

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 1/11/2022-2/11/2022*
	FEI NUMBER 3004286071

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher R. Murabito, General Manager

FIRM NAME Family Dollar Distribution Inc.	STREET ADDRESS 1800 Family Dollar Pkwy
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CITY, STATE, ZIP CODE, COUNTRY West Memphis, AR 72301-2974	TYPE ESTABLISHMENT INSPECTED Distributor
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This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
The following observations pertain to human food products stored and distributed from your facility.

OBSERVATION 1

You did not exclude pests from your food plant to protect against contamination of food.

Specifically, during this inspection we observed rodent evidence, including live rodents, dead rodents of various states of decay, rodent excreta pellets (REPs), gnawings, nesting, and odors indicative of rodents throughout the entirety of your facility including areas where human food is routinely stored. Examples include but are not limited to the following:

On 01/11/2022, on the north wall of the shipping dock and north most wall of the warehouse, we observed:

- Too numerous to count (TNTC) REPs on the floor of the north end of the shipping dock where product, including food, is stored for up to (b) (4) awaiting shipment.
- Located in the northwest corner of the north wall of phase (b) (4) of your facility, directly north of food aisles (b) (4), are the ICC Office and break room. The ICC Office is directly below the breakroom, on the ground level of your facility. Per firm management, the ICC office and breakroom were closed off and tile ceiling and carpeting of the ICC office was removed in October of 2021 due to the odor in the rooms. We observed, on 02/08/2022 and 02/09/2022, that the ICC office had been cleared of all office goods and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lauren R Brady, Investigator Michael L Jones, Investigator Margaret M Annes, Investigator Preston B Hoover, Investigator Jocelyn C Turner, Investigator - Dedicated Device Cadre	<p align="center"> <small>Lauren R Brady Investigator Signed By: 2002865057 Date Signed 02-11-2022 10 46 18</small> <input checked="" type="checkbox"/> </p>	DATE ISSUED 2/11/2022

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there was a putrid odor permeating the now cleared out room. The break room above the ICC office also remains closed and in front of the entrance to this area is rodent nesting materials.

On 01/11/2022, 02/01/2022, and 02/07/2022, along the south wall of the warehouse, we observed:

- Four rat carcasses on the conveyer belt mezzanine level along the south wall of your firm by aisles (b) (4) and (b) (4).
- A rat carcass below rack location (b) (4).
- A distinct odor indicating a dead/decaying animal in a section of the unused conveyer belt system, labeled (b) (4), on the mezzanine level located south of aisle (b) (4).

On 01/11/2022, in the northwest corner of the warehouse, we observed:

- A live rat running toward the west wall between pallets stored in the northwest corner of the warehouse in front of receiving door (b) (4).
- Approximately 25 REPs on the floor of rack location (b) (4).

On 01/11/2022, in the northeast corner of the warehouse, we observed:

- Approximately 50 REPs at the north-most end of aisle (b) (4).

On 01/11/2022, in the southwest corner of the warehouse, we observed:

- Approximately 25 REPs on the floor of rack location (b) (4).

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On 01/11/2022, in the southeast corner of the warehouse, we observed:

- TNTC REPs on the equipment and floors of the area in your firm called the “junk yard,” which contains maintenance equipment.

On 02/09/2022, in the center of phase (b)(4) of the facility, we observed:

- Significant gnawings, TNTC REPs, and a strong odor of rodent urine and excreta on a pallet containing (b)(4) cases of mixed nuts which have a best by date of 26/Sep/2020 stored in rack location (b)(4). Multiple bags of product were gnawed open and product was spilling out of cases onto lower levels of the pallet. Gnawings and spilled product could be seen from the top (b)(4) layer down to the 3rd layer of the pallet.

On 01/11/2022, in the center of the entire warehouse, which is also the center of the (b)(4) food storage area consisting of aisles (b)(4), we observed:

- TNTC REPs and a mouse carcass on a pallet containing (b)(4) 8-count cases of Hungry Jack Cheesy Scalloped Potatoes, “BEST BY: OCT1922 E12” stored in rack location (b)(4).

