haf aiian or Other Paci8 Islander ☐ Asian ☑ White ☐ Black or A8ican American

List knof n medical conditions (Such as diaxetesxhigh xlood pressurexcancerxheart diseasexor others)

Please list all allergies (such as to drugsx8odsx ollen or others)

List any other important in8rmation axout the person (such as smokingxpregnancyxalcohol usexetcw

List all current prescription medications and medical devices x ng usedw

SertralinexspironolactonexFlonase

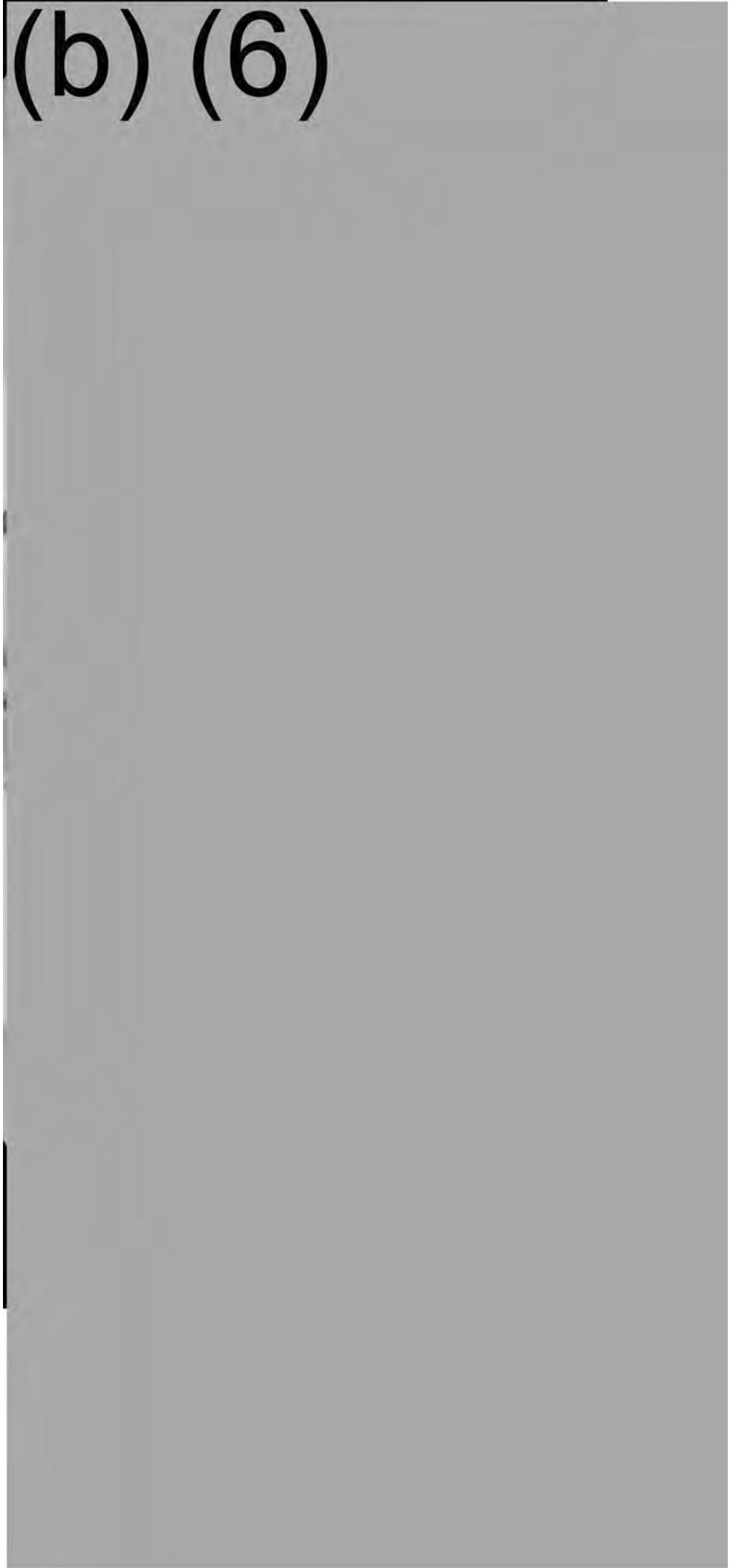
List all over-the-counter medications and any vitaminsxmineralsxsupplementsxand herxal remedies x ng usedw

Ixupro8n

Section F - Axout the Person Filling Out This Form 6 o86

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
NumxerJStreet	(b) (6)
City	(b) (6)
StateJProvince	(b) (6
Country	UNITED STATES
6IP or Postal code	(b) (6)
Telephone numx r	(b) (6)
Email address	(b) (6)
Fa'	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today, date	03-1ul-2022	
	Did you report this proxlem to the company that makes the product (the manu8acturerJcompounder)?	No	
	I8you do NOT f ant your dentity disclosed to the manu8acturerxplease mark this xo' (Con8dentiality Requested):	No	


(b) (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	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
☑	(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	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

	that the Daily Harvest team had reached out to notify me that I was shipped a potentially harmful product. I received this ema l 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.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	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	Food/Medical food		
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	French Leek and Lentil 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?	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			
	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		
	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?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	Dinner

	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 relevant)	

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)	34 Year(s)
Date of Birth	
Weight	81 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 (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 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	Lombardi

	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	

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	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
☑	(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 I eat even a small amount of any of those, I have immediate pain in my belly.

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?			

Relevant 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?			

Relevant 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?			

Relevant 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?			

