DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	11/5/2019-11/7/2019
	FEI NUMBER 3004323645

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Eric R. Nichols, Area Manager

FIRM NAME	STREET ADDRESS
Florida Family Foods LLC dba Krispy Kreme	5310 W Irlo Bronson Memorial Hwy
CITY, STATE, ZIP CODE, COUNTRY Kissimmee, FL 34746-4754	TYPE ESTABLISHMENT INSPECTED Doughnut Manufacturer

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 clean and sanitize your utensils or equipment in a manner that protects against contamination.

Specifically,

a. On 11/05/19, it was observed that equipment parts used on doughnut processing line were placed on the floor in the (b)(4) storage area after being washed and rinsed. The equipment included the (b)(4) tunnel hood through where doughnuts pass under to be (b)(4) and go through finishing phases or packaging. No further cooking is conducted once the doughnuts pass through the (b)(4) tunnel.

b. Employees were observed as they were placing the fryer conveyor back into place after cleaning. The hood directly on top of the fryer conveyor did not have its vent covers in place and had exposed filth and debris. The vent covers were washed, sanitized and in a cart awaiting to be assembled. The vent covers fell on the floor and an employee proceeded to put them back on the cart. Another employee took the fallen vent covers to place them on the hood without being recleaned.

c. The mixer, located next to the employee handwash sink, was found to still have food residue on the base where the paddle connects to the mechanism, after cleaning. Additionally, the base was observed with peeling paint that could fall into the mixing bowl.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ashley Gonzalez, Investigator	X Ashley Gonzalez Investigator Signed By: Ashley Gonzalez -S Date Signed: 11-07-2019 13:59:54	11/7/2019

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d. (b) (4) buckets used for (b) (4) ingredients to be mixed were observed with accumulation of food debris after being cleaned and sanitized.

*****This observation was noted during a previous FDA inspection dated 5/01/2017-5/3/2017.*****

OBSERVATION 2
You did not take a reasonable measure and precaution related to personnel practices.

a. On 11/05/19, multiple times during the inspection employees were observed touching insanitary objects with gloved hands and then continuing to handle in process food without donning new gloves or hand washing.

b. Employees were observed without beard nets while handling in process food.

*****This observation was noted during a previous FDA inspection dated 5/01/2017-5/3/2017.*****

OBSERVATION 3
You did not maintain your plant in a clean and sanitary condition and keep your plant in repair.

Specifically,

a. On 11/05/19, grout was observed missing between some of the tiles throughout the doughnut production area. These areas were observed with standing water and cannot be adequately cleaned and sanitized.

b. The (b) (4) floor in the (b) (4) ingredients and (b) (4) storage was not adequately cleaned and sanitized. Storage room floor was observed with filth, debris, and two dead cockroach-like insects were observed next to and under racks on different sides of (b) (4) storage area. The (b) (4)

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floor also had an area with exposed embedded rocks which could not be adequately cleaned and sanitized.

*****This observation was noted during a previous FDA inspection dated 5/01/2017-5/3/2017.*****

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."