On 01/11/2022, in the northwest corner of the (b)(4) food area, we observed:

- A live rat run from east to west across aisle (b)(4) near bay (b)(4) and a live apparent mouse run from west to east across the north end of aisle (b)(4). All of the floor level of aisle (b)(4) is for food storage.
- Approximately 15 REPs on a pallet of flour located in rack location (b)(4). Eleven of the (b)(4) cases stored on the pallet contained product with gnawings. While unstacking the pallet, two mice exited from

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gnawed-open product bags stacked on the bottom layer of the pallet and ran west under the north end of aisle (b)(4)

On 01/11/2022, in the northeast corner of the (b)(4) food area, we observed:

- Approximately 30 REPs in and around a pallet containing (b)(4) cardboard cases with twelve 5.6-ounce pouches each of Knorr Chicken Flavor Rice & Pasta Blend, "BEST IF USED BY DEC0822 MUE***L05 10815" stored in rack location (b)(4). This pallet also had nesting material and tunnelling in between the bottom layers 1 and 2 of the pallet and at the top (b)(4) layer. Approximately 20 of the cases on the pallet contained significant rodent gnawings.
- TNTC REPs on and around a pallet containing multiple food products, including two lots of Knorr Pasta Alfredo stored in rack location (b)(4). The first lot, which consisted of (b)(4) cases containing twelve 4.4-ounce packages each, "BEST BY FEB2323MUC," had six rodent gnawed individual packages of product. Product spilled out into the case had fluorescing mammalian urine stains. The second lot, which consisted of (b)(4) cases containing twelve 4.4-ounce packages each, "BEST BY MAR2623MUC," had 4 rodent gnawed individual packages of product.

On 01/11/2022, in the southwest corner of the (b)(4) food area, we observed:

- TNTC REPs on and around a pallet of (b)(4) cases containing twelve 10-ounce bags each of Graffiti Taffy, "20265 BEST BY: 04/01/2022," stored in rack location (b)(4).
- A rat running from the maintenance area east toward food aisle (b)(4) that then turned and ran back toward the maintenance area after running into foot traffic in the aisle.

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On 01/11/2022, in the southeast corner of the (b) (4) food area, we observed:

- TNTC REPs on the floor of rack location (b) (4), underneath of a pallet of Chestnut Hill Self-Rising Flour.

On 01/11/2022 and 01/13/2022, in the northwest corner of the (b) (4) food area, consisting of aisles (b) (4) we observed:

- TNTC REPs on the floor surrounding rack location (b) (4).

On 01/11/2022, in the northeast corner of the (b) (4) food area we observed:

- Multiple (no less than 5) rats climbing up rack scaffolding and through a pallet containing potato chips stored in cardboard cases in rack location (b) (4). This area of the aisle also had a strong odor of rodent excreta and urine.
- TNTC REPs and fluorescing product on a pallet containing a case with (b) (4) 3.63-ounce bags of BiGS Taco Supreme Flavored Sunflower Seeds, "BEST BY OCT 12 2022 5628123021." Two of the (b) (4) bags were opened and product that had spilled into the cardboard case had fluorescing mammalian urine stains. The pallet was stored in rack location (b) (4). The pallets in this location smelled of rodent urine and excreta.

On 01/11/2022 and 01/19/2022, in the southwest corner of the (b) (4) food area we observed:

- TNTC REPs on a pallet containing (b) (4) 24-count packages of Jell-O brand Instant Chocolate Jello, "13 MAY 2023***DB08" stored in rack location (b) (4).

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- Following fumigation, upon entering phase (b) (4) of the warehouse on the southwest corner of food area (b) (4) we observed a strong odor indicative of many dead or decaying animals that permeated throughout aisles (b) (4)

On 01/11/2022 and 01/13/2022, in the southeast corner of the (b) (4) food area we observed:

- Four rats crossing aisle (b) (4) from east to west near the south side of the aisle and two more rats crossing aisle (b) (4) from west to east near the south side of the aisle. Food is stored along the entirety of the floor levels of aisles (b) (4).
- TNTC REPs on a pallet of (b) (4) cases containing twelve 3.53-ounce cans each Beach Cliff Red Herring Fillets, "1089CBXSXX BEST BY MAR 2024" stored in rack location (b) (4). Directly next to this pallet, in rack location (b) (4) was a pallet of (b) (4) cases containing eight 6.5-ounce bags each Brims Butter Popcorn, "Best By: 04/01/2022." One case on this pallet had an open bag of popcorn, approximately 10 REPs, and fluorescing stains on the inside of the case.