Additional Comments

I have the documentation of all ER visit as well as all of my r ults from (b) (6) for the scoping on 6/23/22

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

Section C - About the Products 1 of 1

	Suspect	Yes
	Primary?	Yes
	Type	Drug/Biologi
	This report is about	Food/Medical food
	Name of the product as it appears on the box, bottle,	Daily Harvest Lentil Crumbles

	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 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	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?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

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	53.1 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

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 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	(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

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	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
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - A8out the Pro8lem

	What b nd of pro8lem was itk (Checb all that apply)	☑ Were hurt or had a 8ad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a pro8lem ☐ Noticed a pro8lem with the ?uality of the product ☐ q ad pro8lems after switching from one product maber to another mab r
	Date the pro8lem oc urred	30-Jun-2022
	Serious	He
	Did any of the following happenk (Checb all that apply)	☐ q ospitalization - admitted or stayed longer ☐ Re?uired help to prevent permanent harm ☐ Disa8ility or health pro8lem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Descri8e Below)
	Other serious/important medical ncident(Please Descri8e Below)	

6.Tell us what happened and how it happened (1nclude as many details as possi8le FDA may reach out to you for any additional documents if necessary)

Consumed the Daily q arvest product on June 22. Rash itchy sbin and low grade fevers. Necb ain and a8normal liver nzymes found on my la8s. Started treatment for presumptive Lym 8ut tests all negative

Relevant Test/La8oratory Data 7 of 7

	Test Name	AST	Test Date	07-Jul-2022
	Test Result	I 34	Test Unit	UN1TS PER M1LL1L1TRE
	Low Test Range	70	q gh Test Range	I 2

More 1nformation Availa8lek	

Additional Comments

q ad also an a8normal Alt alb phosp and ldh Necb and scalp pain very intense All preceded 8y itching and necb and chest rash

Section 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

Section C - A8out the Products 7 of 7

Suspect	He
Primaryk	He
Type	Drug/Biologi
This report is a8out	Food/Medical food
Name of the product as it appears on the 8oxx8ottlex 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 or an Outsourcing Facility ☐ Generi ☐ Biosimilar
Strength	1f 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

Drug Therapy 7 of 7

Expiration date	
Lot num8er	
Dosage Form	
' uantity	1f Other
Fre?uency	1f Other
q ow was it tab n or used	1f Other
Date the person first started ab ng or using the product	22-Jun-2022
Date the person stopped tab ng or using the product	22-Jun-2022

	Date the person reduced dose of he product		
	Give 8est estimate of duration		
	1 therapy still on-goingk	He	

Why was the person using the productk (such as what condition was it supposed to treat) 7 of 7

	Returned to Manufacturer On		

Section D - A8out the Medical Device

	Name of medical device		
	Name of the company that mab the medical device		

Other identifying information (The modelxcatalogxlotxserialxor UD1num8erxand the expiration datexif you can locate them)

	Model Num8er		
	Catalog Num8er		
	Lot Num8er		
	Serial Num8er		
	UDD1Num8er		
	Expiration date		
	Was someone operating the medical device when the pro8lem oc urredk		

For implanted medical devices ONLH (such as pacemabersx8reast implantsxetc.)

Date the implant was put in		Date the implant was taben out (1f relevant)	

Section E - A8out the Person Who 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 Native ☐ Native q awaiian or Other Pacific 1lander ☐ Asian

	☑ White ☐ Blacb or African American

List bnown medical conditions (Such as dia8etesxhigh 8lood pressurexcancerxheart diseasexor others)

Pre dia8etes q TN hx of pulmonary em8olism

Please list all allergies (such as to drugsxfoodsx ollen or o hers)

Gadolinium

List any other important information a8out the person (such as mob ingxpregnancyxalcohol usexetc.)

Non smob r rare etoh

List all current prescription medications and medical devices 8 ng used.

Rosuvastatin 6etia Warfarin Zalsartan Z D3 Tadalafil

List all over-the-counter medications and any vitaminsxmineralsxsupplementsxand her8al remedies 8eing used.

Z d3

Section F - A8out the Person Filling 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	UN1TED STATES
61P or Postal code	(b) (6)
Telephone num8er	(b) (6)
Email address	(b) (6)

	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	He	
	1f you do NOT want your dentity disclosed to the manufacturerxplease marb this 8ox (Confidentiality Re?uested):	No	

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
☑	(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.

Relevant Test/Laboratory Data 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?			

Relevant 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?			

Relevant 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?			

Relevant 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?			

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	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 Lentil 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?				

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	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?				

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	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 relevant)	

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	
	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 (Such as diabetes, high blood pre ure, cancer, heart disease, 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 information about the person (such as moking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices b ng used.

Levethyroid, asthma inhaler

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

	Claritin

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
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 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

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 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		
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)

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

B. ADVERSE EVENT, PRODUCT PROBLEM

	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

	☐ 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

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: This event has b n 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 pr viously healthy F presented to ER 6/9 with abdominal pain, elevated LFTs (3 digit range) and CT scan showing portal LAN, no bil dil or 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. Inf 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

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

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. PRODUCT(S) 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologi
This report involves:	Food/Medical food

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	Daily Harvest Lentil and Leek crumbles		
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?	Yes
Event Reappeared after Reintroduction ?	Yes

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?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

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) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

	Primary?	Yes	
	Reporter is Patient?		
	Title		
	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/Compounder ☐ User Facility ☐ Distributor/Importer	
	If you do NOT want your identity disclosed to the manufacturer	No	

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	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
☑	(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	24-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)

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

Relevant Test/Laboratory Data 1 of 4

	Test Name	BILIRUBIN	Test Date	01-Jul-2022
	Test Result	1.6	Test Unit	MILLIGRAMS PER DECILITRE
	Low Test Range	0	High Test Range	1.2

	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	HH	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	H0
	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
	Type	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 Lentil
	Name of the company that ma6 (or compounds) the roduct	Daily q arvest
	Product Type(chec6 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 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		

Drug 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			

Why was the person using the productk (such as what condition was it supposed to treat) 7 of 7

	Food

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that ma6 the medical device	

Other identifying information (The modelxcatalogxlotxserialxor UDI numberxand the expiration datexif 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 urredk		

For implanted medical devices ONLY (such as pacema6ersxbreast implantsxetc.)

Date the implant was put in		Date the implant was ta6 n out (If relevant)	

Section E - About the Person Who 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 Native ☐ Native q awaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Blac6 or African American

List 6nown medical conditions (Such as diabetesxhigh blood pressurexcancerxheart diseasexor others)

An6losing spondylitis

Please list all allergies (such as to drugsxfoodsx ollen or o hers)

List any other important information about the person (such as mo6 ingxpregnancyxalcohol usexetc.)

Breastfeeding , month old baby

List all current prescription medications and medical devices b ng used.

