

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

DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772	DATE(S) OF INSPECTION 3/3/2017-3/15/2017*
	FBI NUMBER 1022121

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Robert C. Carl, President

FIRM NAME Dixie Dew Products Inc	STREET ADDRESS 1360 Jamike Ave, PO Box 18310
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CITY, STATE, ZIP CODE, COUNTRY Erlanger, KY 41018-3114	TYPE ESTABLISHMENT INSPECTED Manufacturer
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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:

OBSERVATION 1

Failure to manufacture and package foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically,

- A. Your firm does not conduct a kill step for SoyNut Butter product remaining in your firm's mixing kettle leftover from a production run. Your Plant Manager stated, up to (b) (4) may remain in the kettle overnight or weekend prior to resuming production. You and your Plant Manager stated the (b) (4) the kettle is shut off when product remains in the kettle overnight and/or over the weekend.
- B. According to your Plant Manager and Maintenance Supervisor, your (b) (4) machine, used for fine mixing of the SoyNut Butter and (b) (4), routinely shuts off during processing. Your Plant Manager stated this occurs 1-2 times per day and, this problem has persisted for approximately 15 years despite repeated maintenance intended to correct the problem.
- C. Your firm monitors the SoyNut Butter (b) (4) with an (b) (4) thermometer. Your Plant Manager stated he has never verified the accuracy of this instrument.
- D. According to you and your Plant Manager, your temperature probe and chart recorder, initially engineered to verify and record (b) (4) of product in the large mixing kettle, is not functioning properly and has not been used for well over a year.
- E. During production of I.M. Healthy SoyNut Butter Creamy cups, Lot 065171 on 3/6/2017, a clear liquid

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DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax: (513)679-2772		DATE(S) OF INSPECTION 3/3/2017-3/15/2017*
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substance was observed dripping intermittently from a hole in a ceiling tile in your firm's Soy Butter Processing Room and landing on the Processing Room floor and splashing on food manufacturing equipment below. The dripping liquid persisted throughout the duration of the production run which spanned from approximately (b) (4) . According to you, the liquid was water from a leaking (b) pipe which runs above the ceiling tiles.

- F. The floors, walls, and ceilings in the Soy Butter Processing and Packaging Rooms are heavily coated with apparent old SoyNut Butter build-up from previous production runs. Additionally, standing water and brown and black apparent filth was observed on the Processing Room floor; particularly under equipment in hard to reach places and along the floor/wall junctures. Employee walking platforms used to access equipment during production were also observed to have a heavy coating of apparent old food residue and filth.

OBSERVATION 2

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

Specifically,

- A. Your firm does not have any employee or equipment traffic controls throughout the different operation areas of your firm, or between the facility and outdoors. Employees were observed walking throughout all areas of the facility including inside the boiler room, the exterior of the facility, bathrooms, and other areas outside the firm's different processing rooms. These same employees later walked into the Soy Butter Processing and Packaging Rooms without any controls in place to minimize cross-contamination of the different areas of the facilities. Additionally, your firm has (b) mechanical forklifts, which operate throughout the interior facilities and outside the facility for waste disposal. These forklifts were

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observed moving in and out of your Soy Butter Processing and Packaging Rooms. On 3/13/2017, a green forklift was used to move processing waste from inside the facility to the firm's waste dumpster located outside. The Plant Manager stated these forklifts are never cleaned.

- B. On 3/8/2017, your cleaning supply cabinet was observed in disarray. Bathroom cleaning mops, brooms, and other cleaning equipment were intermingled and in contact with similar cleaning equipment used to clean manufacturing equipment in processing rooms. The mop heads, brooms, brushes and other cleaning tools were in poor repair and covered in apparent old food residue. Many of the mop and broom heads were stained black from apparent filth.
- G. The interior of the (b) (4) bulk soy oil tote your firm used to manufacture the I.M. Healthy SoyNut Butter Creamy cups, Lot 065171 on 3/6/2017, was observed soiled with brown apparent residue. According to your Plant Manager, these totes are never cleaned. Additionally, the top port lid to the tote remained opened during the manufacturing and cleaning process on 3/6/2017.
- H. A stack of wooden pallets were kept on the floor of the Soy Butter Processing Room. The lower pallets were sitting in water and were covered in apparent black mold and filth. These pallets were observed in this condition and location from 3/3/2017 – 3/9/2017.
- I. The nozzle to the (b) (4) and (b) (4) in the Soy Butter Processing Room was observed laying on the Processing Room floor and in standing water multiple times during the inspection as well as during the manufacturing of I.M. Healthy SoyNut Butter Creamy cups, Lot 065171, on 3/6/2017.
- J. On 3/6/2017, during production of I.M. Healthy SoyNut Butter Creamy cups, Lot 065171, the lid to the mixing kettle was stored propped up against the floor and wall of the Soy Butter Processing Room.
- K. Various hand tools used to maintain production equipment in the Soy Butter Processing Room were stored on the floor and on employee walking platforms.
- L. On 3/6/2017, stainless steel filling pipe was stored on the floor of the Soy Butter Packaging Room. You

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stated these filling pipes are no longer used and need to be discarded.

OBSERVATION 3

Hand-washing facilities lack running water of a suitable temperature.