On 01/11/2022 and 01/13/2022, in the center of the (b) (4) food area we observed:

- TNTC REPs on and in between the layers of a pallet containing (b) (4) cases of 7-ounce tubs each Italion Pistachio & Vanilla Duo Spread, "BB 05 05 2023 LOT NO 210517" stored in rack location (b) (4). The pallet also contained significant nesting material underneath the first layer of cases at the front of the pallet and between the second and third level of cases in the center of the pallet. Four individual product containers contained gnaw holes. The area surrounding this rack location had a strong odor of rodent urine and excreta.

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During our review of the pest control records, we observed pest reports from your pest control company which document the capture of between 16 and 107 mice for all months of 2020 and from January through June of 2021. Starting in July of 2021 through December 2021, pest control reports for (b) (4) document the presence of between 1 and 31 roof rats inside multiple areas of the facility, including but not limited to aisles where human food is normally stored. Your firm's maintenance team also monitored and tracked rodent captures made in large bait boxes and glue traps placed by your pest control company along the pick-slot level of aisles (b) (4) from 03/29/2021 to 09/17/2021. During this time period, your firm documented over 2300 rodent captures. In January of 2022, your firm acquired a new pest control company and set up new traps from January 7th through January 12th, 2022. During this five-day span, 150 roof rats were captured from your facility. Following fumigation, between the dates of January 16th-January 20th, 2022, from numbers gathered by your firm employees and your pest control company, approximately 1100 rodent carcasses were removed from your facility.

The food products your firm receives, holds, and distributes are routinely distributed to customers in (b) (4) (b) (4).

OBSERVATION 2

You did not maintain your plant in a clean and sanitary condition and keep your plant in repair.

Specifically, during the inspection, we observed:

On 01/11/2022, 01/13/2022, 01/14/2022, and 02/01/2022:

- Spilled foods underneath multiple rack locations, including but not limited to spilled flour at rack

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location (b) (4) located in the southwest corner of food area (b) (4) spilled dog food at rack location (b) (4) located in the southwest corner of food area (b) (4) spilled cereals under rack locations (b) (4) (b) (4), in the southeast corner of food area (b) (4) and (b) (4), in the northeast corner of food area (b) (4)

- The firm's compacter, located on the southwest corner of the shipping area and attached to the outside wall of the facility, has gaps at least 2 inches wide across the entire top and holes ranging in diameter from 1 inch to 12 inches on both the north and south facing sides that penetrate all the way through the sheet metal and can be seen from both inside and outside the building. Additionally, the compacter has a strong odor of rotting garbage that is noticeable both inside and outside the firm at a distance of up to 5 feet away. The compacter has a (b) (4) door for access from inside the firm, located approximately 25 feet from the (b) (4) food area consisting of aisle (b) (4), which is held open during the firm's operational hours unless the attached dumpster is being changed out.
- Multiple dock doors and dock plates in both shipping and receiving areas with gaps ranging in size exposing the facility to the environment, including but not limited to the following examples:
 - Receiving doors (b) (4) and (b) (4) with gaps up to 3 inches in length and 1 inch in height on the left and right sides of the bottoms of the doors.
 - Shipping doors (b) (4) and (b) (4) with gaps running the entirety of each side of the dock plates at least 2 inches in width.
 - Receiving doors (b) (4), (b) (4), and (b) (4) with damage in the bottom center of the doors, leaving gaps at least 6 inches in length and 2 inches in height.
- Multiple holes in rubber sealants and gaps surrounding pipes and wiring exiting the building on the south and east walls.

OBSERVATION 3

You did not keep the grounds around your plant in a condition that would protect against the contamination of food.

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Specifically, during the inspection, we observed:

On 01/13/2022 and 01/14/2022:

- Debris, food trash, and wooden pallet pieces were observed in piles surrounding the compacter and below docks doors on both shipping and receiving area walls of the firm. Trash was piled up to 1.5 feet tall and extended up to 2 feet out from the facility's walls.
- Food trash and other dirt was observed piled below and surrounding the compacter on the west side of the shipping dock.
- Multiple pallets of food product intended for disposal were observed stored approximately 50 feet from the shipping dock and compacter area. Per firm management, pallets are to be placed into dumpsters immediately rather than sitting outside of dumpsters on the ground in the firm's truck-yard. The pallets of food product were noted at 5:00PM on 01/13/2022 and remained in the area until at least 12:00PM on 01/14/2022.

The following observations pertain to animal food products stored and distributed from your facility.