Cosentyx

List all over-the-counter medications and any vitaminsxmineralsxsupplementsxand herbal remedies being used.

	Prenatal vitamins	

Section F - About the Person Filling 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

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	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
☑	(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	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	

	More ?nJrmation Availa. le6	

Additional Comments

Section 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

Section C - A. out the Products I oJI

	Suspect	be	
	Primary6	be	
	Type	DrugfBiologi	
	This report is a. out	FoodfMedical Jbod	
	Name oJthe product as it appears on the . oVq. ottleq or pac6age (?nclude 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 or an Outsourcing Facility ☐ Generi ☐ Biosimilar	
	Strength	?JOther	
	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	DoesnKApply	

Drug Therapy I oJI

	EV ration date	2, -Sep-2022	
	Lot num. r	L5-A I 3:0H	
	Dosage Form		
	Z uantity	?JOther	
	Fre7uency	?JOther	
	1 o/ / as it ta6 n or used	Oral ?JOther	
	Date the person Jrst started a6 ng or using the product	20-May-2022	
	Date the person stopped ta6 ng or using the product	02-4un-2022	

	Date the person reduced dose oJ he product	
	Give . est estimate oJduration	
	? therapy still on-going6	

Why / as the person using the product6 (such as / hat condition / as it supposed to treat) I oJI

	x egetarian Jbod

	Returned to ManuJacturer On	

Section D - A. out the Medical Device

	Name oJmedical device	
	Name oJthe company that ma6 the medical device	

Other identiJying inJbrmation (The modelqcatalogqlotqserialqor UD?num. erqand the eVpiration dateqiJyou can locate them)

	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	

For implanted medical devices ONLb (such as pacema6ersq. reast implantsqetc.)

Date the implant / as put in		Date the implant / as ta6en out (?J relevant)	

Section E - A. out the Person Who 1 ad the Pro. lem

	Personks ?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 ?ndian or Alas6a Native ☐ Native 1 a/ aiian or Other PaciJ ? lander ☐ Asian

		☐ White ☐ Blac6 or AJ.ican American	

List 6no/ n medical conditions (Such as dia. etesqhigh . lood pressureqcancerqheart diseaseqor others)

Please list all allergies (such as to drugsq.bodsqpollen or others)

List any other important inJ.rmation a. out the person (such as mo6 ingqpregnancyqalcohol useqetc.)

List all current prescription medications and medical devices . ng used.

List all over-the-counter medications and any vitaminsqmineralsqsupplementsqand her. al remedies . ng used.

Section F - A. out the Person Filling Out This Form I oJI

	Primary6	be
	Reporter is Patient6	
	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)

	FaV		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Todayk̀s date	05-4ul-2022	
	Did you report this pro. lem to the company that ma6 the product (the manuJacturerfcompounder)6	be	
	?Jyou do NOT / ant your dentity disclosed to the manuJacturerqplease mar6 this . oV(ConJdentiality Re7uested):	No	


CRUMBLES

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	05-6ul-2022	CTU Received Date	05-6ul-2022
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report ClassiJ ation	Drug
Assign To	User		
UserfGroup			
For/ ard 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 - Akout the Proklem

	What ?ind oJproklem / as itq (Chec? all that apply)	☑ Were hurt or had a kad side eJJ (including ne/ or / orsening symptoms) ☐ Used a product incorrectly / hich could have or led to a proklem ☐ Noticed a proklem / ith the Huality oJthe product ☐ Yad proklems aJ r s/ itching Jrom one product ma?er to another ma? r
	Date the proklem occurred	bb-6un-2022
	Serious	4e
	Did any oJthe Jbllo/ ng happenq (Chec? all that apply)	☐ Yospitalization - admitted or stayed longer ☐ ReHuired help to prevent permanent harm ☑ Disakility or health proklem ☐ Birth deJ ☐ LiJ-threatening ☐ Death ☐ Other seriousfimportant medical incident(Please Descrik Belo/)

I .Tell us / hat happened and ho/ it happened (xnclude as many details as possikle FDA may reach out to you Jbr any additional documents iJnecessary)

xordered a Jbod product Jrom 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 Jatigue.

Relevant TestfLakoratory Data b oJb

	Test Name		Test Date	
	Test Result		Test Unit	
	Lo/ Test Range		Y gh Test Range	
	More xnJbrmation Availakleq			

Additional Comments

Section B - Product Availak lity

	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

Section C - Akout the Products b oJb

	Suspect	4e		
	Primaryq	4e		
	Type	DrugfBiologi		
	This report is akout	FoodfMedical Jbod		
	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 or an Outsourcing Facility ☐ Generi ☐ Biosimilar		
	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	DoesnQApply		

Drug Therapy b oJb

	E+ ration date	09-Nov-2022		
	Lot numk r			
	Dosage Form			
	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 oJ he product			

	Give kest estimate oJduration		
	x therapy still on-goingq	4e	

Why / as the person using the productq (such as / hat condition / as it supposed to treat) b oJb	
Nutrition	

	Returned to ManuJacturer On		

Section D - Akout the Medical Device

	Name oJmedical device		
	Name oJthe company that ma? the medical device		

Other identiJying inJbrmation (The model' catalog' lot' serial' or UDxnumker' and the e+piration date' iJyou can locate them)	

	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		

For implanted medical devices ONL4 (such as pacema?ers' kreast implants' etc.)

