DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556 ORAPHARM1_RESPONSES@fda.hhs.gov	8/25/2020-11/2/2020* FEI NUMBER 3005543749

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dennis Katz, President and Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Hopkinton Drug, Inc.	52 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hopkinton, MA 01748-1214	Producer of Non-Sterile Drug Products

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

Non-microbial contamination was observed in your production area.

Specifically,

- Thick white powder residues were observed on the ceiling intake vent over the (b) (4) (b) (4) hood (Asset# (b) (4)) and on top of the (b) (4) hood within the firm's hazardous drug room (b) (4). The (b) (4) hood and room are utilized in the production of the following hazardous drug products: Cholestyramine Pure Powder, Estrogen, Testosterone, Progesterone, Methylene Blue, and Disulfiram.

- Large amounts of blue colored staining were observed on the inside of the door to the (b) (4) (b) (4) glasswasher within the firm's hazardous drug room. The glasswasher is utilized in the cleaning of glassware and equipment for the production of hazardous drug products.

- Flaking paint, rust spots and yellow colored staining were observed on the interior of the firm's (b) (4) (Asset (b) (4)) balance which was located within the (b) (4) (b) (4) Asset#: (b) (4) (b) (4) hood. The balance/hood are utilized in the weighing/production of the following non-hazardous drug products: creams/ointments and nasal sprays (Vasoactive intestinal peptide).

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Erik W Koester, Investigator Jonathan G Matrisciano, Investigator Daniel L Zheng, Investigator	X Erik W Koester Investigator Signed By: Erik W. Koester -S Date Signed: 11-10-2020 12:52:16	11/10/2020

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- Yellow colored stains were noted on the (b) (4) to the following (b) (4) hoods: (b) (4) (b) (4), Asset#: (b) (4) and (b) (4). There is no assurance that the (b) (4) hoods are functioning as they are purported to prevent cross contamination since the firm is not following manufacture's guidelines in the changing of the (b) (4). These hoods are utilized in the production of the following non-hazardous drug products: dry capsules (b) (4), suspensions/solutions (b) (4) suppositories, and vasoactive intestinal peptide nasal sprays.

OBSERVATION 2

You produced hazardous drugs without providing adequate segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

- You did not use a cleaner suitable for removing pharmaceutical residues and there is no evidence that the household cleaners used (b) (4) are capable of removing hazardous materials such as hormones, antibiotics and controlled substances.

- A (b) (4) beaker within the firm's clean glassware storage area was observed with an unknown opaque residue on the interior of the beaker.

- Several containers of the following finished non-hazardous drug product were observed being stored within the firm's hazardous drug production room: Naltrexone 1.5mg lot# 07312020:97@1. In addition, review of the firm's (b) (4) for the following non-hazardous drug products revealed that they had been processed within the firm's hazardous drug room: Naltrexone 3mg capsule lot# 07082020:33@7 and Naltrexone 3mg capsule lot#

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08012020:33@1.

***DATES OF INSPECTION**

8/25/2020(Tue), 8/26/2020(Wed), 8/27/2020(Thu), 8/28/2020(Fri), 8/31/2020(Mon), 9/01/2020(Tue), 9/02/2020(Wed), 10/22/2020(Thu), 10/23/2020(Fri), 11/02/2020(Mon)

AMENDMENT 1

	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE	Erik W Koester, Investigator Jonathan G Matrisciano, Investigator Daniel L Zheng, Investigator	X Erik W Koester Investigator Signed By: Erik W. Koester -S Date Signed: 11-10-2020 12:52:16	11/10/2020

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."