OBSERVATION 4

You did not hold animal food for distribution under conditions that protect against contamination and minimize deterioration.

Specifically, during the inspection, we observed the following:

- On 01/11/2022, 01/13/2022, and 01/14/2022, we observed insanitary conditions in the area of your warehouse where bagged pet foods are stored. The bagged pet foods were held under storage

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conditions with evidence of rodent activity, such as gnaw holes in packaging material, REPs, nesting materials, urine stains, live rodents, and rodent carcasses. These conditions were observed in the center of each of the (b) (4) food areas of your warehouse, consisting of aisles (b) (4) and (b) (4). These conditions were also observed in all four corners and the center of the warehouse. Prior to fumigation, per the inventory list your firm provided, there were (b) (4) individual containers of pet food held in the warehouse.

OBSERVATION 5

You did not take effective measures to exclude pests from your plant and protect against contamination of animal food by pests.

Specifically, during the inspection, we observed:

On 01/11/2022, in the southwest corner of food area (b) (4) we observed:

- Rodent gnawings on seven out of (b) (4) bags of Pedigree High Protein Chicken & Turkey Flavored dog food, "BEST BY 11 29 22 14882KKMO8" stored on a pallet bags in rack location (b) (4) on the southwest corner of food area (b) (4). This pallet also contained TNTC apparent REPs on and around the bags of dog food.

On 01/11/2022, in the small food storage area northeast of food area (b) (4) we observed:

- Approximately 40 REPs on a pallet containing (b) (4) bundles of four 3.15-pound bags of Friskies Tender & Crunchy Combo cat food, "LOT 13341083***BEST BEFORE END NOV 2022" stored in rack location (b) (4). One of the 3.15-pound bags also contained a circular gnaw-hole approximately 1.5 inches in diameter.

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On 01/11/2022, on the northwest side of food area (b) (4) we observed:

- TNTC REPs on and around a pallet containing (b) (4) 16-pound bags of Family Pet Gravy Style Beef Flavored dog food held in rack location (b) (4) on the northwest corner of food area (b) (4)

On 01/13/2022, in the northeast corner of food area (b) (4) we observed:

- TNTC REPs on a pallet containing (b) (4) twelve-pound bags of Purina Friskies Surfin' & Turfin' Favorites dry cat food, "1274108***L05," "BEST BY APR 2023" stored in rack location (b) (4) on the northeast corner of food area (b) (4). Three bags on the lowest layer of the pallet also contained gnaw holes ranging from 2 inches to 4 inches in diameter.

On 02/01/2022, 02/07/2022, and 02/09/2022, on the west side of the small food storage area located northeast of food area (b) (4) we observed:

- Apparent bird droppings covering an area of flooring 1.5 feet wide and 3 feet long off the northwest end of aisle (b) (4). A dead apparent bird was seen caught in bird netting overtop of this area. We observed an employee mop the area on 02/01/2022 at the request of firm management. On 02/09/2022, we observed new bird droppings covering the same area as observed on 02/01/2022. Aisle (b) (4) is primarily used for storage of pallets containing large bags of animal food.

During our review of the pest control records, we observed pest reports from your pest control company which document the capture of between 16 and 107 mice for all months of 2020 and from January through June of 2021. Starting in July of 2021 through December 2021, pest control reports for (b) (4) document the presence of between 1 and 31 roof rats inside multiple areas of the facility, including but not limited to aisles where animal food is normally stored. Your firm's maintenance team also monitored and tracked rodent

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DISTRICT ADDRESS AND PHONE NUMBER 1201 Main Street, Suite 7200 Dallas, TX 75202 (214) 253-5200 Fax: (214) 253-5314	DATE(S) OF INSPECTION 1/11/2022-2/11/2022*
	FEI NUMBER 3004286071

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher R. Murabito, General Manager

FIRM NAME Family Dollar Distribution Inc.	STREET ADDRESS 1800 Family Dollar Pkwy
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CITY, STATE, ZIP CODE, COUNTRY West Memphis, AR 72301-2974	TYPE ESTABLISHMENT INSPECTED Distributor
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captures made in large bait boxes and glue traps placed by your pest control company along the floor level of racks (b) (4) from 03/29/2021 to 09/17/2021. During this time period, your firm documented over 2300 rodent captures. In January of 2022, your firm acquired a new pest control company and set up new traps from January 7th through January 12th, 2022. During this five-day span, 150 roof rats were captured from your facility. Following fumigation, between the dates of January 16th-January 20th, 2022, from numbers gathered by your firm employees and your pest control company, approximately 1097 rodent carcasses were removed from your facility.