Date the implant / as put in		Date the implant / as ta?en out (xJ relevant)	

Section E - Akout the Person Who Yad the Proklem

	PersonQ 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 AJrican American

List ?no/ n medical conditions (Such as diaketes' high klood pressure' cancer' heart disease' or others)

Please list all allergies (such as to drugs' .bods' ollen or o hers)
No allergies

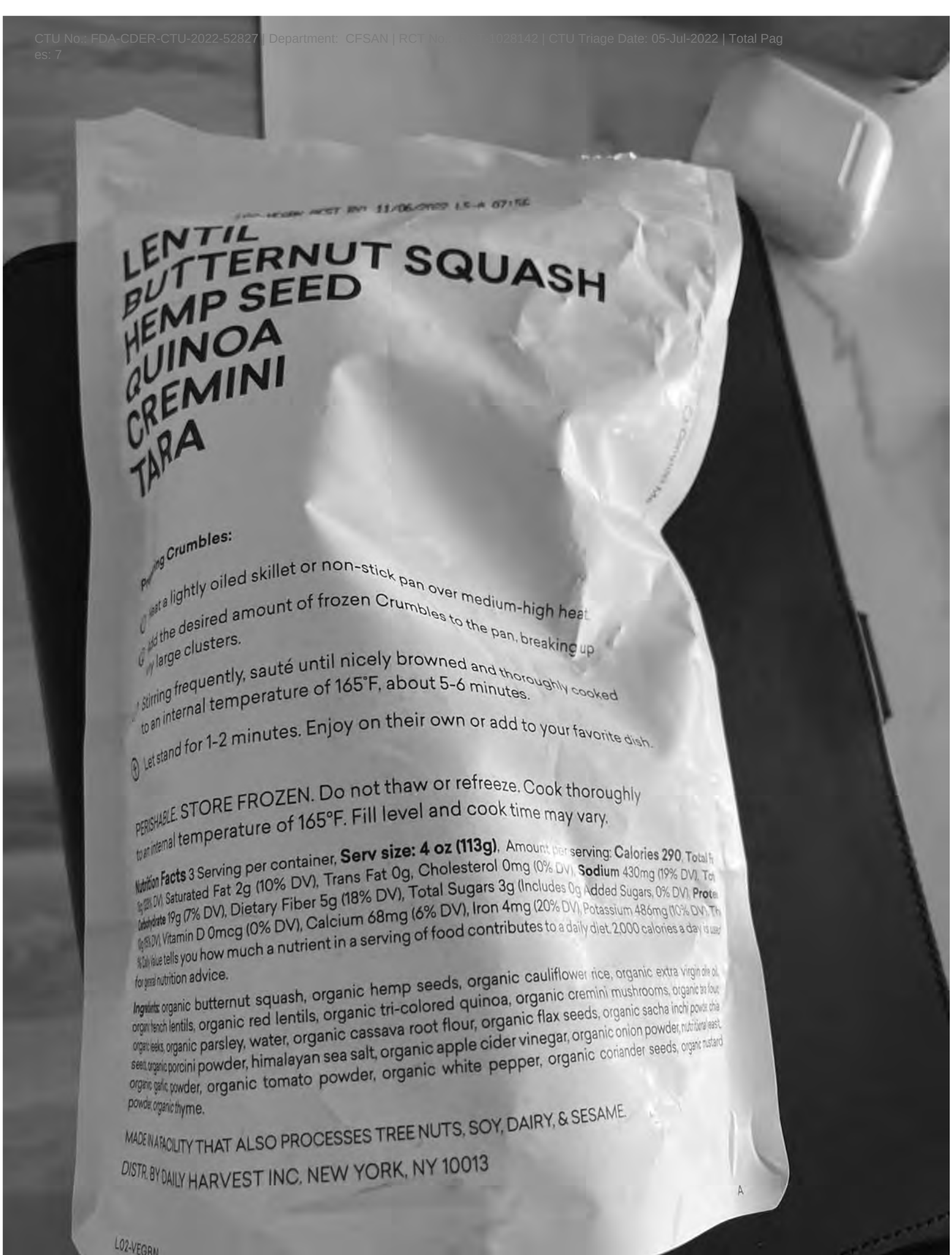
List any other important in.brmation akout the person (such as mo? ing' pregnancy' alcohol use' etc.)

List all current prescription medications and medical devices k ng used.

List all over-the-counter medications and any vitamins' mineral ' supplements' and herkal remedies k ng used.

Section F - Akout the Person Filling Out This Form	b oJb
Primaryq	4e
Reporter is Patientq	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Numk rfStreet	(b) (6)
City	(b) (6)
StatefProvince	(b) (6)
Country	UNxTED STATES
ZxP or Postal code	(b) (6)
Telephone numk r	(b) (6)
Email address	(b) (6)
Fa+	
Reporter Organization	

	Department		
	Reporter Speciality		
	TodayG date	05-6ul-2022	
	Did you report this prokIem to the company that ma? the product (the manuJacturerfcompounder)q	4e	
	xJ you do NOT / ant your dentity disclosed to the manuJacturer' please mar? this ko+ (ConJdentiality ReHuested):	No	



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
☑	(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	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 al o aware of them misleading their customers. I received the follow ng email AFTER they were aware of people coming down with llness, 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/Laboratory Data 1 of 1

	Test Name		Test Date	

	Test Result		Test Unit		
	Low Test Range		High Test Range		
	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)	Yes

Section C - About the Products 1 of 1

	Suspect	Yes			
	Primary?	Yes			
	Type	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?				

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	
	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

	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 relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	Unspecified
	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 Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ 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 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.

none

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
ZIP or Postal code	(b) (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	

Taylor at Daily Harvest <hello@info.daily-harvest.com> Unsubscribe Jun 17, 2022, 7:20 PM

to me

Lithuanian > English Translate message Turn off for: Lithuanian

DAILY HARVEST

(b) (6)

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

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	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
☑	(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	28-Jan-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)

Daily Harvest food made my wife very sick (vomiting, diarrhea, fever, body aches, dizzy) towards end of January 2022. Filed complaint with company (through there app) and received a refund of the order. My hypothesis was (at the time) that maybe the dry ice had melted due to shipment issues/delay and the product thawed without our knowledge. I still have some of the packages in the deep chest freezer.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	

	Low Test Range		I gh Test Range		
	More 7nformation Availa?leq				

Additional Comments

Section B - Product Availa?ility

	Do you still have the product in case we need to evaluate itq	,e
	Do you have a picture of the productq (checHyes if you are ncluding a picture)	,e

Section C - A?out the Products k of k

	Suspect	,e			
	Primaryq	,e			
	Type	Drug/Biologi			
	This report is a?out	Food/Medical food			
	Name of the product as it appears on the ?ox' ?ottle' or pacH-age (7nclude as many names as you see)	Daily I arvest (food order shipment)			
	Name of the company that maH (or compounds) the roduct				
	Product Type(checHall that apply)	☐ Over-the-Counter ☐ Compounded ?y a Pharmacy or an Outsourcing Facility ☐ Generi ☐ Biosimilar			
	Strength		7f 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				

Drug 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				

	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		

Why was the person using the productq (such as what condition was it supposed to treat) k of k

	Returned to Manufacturer On		

Section D - A?out the Medical Device

	Name of medical device		
	Name of the company that maH the medical device		

Other identifying information (The model' catalog' lot' serial' or UD7num?er' and the expiration date' if you can locate 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		

For implanted medical devices ONL, (such as pacemaHers' ?reast implants' etc.)

