DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	10/22/2019-10/23/2019
	FEI NUMBER 3004794454

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James M. Lewis, General Manager

FIRM NAME	STREET ADDRESS
Krispy Kreme Doughnut Corporation	1021 Polaris Pkwy
CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43240-2004	TYPE ESTABLISHMENT INSPECTED Bakery

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

You did not take a reasonable measure and precaution related to personnel practices.

Specifically,

a) On 10/22/2019, We observed (b) (4) hand sinks unaccessible as storage racks were store in front and not available for employees to use during production, and no hot water was available for use.

b) On 10/22/2019, we observed no paper towels at (b) (4) of the hand sinks located in the processing area.

OBSERVATION 2

Your plant was not constructed and designed to facilitate maintenance and sanitary operations.

Specifically,

a) On 10/22/2019, we observed a 3 inches by 3 inches crack on the floor by the retail curve on production line.

b) On 10/22/2019, we observed two missing floor tiles on the processing area approximately 1 ft. below from the mixer machine.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Carlos H Ruiz Nunez, Investigator Evan M Kupper, Investigator X Evan M Kupper Investigator Signed By: 2002678701 Date Signed: 10-23-2019 12:03:13 Carlos H. Ruiz -S	10/23/2019

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c) On 10/22/2019, we observed an approximately 8 inches by 12 inches hole on the wall under the drive-thru window.

d) On 10/22/2019, we observed apparent dirt and dust on the vents 4ft. above the processing area.

OBSERVATION 3

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

Specifically,

a) On 10/22/2019, we observed (b) (4) uncovered buckets of filling, on a table in the production area.

b) On 10/22/2019, we observed a box of donut filling placed directly on the floor in the filling area.

c) On 10/22/2019, we observed (b) (4) buckets containing filling for donuts with apparent food build-up on outside surface of buckets.

d) On 10/22/2019, we observed a box of lemon filling stored directly on the floor in the (b) (4) room.

e) On 10/22/2019, we observed an uncovered cinnamon bucket stored on a table approximately 2 ft. from the drive-thru window.

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f) On 10/22/2019, we observed baking pans with product residues stored approximately 1 inch directly above finished products.

OBSERVATION 4

Your equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against contamination.

Specifically,

a) On 10/22/2019, we observed finished product covers with apparent mold and food residue on both exterior and interior surfaces.

b) On 10/22/2019, we observed apparent food residue and build-up on the underside of the surface used to proof donuts.

c) On 10/22/2019, we observed storage racks with apparent food residue on all shelves stored approximately 2 ft. from the processing area.

d) On 10/22/2019, we observed (b) (4), using to move ingredients with apparent food residue and build-up.

e) On 10/22/2019, we observed apparent food residue and build-up on the overhead arm of the mixer.

AMENDMENT 1

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f) On 10/22/2019, we observed apparent food residue and build-up on the lowest shelf of the packing table.

AMENDMENT 1

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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."