Specifically, there was no hot water³ to the handwashing sink and the two-compartment sink located in the Soy Butter Processing Room. According to your maintenance supervisor, the hot water tank for these sinks has been out of repair for two years. Additionally, the hand soap dispenser for the hand sink was not operable. Your Plant Manager stated he will sometimes use the (b) hose to wash his hands in the hand wash sink since this is the only hot water in the room.

OBSERVATION 4

Failure to maintain equipment in an acceptable condition through appropriate cleaning and sanitizing.

Specifically,

- A. You and your Plant Manager stated you have not disassembled any SoyNut Butter processing equipment and all associated piping for cleaning and sanitizing since December of 2015.
- B. Per your Plant Manager, your firm does not routinely wash and sanitize smaller pipes, pipe fittings, gaskets, seals and the rubber (b) (plug) when broken down following a production run of SoyNut Butter. These are all food contact surfaces.
- C. During a walkthrough of your Soy Butter Processing and Packaging Rooms on 3/3/2017, a substantial amount of dried apparent old SoyNut Butter residue from previous production runs was observed on food contact surfaces of the (b) (4) (b) (4) large mixing kettle and (b) (4) (b) (4)). On 3/6/2017, apparent old SoyNut Butter was observed on the mechanical mixing arms inside the (b) (4) (b) (4) of the 15oz jar filling machine. Additionally the (b) (4) to this

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machine were also observed soiled with old SoyNut Butter food residue.

- D. A substantial amount of dried apparent old SoyNut Butter residue from previous production runs coated non-food contact surfaces of processing equipment in the Soy Butter Processing and Packaging Rooms. According to you, the equipment is not routinely cleaned since the SoyNut Butter product cannot come into contact (b) (4). Additionally, old apparent SoyNut Butter residue heavily coated (b) (4) control buttons and knobs, overhead electrical cables and (b) (4) piping fixtures located throughout the Processing Room.
- E. The SoyNut Butter cup conveyor belt used to convey packaged I.M. Healthy SoyNut Butter Creamy cups, Lot 065171 on 3/6/2017, was visibly stained with apparent old SoyNut Butter residue.

OBSERVATION 5

Employees did not wash hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically, during production of I.M. Healthy SoyNut Butter Creamy cups, Lot 065171 on 3/6/2017, an employee was observed handling manufacturing equipment which was in contact with the process floor and proceeded to wash his hands in a handwash station without hand soap or hot water prior to continuing with the manufacturing process which involved handling packaged food ingredients and finished product containers and packaging.

OBSERVATION 6

Failure to perform microbial testing where necessary to identify possible food contamination.

Specifically, the buffer solutions and culture plates used by your firm to conduct internal coliform, APC and yeast and mold testing on your firm's finished products had expiration dates of 7/2016 and 10/2015 respectfully.

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OBSERVATION 7

The plant is not constructed in such a manner as to allow floors and ceilings to be adequately cleaned and kept clean and kept in good repair.

Specifically, the floors in the Soy Butter Processing and Syrup Rooms had missing tiles or were heavily pitted, cracked or in general poor repair throughout. Additionally, some ceiling tiles in the same rooms were observed misaligned or in poor repair with holes and/or broken tiles. Furthermore, an approximate one foot opening between the outside of the walk-in refrigerator and warehouse room was observed along the back wall and floor of the unit. According to your Plant Manager, it was most likely caused by an employee moving a palletized product with a forklift.

OBSERVATION 8

Failure to provide adequate ventilation to minimize odors and vapors in areas where they may contaminate food.

Specifically, during production of I.M. Healthy SoyNut Butter Creamy cups, Lot 065171 on 3/6/2017, a suspended haze was observed in the Soy Butter Processing and Packaging Room. According to your Plant Manager, the haze is created by the exhaust of the (b) (4) machine and consists of a water and oil particulate mix. The lid to the large mixing kettle containing product was removed when this was observed.

OBSERVATION 9

Effective measures are not being taken to exclude pests from the processing areas.

Specifically,

- A. On 3/13/2017, an opened (b) (4) bag in box (b) (4) product in your firm's walk-in cooler was observed with an apparent 3" diameter rodent defiled marking that penetrated the box and product. Additionally, apparent mold was growing on the surface of the butter.

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B. An apparent fly infestation in your firm's Quality Control and Product Development Laboratory was observed on 3/13/2017. Small apparent flies and fly larvae, too numerous to count, were inside an unplugged chest freezer. A sealed blue plastic bag was inside the freezer and according to your Plant Manager, contained an egg product that became rotten when power was disconnected. The small apparent flies were observed along the laboratory counters and flying throughout the laboratory.

OBSERVATION 10

Failure to remove litter and waste that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures.

Specifically, a heavy build-up of discarded SoyNut Butter and other products coated the internal surfaces of your firm's dumpster located on the exterior of the building near the loading dock. On 3/7/2017, the dumpster's side doors were open allowing easy access for pests.

***DATES OF INSPECTION**

3/03/2017(Fri), 3/06/2017(Mon), 3/07/2017(Tue), 3/08/2017(Wed), 3/09/2017(Thu), 3/13/2017(Mon), 3/15/2017(Wed)

3/15/2017

3/15/2017

Mary B Sheets

Mary B Sheets
Investigator
Signed by: Mary B. Sheets -S2

Kenneth E Felkley

Kenneth E Felkley
Investigator
Signed by: Kenneth Felkley -S

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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."