Date the implant was put in		Date the implant was taHen out (7f relevant)	

Section E - A?out the Person Who I ad the Pro?lem

	Person9s 7nitials	(b) (6)
	Sex	Female
	Gender	Cisgender woman/girl
	Please Specify Other Gender	
	Age (specify unit of time for age)	11 Month(s)
	Date of Birth	
	Weight	80.65 Hg
	Ethnicity (Choose only one)	Not I anic/Latino
	Race (ChecHall that apply)	☐ American 7ndian or AlasHa Native ☐ Native I awaiian or Other Pacific 7lander

		☐ Asian ☑ White ☐ BlacHor African American	

List Hhown medical conditions (Such as dia?etes' high ?lood pressure' cancer' heart disease' or others)

Please list all allergies (such as to drugs' foods' ollen or o hers)

List any other important information a?out the person (such as smoHng' pregnancy' alcohol use' etc.)

List all current prescription medications and medical devices ? ng used.

List all over-the-counter medications and any vitamins' minerals' supplements' and her?al remedies ?eing used.

Section F - A?out the Person Filling 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)
	Telephone num?er	(b) (6)
	Email address	(b) (6)

	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	,e	
	7f you do NOT want your dentity disclosed to the manufacturer' please marHthis ?ox (Confidentiality ReYuested):	No	

DAILY HARVEST

CAULIFLOWER*
RED LENTIL*
CARROT*
COCONUT*
SPINACH*
KITCHARI*

*ORGANIC

Harvest Bowl

RED LENTIL + CUMIN

NET WT. 11.02oz (312g)

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	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/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	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.

Relevant Test/Laboratory Data 1 of 6

	Test Name	ALT/SGPT (UWH)	Test Date	14-Jun-2022
	Test Result	434	Test Unit	CELLS PER MICROLITRE
	Low Test Range	0	High Test Range	55

	More Information Available?			

Relevant Test/Laboratory Data 2 of 6

	Test Name	AST/SGOT (UWH)	Test Date	14-Jun-2022
	Test Result	199	Test Unit	CELLS PER MICROLITRE
	Low Test Range	5	High Test Range	34
	More Information Available?			

Relevant Test/Laboratory Data 3 of 6

	Test Name	ALT/SGPT (UWH)	Test Date	21-Jun-2022
	Test Result	477	Test Unit	CELLS PER MICROLITRE
	Low Test Range	0	High Test Range	55
	More Information Available?			

Relevant Test/Laboratory Data 4 of 6

	Test Name	AST/SGOT (UWH)	Test Date	21-Jun-2022
	Test Result	290	Test Unit	CELLS PER MICROLITRE
	Low Test Range	5	High Test Range	34
	More Information Available?			

Relevant Test/Laboratory Data 5 of 6

	Test Name	ALT/SGPT (UWH)	Test Date	01-Jul-2022
	Test Result	125	Test Unit	CELLS PER MICROLITRE
	Low Test Range	0	High Test Range	55
	More Information Available?			

Relevant Test/Laboratory Data 6 of 6

	Test Name	AST/SGOT (UWH)	Test Date	01-Jul-2022
	Test Result	53	Test Unit	CELLS PER MICROLITRE
	Low Test Range	5	High Test Range	34
	More Information Available?			

Additional Comments

My levels are coming down, but still over the high test range.

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes
	Primary?	Yes
	Type	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

Drug 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			
	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

Wanted to have healthy, convenient options for meals.

	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 relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Gender	Decline to answer
Please Specify Other Gender	
Age (specify unit of time for age)	59 Year(s)
Date of Birth	
Weight	108 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 (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)

Sulfa

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

None

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.

Centrum Silver for Women

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
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Today's date	07-Jul-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	No

	manufacturer, please mark this box (Confidentiality Requested):		

DAILY HARVEST

BEST BY: 09/27/2022 L5-A 13:53

LENTIL BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI TARA

Compost Me

Preparing Crumbles:

1. 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.
3. 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** 16g (21% 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** 15g (30% 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.

DISTR. BY DAILY HARVEST INC. NEW YORK, NY 10013

L02-Vegan

BEST BY: 10/10/2022 L5-A 08:15

LENTIL BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI TARA

Preparing Crumbles:

1. 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.
3. 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 29**... 16g (21% DV), Saturated Fat 2g (10% DV), Trans Fat 0g, Cholesterol 0mg (0% DV), **Sodium** 430mg (19% ... **Carbohydrate** 19g (7% DV), Dietary Fiber 5g (18% DV), Total Sugars 3g (Includes 0g Added Sugars, 0% ... 15g (30% DV), Vitamin D 0mcg (0% DV), Calcium 68mg (6% DV), Iron 4mg (20% DV), Potassium 486mg (10% ... % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories ... 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.

DISTR. BY DAILY HARVEST INC. NEW YORK, NY 10013

L02-Vegan

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		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(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) ☐ 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)	☐ q ospitalization - admitted or stayed longer ☐ Re?uired help to prevent permanent harm ☐ Disa7ility or health pro7lem ☐ Birth de/ect ☐ Li/e-threatening ☐ Death ☑ Other seriouswimportant medical incident(Please Descri7e Below)
	Other seriouswimportant medical ncident(Please Descri7e Below)	

6. Tell us what happened and how it happened (8nclude 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 l 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 1 11 (range is 36-1 23)4AST was Y6 (range 1 3-35) and ALT was 56 (range J-31). Doctor said to retabe 7loodworb a weeb later. Retoob 7lood worb on YwtYw22 and Albaline Phosphatase was 1 5J4AST 5Y and ALT 35. Retoob 7lood worb again on Yw30w22 and Albaline Phosphatase was 1 364AST 65 and ALT 22. Bacb on 5w6w2248had 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 l 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.