The food products your firm receives, holds, and distributes are routinely distributed to customers in (b) (4) (b) (4).

The following observations pertain to drug products stored and distributed from your facility.

OBSERVATION 6

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

- Your firm failed to implement appropriate and timely corrective action to ensure that product that may be injurious to health due to potential contamination by rodent urine and excreta and/or had been chewed or gnawed by rodents, or may have been subjected to filth conditions such as dirt and debris, was not distributed to your stores.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lauren R Brady, Investigator Michael L Jones, Investigator Margaret M Annes, Investigator Preston B Hoover, Investigator Jocelyn C Turner, Investigator - Dedicated Device Cadre	Lauren R Brady Investigator Signed By: 2002865057 Date Signed: 02-11-2022 10:46:18 X	DATE ISSUED 2/11/2022

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Your firm was aware of an increased presence of rodents in the Distribution Center (DC) since at least January 2020. Per your General Manager, on October 26, 2021, when a fire drill was conducted, dozens of rats could be seen running around the facility due to the loud and sustained sound of the fire alarm. At some time during October 2021, your firm stopped using the breakroom and Inventory Control Center (ICC) room located West of Dock Door (b) (4) on the North side of the building due to the significant foul stench/odor of rodents in the facility.

Your firm lacks a system for receiving and tracking reports from your stores of potentially contaminated product received from the Distribution Center (DC). However, your firm was able to provide some emails dated January 8, 10, 12, and 13, 2022 containing reports from various stores serviced by your Distribution Center of product that was received with rodent excreta pellets and/or that was gnawed/chewed, a report of a "live large rat" found in a box received, and a report of a large rat jumping out of a pallet received from the Distribution Center.

Your firm continued to ship products, including drug products, to stores up until January 13, 2022, when fumigation of the facility occurred.

- Your firm did not remove drugs products from your facility prior to fumigation as outlined in the Applicator Manual for the (b) (4) ® gas fumigant used.

Examples of drug products distributed by your facility include Over-the-Counter (OTC) products such as various Ibuprofen products, Infant and Children's Tylenol, Extra Strength Tylenol Rapid Release Gels, Omeprazole products, hand sanitizer, cough, cold and flu products and antihistamines.

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OBSERVATION 7

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition and free of infestation by rodents, birds insects, and other vermin.

Specifically, your firm has documentation since at least January 2020 of rodents (mice and/or rats) within your facility. Your firm's maintenance team also monitored and tracked rodent captures made in large bait boxes and glue traps placed by your pest control company along the pick-slot level of aisles (b) (4) from 03/29/2021 to 09/17/2021. During this time period, your firm documented over 2300 rodent captures. In January of 2022, your firm acquired a new pest control company and set up new traps from January 7th through January 12th, 2022. During this five-day span, 150 roof rats were captured from your facility. Your firm performed a fumigation on January 14-16, 2022, and over 1100 dead rats have so far been "harvested" post-fumigation. In addition, we saw several dead mice and rats inside and outside the warehouse as well as a foul odor/stench coming from several places within the facility that is indicative of a dead and decaying animal. We also saw evidence of rodent activity to include rodent excreta pellets and rodent hair. For example,

- Rodent activity could be seen (rodent excreta pellets) in various areas within the warehouse and in and on several pallets of products to include drugs. For example,
 - Rodent excreta pellets were observed on the case boxes and a pallet containing lot #Z21M044 of Vagisil Maximum Strength Anti-Itch Crème. There was a foul stench/odor indicative of a dead and decaying animal in the pallet of clothing/apparel in the slot directly below where this drug product was stored (Slot #(b) (4)).
 - Rodent excreta pellets were observed on the case boxes and pallet containing lot #1LE2264 of GoodSense brand Omeprazole Delayed Release Tablets 20mg (42 tablets/box) located in Slot #(b) (4) .

