

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

DISTRICT ADDRESS AND PHONE NUMBER 550 Main Street Cincinnati, OH 45202 (513)322-0700 Fax: (513)679-2772	DATE(S) OF INSPECTION 7/14/2022-7/15/2022
	FBI NUMBER 3004794454

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Eric D. McCarty, General Manager
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FIRM NAME Krispy Kreme Doughnut Corporation	STREET ADDRESS 1021 Polaris Pkwy
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CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43240-2004	TYPE ESTABLISHMENT INSPECTED Donut 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 I OBSERVED:

OBSERVATION 1

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

Specifically,

During the walk-through on 07/14/2022 I observed the following:

- 1.) An accumulation of food debris on the underside of the "(b) (4)" and behind the "(b) (4) (b) (4)".
- 2.) Exposed tile above clean dishes in the "(b) (4)" room and above the "(b) (4) Tunnel".
- 3.) The wall in the "(b) (4) Room" portion of the production area to be cracked.

OBSERVATION 2

You did not conduct operations under conditions and controls necessary to minimize the potential for contamination of food.

Specifically,

During the walk-through on 07/14/2022 I observed the following:

- 1.) An accumulation of particulate matter on ceiling vents in the "(b) (4) Room", "Load Out Dock" area, next to the extruder, over the "Retail Curve", in the "Filling" section of the production area, and the general storage area. The vent in the "Retail Curve" area is directly above ready-to-eat product.
- 2.) An accumulation of particulate matter on the ceiling tile near the "Retail Curve".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Catherine D Djordjevic, Investigator	Catherine D Djordjevic Investigator Signed By: Catherine D. Djordjevic as Date signed: 07-15-2022 11:18:28 X	DATE ISSUED 7/15/2022

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
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3.) Storage racks for finished product to have an accumulation of food residue. 4.) A bag of raw material that had gotten wet due to overspray while an employee was cleaning in the production area. 5.) Buckets of " (b) (4) Cream Cheese Filling", best by (b) (4) , stored directly on the floor in the "Load Out Dock" area. 6.) A container of soap to be stored on a storage rack directly above a bag of sprinkles in the "Filling" section of the production area. Items such as a mop head and tool bag were observed to be stored directly on top of boxes of product.			
OBSERVATION 3 Your plant did not have adequate sanitary facilities and accommodations. Specifically, During the walk-through on 07/14/2022 I observed the following: 1.) The hand sink near the " (b) (4) mixer" did not have soap or paper towels. A build-up of residue was also observed inside the basin and near the hot water handle. 2.) The hand sink in the front retail area had no soap. A blender was also observed to be inside the sink while a sign stating "Do not rinse dishes in this sink" was posted above the sink.			
OBSERVATION 4 Your equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against contamination. Specifically, During the walk-through on 07/14/2022 I observed the following: 1.) The walk-in cooler to be leaking water on the floor at the cooler door. 2.) A clean bowl to be chipped in the (b) (4) room.			
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- 3.) Clean mixing bowls and mixer attachments to be stored in direct contact with a rusted surface in the (b) (4) room.
- 4.) A mixing paddle that was stated to be clean with a build-up of rust and food debris in the (b) (4) room.

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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."