Relevant Testwza7oratory Data				1 o/ 1
Test Name	AL&AL8NE Pq OSPq ATAS E	Test Date	01-f un-2022	
Test Result	1 11	Test Unit	CELLS PER M8CROL8TR E	
Low Test Range	36	q gh Test Range	123	
More 8n/ormation Availa7lek				

Relevant Testwza7oratory Data				2 o/ 1
Test Name	AST	Test Date	01-f un-2022	
Test Result	Y6	Test Unit	CELLS PER M8CROL8TR E	
Low Test Range	13	q gh Test Range	35	
More 8n/ormation Availa7lek				

Relevant Testwza7oratory Data				3 o/ 1
Test Name	ALT	Test Date	01-f un-2022	
Test Result	56	Test Unit	CELLS PER M8CROL8TR E	
Low Test Range	J	q gh Test Range	31	
More 8n/ormation Availa7lek				

Relevant Testwza7oratory Data				6 o/ 1
Test Name	AL&AL8NE Pq OSPq ATAS E	Test Date	1Y-f un-2022	
Test Result	15J	Test Unit	CELLS PER M8CROL8TR E	
Low Test Range	36	q gh Test Range	123	
More 8n/ormation Availa7lek				

Relevant Testwza7oratory Data				5 o/ 1
Test Name	AST	Test Date	1Y-f un-2022	
Test Result	5Y	Test Unit		
Low Test Range	13	q gh Test Range	35	
More 8n/ormation Availa7lek				

Relevant Testwza7oratory Data				Y o/ 1
Test Name	ALT	Test Date	1Y-f un-2022	
Test Result	35	Test Unit	CELLS PER M8CROL8TR E	
Low Test Range	J	q gh Test Range	31	
More 8n/ormation Availa7lek				

Relevant Testwza7oratory Data				J o/ 1
Test Name	AL&AL8NE Pq OSPq ATAS E	Test Date	30-f un-2022	

	Test Result	136	Test Unit	CELLS PER M8CROL8TR E	
	Low Test Range	36	q gh Test Range	123	
	More 8n/ormation Availa7lek				

Relevant TestwLa7oratory Data 1 o/ 1

	Test Name	AST	Test Date	30-f un-2022	
	Test Result	65	Test Unit	CELLS PER M8CROL8TR E	
	Low Test Range	13	q gh Test Range	35	
	More 8n/ormation Availa7lek				

Additional Comments

	AST on Yw80w22 was 22 in normal range.

Section 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 ncluding a picture)	He

Section C - A7out the Products 1 o/ 1

	Suspect	He
	Primaryk	He
	Type	DrugwBiologi
	This report is a7out	FoodwMedical /ood
	Name o/ the product as it appears on the 7o, 47ottle4 or pacbage (8nclude as many names as you see)	Daily q arvest French Lentil l Leeb Crum7les
	Name o/ the company that mab (or compounds) the roduct	Daily q arvest
	Product Type(checb all that apply)	☐ Over-the-Counter ☐ Compounded 7y a Pharmacy or an Outsourcing Facility ☐ Generi ☐ Biosimilar
	Strength	8' Other
	NDC num7er	
	Did the pro7lem stop a/ter the rson reduced the dose or opped tab ng or using the roductk	No
	Did the pro7lem return i/ the rson started tab ng or using the roduct againk	Doesn't Apply

Drug Therapy 1 o/ 1

	E, ration date				
	Lot num7er				
	Dosage Form				
	Quantity		8 Other		
	Fre?uency		8 Other		
	q ow was it tab n or used		8 Other		
	Date the person /irst started ab ng or using the product	2Y-May-2022			
	Date the person stopped tab ng or using the product	2Y-May-2022			
	Date the person reduced dose o/ he product				
	Give 7est estimate o/ duration				
	8 therapy still on-goingk				

Why was the person using the productk (such as what condition was it supposed to treat) 1 o/ 1

	Returned to Manu/acturer On	

Section D - A7out the Medical Device

	Name o/ medical device	
	Name o/ the company that mab the medical device	

Other identi/ying in/ormation (The model4catalog4lot4serial4or UD8num7er4and the e, piration date4i/ you can locate them)

	Model Num7er	
	Catalog Num7er	
	Lot Num7er	
	Serial Num7er	
	UDD8Num7er	
	E, ration date	
	Was someone operating the medical device when the pro7lem oc urredk	

For implanted medical devices ONLH (such as pacemabers47reast implants4etc)

Date the implant was put in		Date the implant was taben out (8 relevant)	

Section E - A7out the Person Who q ad the Pro7lem

	Person's 8nitials	(b) (6)

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 anicw Latino
Race (Checb all that apply)	☐ American 8ndian or Alasba Native ☐ Native q awaiian or Other Paci/ic 8lander ☐ Asian ☑ White ☐ Blacb or A/rican American

List bnown medical conditions (Such as dia7etes4high 7lood pressure4cancer4heart disease4or others)

cancer

Please list all allergies (such as to drugs4/oods4pollen or others)

azithromycin4and hydrocodone4acetaminophen

List any other important in/ormation a7out the person (such as mob ing4pregnancy4alcohol use4etc.)

List all current prescription medications and medical devices 7 ng used.

List all over-the-counter medications and any vitamins4minerals4supplements4and her7al remedies 7eing used.

magnesium glycinate4polyresveratrol-sr 4curcumin4ashwagandha4vit d34multivitamin4calcium4vit B4Pro7iotic4zinc4vit c4 urbey tail4reishi4

Section F - A7out the Person Filling Out This Form 1 o/ 1

Primaryk	He
Reporter is Patientk	
Title	
Last name	(b) (6)

	Middle Name		
	First name	(b) (6)	
	Num7erw6treet	(b) (6)	
	City	(b) (6)	
	Statew Province	(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/acturerwcompounder)k	No	
	8 you do NOT want your dentity disclosed to the manu/acturer4please marb this 7o, (Con/identiality Re?uested):	He	

daily-harvest.com/home?tab=collections&scrollTo=crumbles&page=/account/ratings

An update on our voluntary recall of French Lentil + Leek Crumbles. Details here

DAILY HARVEST

FOR YOU ALL COLLECTIONS

Filters

Gotta Haves

Back in Stock

Smoothies

Harvest Bowls

Harvest Bakes

Flatbreads

Crumbles

Soups

Forager Bowls

Scoops

Bites

Lattes

Mylk

Out of Stock

Walnut + Thyme
Crumbles

We're working hard to restock ASAP, so check back soon.