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- One (1) rodent excreta pellet was observed on a case of Lot #13461707C2 of Crest Outlast Mint Toothpaste (5.4oz tube) in Slot #(b) (4) .
- Rodent excreta pellets were observed on a pallet containing Batch #0545989 of Swan brand Medicated Chest Rub in Slot #(b) (4) .
- Rodent excreta pellets were observed on several cases of lot #3261LZ of Listerine Total Care Freshmint Anticavity Fluoride Mouthwash located in Slot #(b) (4) .
- We observed dead rodents (mice and rats) in various sections inside and outside the warehouse. Some had been there for some time (body desiccated) and/or were more recently deceased. These include:
 - On 02/01/2022 we observed one (1) large dead rat near Slot #(b) (4) in the (b) (4) room where hand sanitizer was observed stored.
 - On 02/07/2022, we saw a dead rat between the two conveyor belts on a section of the old conveyor system that ran through Aisle (b)(4) (Upper West Side Belt).
 - On 02/01/2022 we saw a dead mouse between Slot #s (b) (4) and (b) (4)
 - On 02/02/2022, we observed a dead rodent near Slot #(b) (4) .
 - On 02/07/2022, we observed two (2) dead rats along the North wall just to the West of Dock Door (b) (4) .
- On 02/1, 4 & 7/2022, we noted a foul stench/odor coming from a section of the machinery for the old conveyor system located across from Aisle (b)(4) that was indicative of a dead and decaying animal.
- On 02/4 & 7/2022, we noted a foul stench/odor coming from Slot #s (b) (4) & (b) (4) in the Repack Area of Aisle (b)(4) that was indicative of a dead and decaying animal. Rodent hair (b) (f)(E)

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(b) (7)(E) in the area directly under the cartons containing lot #1LE1990A of Good Sense Brand Ibuprofen (250 coated tablets) and lot #AJM011 of Children's Tylenol.

- On 02/07/2022, we observed evidence of rodent activity in and around a breakroom and old ICC (Inventory Control Center) room located on the North side of the building and just to the West of Dock Door (b) (4). This included a strong foul odor/stench of dead and decaying rodents, rodent pellets, and evidence of rodents nesting. Your firm stopped using these rooms in October 2021 due to the strong odor/stench of rodents.
- On 02/07/2022, we observed two (2) dead birds inside the facility. One was on the East side of the mezzanine level under part of the old conveyor system, and one was in a net at the upper level of some racks in Aisle (b) (4), just South of the shipping docks. We also observed bird droppings near Slot #(b) (4) (b) (4), which is below area where dead bird was seen in the net.

Your firm has no written procedures for the cleaning of the Distribution Center, to include the racks where all products, including drug products, are stored prior to shipment to stores. Dirt and debris was observed built up in, on and under the rafters and shelves, including shelving in the Repack Area of Aisle (b) (4) where many drug products are stored.

OBSERVATION 8

Buildings used in the holding of a drug product are not maintained in a good state of repair.

Specifically, during our walk-through of the facility on 01/19-21/2022 and 02/01-02, 4, 7, 8 & 9/2022, we observed the following.

- Overhead doors located in various parts of the receiving and shipping areas had gaps where light could be seen coming from the bottom of the door. In addition, gaps and light could be seen in and around the dock plates/levelers located adjacent to the overhead doors. These gaps were big enough to allow rodents and other pests to enter the facility. These doors include but are not limited to Dock Doors (b) (4),

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(b) (4), (b) (4), (b) (4), (b) (4), (b) (4), (b) (4), (b) (4), (b) (4), (b) (4), (b) (4) and (b) (4).

- Your firm has remnants of an old system that was used to pick products from the warehouse and convey them to the shipping area. This system was decommissioned sometime during the end of 2019 and/or beginning of 2020 however, it has not been completely dismantled and removed and has become a harborage area for rodents. The system is in disrepair and is rusting. In addition, there are cobwebs, dirt, dust and debris that has built up under and around the conveyor system in the mezzanine level of the warehouse.
- Shelving in the warehouse has dirt and debris built up in, on and under the rafters and shelves, including shelving in the Repack Area of Aisle (b) (4) where many drug products are stored.
- The trash compactor near Door (b) (4) is in disrepair with parts that have been rusted through creating openings where rodents and other pests can enter the facility. There was trash and debris in and around the trash compactor and a dead rodent was observed on 01/21/2022 just outside the compactor.
- The "(b) (4)" system that is used to carry re-usable plastic totes into the repack areas in Aisles (b) (4) where drugs and other products are placed for shipment to stores had rusted platforms where the totes are carried up to the pick level as well as rust along the (b) (4) used to (b) (4). Dirt and debris have built up under the conveyor that moves these totes from the pick lines to the lower level for palletizing and shipment to stores.
- On 01/21/2022 and 02/01/2022, we walked the perimeter of the warehouse and noted the following:
 - Trash and debris can be seen around receiving and shipping dock doors, including trash and debris under the dock leveler.

