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	9/12/2022-9/30/2022* FEI NUMBER 3005636572

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lawrence Ford, Staff Pharmacist

FIRM NAME	STREET ADDRESS
South Berwick Pharmacy Seacoast Compounding, Inc.	289 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
South Berwick, ME 03908-1543	Producer of Non-Sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectio nal 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 produced hazardous drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of u tensils to prevent cross-contamination.

Specifically,

- ☐ Your firm utilizes a (b) (4) biological safety cabinet for the production of both hazardous and non-hazardous drug products. Cleaning of the interior of the biological safety cabinet consists only of a wiping with (b) (4) before and after each batch production. The firm produces the following non-sterile hazardous drug products: Colchicine, Cyclosporine, Methimazole, Tacrolimus. In addition, the firm produces the following hormones, antibiotics and highly potent drugs: Estradiol, Estrone Progesterone, Testosterone, Enrofloxacin, Doxycycline Hyclate and Clobetasol. The firm has no assurance that the current cleaning method is effective at removing hazardous drug residues on surfaces nor does the f irm have a formal decontamination procedure for use following the production o f hazardous drug products.

- ☐ Your firm cleans product contact glassware, and utensils with household cleaners ((b) (4) and (b) (4) dishwashing liquid) after they are used for production of all hazardous and non-hazardous non-sterile drug products. There is no assurance that the cleaning process removes product and cleaning agent residue from glassware and utensils.

- ☐ Your firm uses (b) (4) as a final rinse after cleaning even though your procedure, SOP# 6.001 Glassware – (b) (4) Glassware, utensils or equipment for the production of hazardous non -sterile drug products are not dedicated.

OBSERVATION 2

Non-microbial contamination was observed in your production area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Erik W Koester, Investigator Daniel L Zheng, Investigator	X Erik W Koester Investigator Signed By: Erik W. Koester -S Date Signed: 09-30-2022 13:13:47	9/30/2022

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Specifically,

☐ A yellow crusty substance was observed on the HEPA filter within the (b) (4) biological safety cabinet (b) (4) . In addition, opaque residues were noted on the interior walls of the biological safety cabinet. The aforementioned cabinet is utilized for the production of all hazardous and non-hazardous non-sterile drug products.

☐ Light brownish stains were noted on the interior of the firm's (b) (4) (located inside of the (b) (4) biological safety cabinet), the base of the (b) (4) the face of the (b) (4) sealer (b) (4) and on the front of the (b) (4) The aforementioned equipment are utilized in the production of the firm's non-sterile drug products.

☐ Heavy dust buildup was noted on top of the (b) (4) biological safety cabinet and cobwebs were observed on the walls within the production room.

OBSERVATION 3
Vermin was observed in your production area.

Specifically,

Dead insects were observed behind the (b) (4) front facing of the (b) (4) biological safety cabinet (b) (4) . In addition, several live flying insects were observed within the production area.

OBSERVATION 4
You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

☐ Your firm uses (b) (4) for use in production of non-sterile drug products. For example, the firm utilized (b) (4) instead of (b) (4) in the production of (b) (4) lot# (b) (4) . The aforementioned lot of (b) (4) was used in the production of Ketamine Nasal Spray lot# 06022022@(b) and lot# 08232022@(b)(4)

☐ Your firm released multiple lots of non-sterile drug products that were produced from expired components. There is no assurance

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Erik W Koester, Investigator
Daniel L Zheng, Investigator

X Erik W Koester
Investigator
Signed By: Erik W. Koester -S
Date Signed: 09-30-2022
13:13:47

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9/30/2022

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that the expired components continue to meet pharmaceutical grade specifications. For example:

1. You produced Clobetasol in Dermazinc 0.05 Solution lot 06232022@(b)(4) on 6/23/2022 using Clobetasol Propionate USP Micronized lot (b) (4) with expiry 2/28/2021 as the API. This product was used to fill Rx (b) (6) issued 6/23/2022.

2. You produced Clobetasol in Dermazinc 0.05 Solution lot 08232022@(b)(4) on 8/23/2022 using Clobetasol Propionate USP Micronized lot (b) (4) with expiry 2/28/2021 as the API. This product was used to fill Rx (b) (6) issued 8/23/2022.

3. You produced Betamethasone in Dermazinc Body Wash 144mg Suspension lot 08052022@(b)(4) on 8/5/2022 using Betamethasone Dipropionate USP Micronized lot (b) (4) with expiry 1/31/2021 as API as well as Dermazinc Body Wash lot (b) (4) with expiry 2/11/2021 as API. This product was used to fill Rx (b) (6) issued on 8/4/2022.

4. You produced Diazepam 10mg Suppository lot 06292022@(b)(4) on 6/29/2022 using Silica Gel Micronized lot (b) (4) with expiry 1/31/2022 as excipient. This product was used to fill Rx (b) (6) issued 6/27/2022, Rx (b) (6) issued (b) (6), and Rx (b) (6) filed 7/13/2022.

***DATES OF INSPECTION**
9/12/2022(Mon), 9/13/2022(Tue), 9/15/2022(Thu), 9/21/2022(Wed), 9/30/2022(Fri)

X Daniel L Zheng
Investigator
Signed By: Daniel L. Zheng -S
Date Signed: 09-30-2022 13:14:40

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	Erik W Koester, Investigator Daniel L Zheng, Investigator	X Erik W Koester Investigator Signed By: Erik W. Koester -S Date Signed: 09-30-2022 13:13:47	9/30/2022

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."