Temporarily Discontinued

French Lentil + Leek
Crumbles

This item is temporarily discontinued. Please dispose of this item and do not eat it. Details here.

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	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		
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	26-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)

Ingested Daily Harvest French Lentil + Leek crumbles, started having symptoms consistent with liver damage 2-3 weeks later. Blood tests confirmed liver damage/irritation.

Relevant 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 DECILITRE
	Low Test Range	0.2 mg/dL	High Test Range	1.2 mg/dL

	More Hn/ormation Availa6le8			

Relevant Testw La6oratory Data 2 o/ 9

	Test Name	AL' ALHNE P? OSP? ATAS E	Test Date	04-f ul-2022
	Test Result	235 Uw L	Test Unit	CELLS PER MHCROLHTR E
	Low Test Range	35 Uw L	? gh Test Range	499 Uw L
	More Hn/ormation Availa6le8			

Relevant Testw La6oratory Data 3 o/ 9

	Test Name	ASTw6GOT	Test Date	04-f ul-2022
	Test Result	4x2 Uw L	Test Unit	CELLS PER MHCROLHTR E
	Low Test Range	40 Uw L	? gh Test Range	35 Uw L
	More Hn/ormation Availa6le8			

Relevant Testw La6oratory Data 9 o/ 9

	Test Name	ALT (SGPT)	Test Date	04-f ul-2022
	Test Result	9J9 Uw L	Test Unit	CELLS PER MHCROLHTR E
	Low Test Range	1 Uw L	? gh Test Range	97 Uw L
	More Hn/ormation Availa6le8			

Additional Comments

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
	Type	DrugwBiologi
	This report is a6out	
	Name o/ the product as it appears on the 6oK+6ottle+ or pacbage (Hnclude 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

	Product Type(checb all that apply)	☐ Over-the-Counter ☐ Compounded 6y a Pharmacy or an Outsourcing Facility ☐ Generi ☐ Biosimilar		
	Strength		H/ Other	
	NDC num6er			
	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	DoesnK Apply		

Drug 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		

Why was the person using the product8 (such as what condition was it supposed to treat) 4 o/ 4

	Returned to Manu/acturer On	

Section D - A6out the Medical Device

	Name o/ medical device	
	Name o/ the company that mab the medical device	

Other identi/ying in/ormation (The model+catalog+lot+serial+or UDH-num6er+and the eKpiration date+i/ you can locate them)

	Model Num6er	
	Catalog Num6er	
	Lot Num6er	

	Serial Num6er	
	UDDH-Num6er	
	EK ration date	
	Was someone operating the medical device when the pro6lem oc urred8	

For implanted medical devices ONLq (such as pacemabers+6reast implants+etcl)

Date the implant was put in		Date the implant was tab n out (H/ relevant)	

Section E - A6out the Person Who ? ad the Pro6lem

	Personks Hnitials	(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	JxIx5 bg
	Ethnicity (Choose only one)	Not ? anicw Latino
	Race (Checb all that apply)	☐ American Hndian or Alasba Native ☐ Native ? awaiian or Other Paci/ic Hslander ☐ Asian ☑ White ☐ Blacb or A/rican American

List bnown medical conditions (Such as dia6etes+high 6lood pressure+cancer+heart disease+or others)

slightly high cholesterol+history o/ cardiomyopathy

Please list all allergies (such as to drugs+/oods+pollen or others)

contrast

List any other important in/ormation a6out the person (such as mob ing+pregnancy+alcohol use+etcl)

List all current prescription medications and medical devices 6 ng usedl

Ramipril+Rosuvastatin+Carvedilol

List all over-the-counter medications and any vitamins+minerals+supplements+and her6al remedies 6eing usedl	
Xyzal Allergy	

Section F - A6out the Person Filling Out This Form		4 o/ 4
Primary8	qe	
Reporter is Patient8		
Title		
Last name	(b) (6)	
Middle Name		
First name	(b) (6)	
Num6erv6Street	(b) (6)	
City	(b) (6)	
Statev Province	(b) (6)	
Country	UNHTED 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/acturerv compounder)8	qe	
HI you do NOT want your dentity disclosed to the manu/acturer+please marb this 6oK (Con/identiality Rekuested):	No	

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	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		
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 oc urred	20-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)

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 Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

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	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?	Yes		
Did the problem return if the 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		If Other	
Date the person first started aking or using the product	19-May-2022		
Date the person stopped taking or using the product	19-May-2022		

	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

	Meal

	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 relevant)	

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	49.95 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 (Such as diabetes, high blood pre ure, cancer, heart disease, or others)

Hashimoto's

Please list all allergies (such as to drugs, foods, pollen or o hers)

N/A

List any other important information about the person (such as moking, pregnancy, alcohol use, etc.)

Healthly, non-smoker, non-drinker

List all current prescription medications and medical devices b ng used.