Work Order DC202-1892008 dated 03/10/2021 for Door (b) (4) noted "dock plate at door (b) (4) would not go down all the way, the front flap was sticking and had too much trash in it". This is

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one of the doors where "dunnage", including empty totes, is returned from stores and offloaded into the warehouse.

- Active ant hills could be seen in various locations on the south and east side of the building.
- At various locations where there are open pipes that are part of the fire suppression system where water is released during testing of the system, we noted significant erosion to include erosion around cement slabs outside of exit doors and near the foundation of the building.
- Holes could be seen around electrical outlets and other places in the cement wall.
- There were numerous empty trailers that were rusted and/or had doors left open in the Truck Yard that could provide potential harborage for pests. A desiccated carcass of a dead rodent could be seen in one trailer (#(b) (4)).
- Open trash bins with garbage, pallets and debris that could provide harborage for pests were in the Truck Yard. A recently deceased rat was observed outside the open trash receptacles on 02/01/2022. On 01/21/2022, we saw popcorn and other debris strewn outside the same trash receptacle.

OBSERVATION 9

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

Specifically, racks in Repack Aisles (b) (4) which are used to store cases of individual retail units to include drug products, are not of an appropriate design to facilitate cleaning underneath the racks. The racks are approximately (b) (4) feet deep. We observed dirt and debris in the entire area under the racks, as well as

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(b) (7)(E) rodent hair under Slot #s (b) (4) & (b) (4) where cartons containing lot #1LE1990A of Good Sense Brand Ibuprofen (250 coated tablets) and lot #AJM011 of Children's Tylenol are stored.

OBSERVATION 10

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your firm has re-usable plastic totes that are used to ship individually picked retail units to your stores, including drug products. These totes can be stored at the retail stores outside near trash dumpsters for (b) (4) before being returned to the Distribution Center. Your firm has also received reports from stores of product being shipped from your Distribution Center with rodent excreta pellets and/or that was gnawed/chewed. Photos from these reports show some of these products inside of the totes.

Your firm does not have any written procedures for handling the return of these totes to your facility to ensure rodents and other pests do not enter your facility via this route. Your firm does not have written procedures for the cleaning and sanitization of these totes. Your firm does not clean all totes or sanitize any tote before being re-used.

OBSERVATION 11

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

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Specifically, your firm does not monitor nor control temperature or humidity within your warehouse. Your firm stores drug products on various levels within the warehouse where temperatures can exceed (b) (4) °F at the floor level during the summer months and reach higher temperatures in the upper levels of the warehouse.

Your Facility Manager stated he has seen temperatures that can be as high as (b) (4) °F in the upper parts of the Distribution Center using (b) (4). He stated he does not document when he checks temperatures, and your firm has no written procedure regarding this practice.

We observed several drug products that were labeled with storage temperatures of 20-25°C (68-77°F) with some stating to “protect from moisture”, “avoid high humidity” and/or “avoid excessive heat”. These products include Extra Strength Tylenol Rapid Release Gelcaps, Family Wellness brand Maximum Strength Cold & Flu softgels, and Good Sense brand Omeprazole Delayed Release Tablets 20mg.

OBSERVATION 12

Distribution records do not contain the lot or control number of drug product.

Specifically, your firm does not document in your inventory control system the lot numbers of drug products received by your facility. In addition, your firm does not document the lot numbers of drug products that are shipped/distributed from your facility to your stores.

***DATES OF INSPECTION**

1/11/2022(Tue), 1/13/2022(Thu), 1/14/2022(Fri), 1/19/2022(Wed), 1/20/2022(Thu), 1/21/2022(Fri), 2/01/2022(Tue), 2/02/2022(Wed), 2/03/2022(Thu), 2/04/2022(Fri), 2/07/2022(Mon), 2/08/2022(Tue), 2/09/2022(Wed), 2/10/2022(Thu), 2/11/2022(Fri)

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Preston B Hoover
Investigator
Signed By: Preston B. Hoover -S
Date Signed: 02-11-2022 10:46:57

Margaret M Annes
Investigator
Signed By: Margaret M. Annes -S
Date Signed: 02-11-2022 10:48:25

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."