Levothyroxine

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

N/A

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
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)

	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	

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	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		
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 oc urred	03-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)

On 06/02/22, I consumed ¾ cup of Daily Harvest French Lentil and Leek Crumbles. Within 16 - 18 hours, I experienced severe chills, nausea, gastrointestinal illness, stomach, abdominal pa n, painful and swollen joints, and fever. After seven or eight hours, my husband took me to the emergency room and I was admit d there for treatment. After saline and then bloodwork, was discovered that my liver enzymes were quite high and tha my magnesium was low. I was released with the diagnosis of viral syndrome. For weeks after that, my skin was jaundiced as were the corners of my eyes and gums. My stomach and intestines were sore, my appetite was poor, and I experienced fatigue and lethargy.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	03-Jun-2022
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	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	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 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 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		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		

	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

his is a food product

	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 relevant)	

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	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

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)

dust, mildew/mold

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.

entrum womens +50, fish oil, citracal,

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	
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	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	

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 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	10-Jul-2022	CTU Received Date	10-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)	

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	OB nurse SJH
	Age	34 Year(s)
	Date of Birth	
	Sex	Undifferentiated
	Gender	Other Gender category
	Please Specify Other Gender	non-binary
	Weight	63 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

B. ADVERSE EVENT, PRODUCT PROBLEM

	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

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	09-Jul-2022
Date of this Report	10-Jul-2022

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Hyperbilirubinem a and hepatitis with daily harvest French Lentil & Leek Crumbles. intractable vomiting

Relevant Test/Laboratory Data 1 of 2

Test Name	TBILI	Test Date	09-Jul-2022
Test Result	6.4	Test Unit	MILLIGRAMS PER DECILITRE
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 2 of 2

Test Name	ALT	Test Date	09-Jul-2022
Test Result	0.336	Test Unit	UNITS PER MILLILITRE
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Condition

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)	No

D. PRODUCT(S) 1 of 1

Suspect	Yes
Primary?	Yes

	Type	Drug/Biologi		
	This report involves:	Food/Medical food		

Name,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)	☑ OTC ☐ Compounded ☐ Generi ☐ Biosimilar		
	Event Abated After Use Stopped or Dose Reduced?			
	Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

	Dose or Amount		If Other	
	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			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

	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) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	(b) (6)		
Middle Name			
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 ☐ User Facility ☐ Distributor/Importer		

	If you do NOT want your identity disclosed to the manufacturer	No	

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	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		
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 oc urred	16-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)

I ate Daily Harvest French Lentil and Leek Crumbles multiple times between June 6- June 15. In that week I experienced vere abdominal pain. On June 16 the pain got worse and was ac ompanied by headache and nausea. I called a nurse hotline that recommended I go to urgent care. Urgent care sent me to the ER and I stayed the night in the hospital. I had extensive bloodwork tested as well as ultrasound, x-ray, and CT scan. All that was found was elevated liver enzymes. Today, my liver enzymes are still high but are on a downward trend.

Relevant Test/Laboratory Data 1 of 5

	Test Name	COMPREHENSIVE META BOLIC PANEL	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

	More Information Available?			

Relevant 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?			

Relevant Test/Laboratory Data 3 of 5

	Test Name	BILIRUBIN TOTAL	Test Date	17-Jun-2022
	Test Result	3.4	Test Unit	MILLIGRAMS PER DECILITRE
	Low Test Range	.2	High Test Range	1.0
	More Information Available?			

Relevant Test/Laboratory Data 4 of 5

	Test Name	BILIRUBIN DIRECT	Test Date	17-Jun-2022
	Test Result	1.5	Test Unit	MILLIGRAMS PER DECILITRE
	Low Test Range	0	High Test Range	.2
	More Information Available?			

Relevant 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?			

Additional Comments

Section 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

Section C - About the Products 1 of 1

	Suspect	Yes
	Primary?	Yes
	Type	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 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?	Yes		
	Did the problem return if the rson started taking or using the roduct again?	Yes		

Drug 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		

Why was the person using the product? (such as what condition was it supposed 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 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 relevant)	

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	62.1 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 (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)

mold

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.

atrovent

List all over-the-counter medications and any vitamins, mineral , supplements, and herbal remedies being used.

ostnatal vitamins

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
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)?	No
If you do NOT want your dentity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes

L02-VEGBN BEST BY 10/23/2022 L5-A 15:32

LENTIL BUTTERNUT SQUASH HEMP SEED QUINOA CREMINI TARA

Compost Me

***Preparing* Crumbles:**

1. 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.
3. 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

DISTR. BY DAILY HARVEST INC. NEW YORK, NY 10013

A

L02-VEGBN

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	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		
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	09-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 the Daily Harvest French Lentils and Leak Crumbles. I had severe illness including extreme pain, fever, nausea and liver damage. I continue to experience symptoms over a month later.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	

	Low Test Range		High Test Range		
	More xnformation AvailaqleY				

Additional Comments

Section 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

Section C - Aqout the Products 4 of 4

	Suspect	,e			
	PrimaryY	,e			
	Type	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)	Daily Harvest French Lentil QLeeHCrumqles			
	Name of the company that maH (or compounds) the roduct	Daily Harvest			
	Product Type(checHall that apply)	☐ Over-the-Counter ☐ Compounded qy a Pharmacy or an Outsourcing Facility ☐ Generi ☐ Biosimilar			
	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				

Drug 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				

	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	

Why was the person using the productY (such as what condition was it supposed to treat) 4 of 4

	Returned to Manufacturer On	

Section D - Aqout the Medical Device

	Name of medical device	
	Name of the company that maH the medical device	

Other identifying information (The modelVcatalogVlotVserialVor UDxnumqerVand the e' piration dateVif you can locate them)

	Model Numqer	
	Catalog Numqer	
	Lot Numqer	
	Serial Numqer	
	UDDxNumqer	
	E' ration date	
	Was someone operating the medical device when the proqlem oc urredY	

For implanted medical devices ONL, (such as pacemaHersVqreast implantsVetc.)

Date the implant was put in		Date the implant was taHen out (xf relevant)	

Section E - Aqout the Person Who H ad the Proqlem

	Person6s 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 H awaiian or Other Pacific xlander

		☐ Asian ☐ White ☐ BlacHor African American	

List Hhown medical conditions (Such as diaqetesVhigh qlood pressureVcancerVheart diseaseVor others)

Please list all allergies (such as to drugsVfoodsVpollen or others)

List any other important information aqout the person (such as smoHngVpregnancyValcohol useVetc.)

List all current prescription medications and medical devices q ng used.

List all over-the-counter medications and any vitaminsVmineralsVsupplementsVand herqal remedies qeing used.

Section F - Aqout the Person Filling 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	(b) (6)
	Country	UNxTED STATES
	ZxP or Postal code	(b) (6)
	Telephone numqer	(b) (6)
	Email address	(b) (6)

	Fa'		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today6 date	42-Jul-2022	
	Did you report this proqlem 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	