DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov	3/14/2022-3/24/2022* FEI NUMBER 3001779702

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph M. Costa, President and COO

FIRM NAME	STREET ADDRESS
Wedgewood Village Pharmacy, LLC	405 Heron Dr Ste 200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Swedesboro, NJ 08085-1749	Producer of sterile and 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,

A.The firm does not keep production hoods utilized for the preparation of drug products clean and sanitary. Hood (b) (4) in room(b) (4) is utilized in the production of non-hazardous human and veterinary non-sterile drug products. The following observation was made regarding hood(b) (4) during the current inspection:

- On 3/15/2022, hood (b) (4) was inspected and noted to have unknown brown grime throughout the hood in the production area. Since September 2021, hood(b) (4) has been utilized to produce(b) (4) lots of veterinary and human drug products to include benzocaine/lidocaine/tetracaine (20%/8%/4%) topical gel lot 000-03743964 (human drug, BUD 7/30/2022) and Amitriptyline HCl 7.5mg/0.05ml Twist-A-Dose Transdermal Gel 1.5 ml Pen lot 000-03396931 (veterinary drug, recalled due to mold contamination).

B. The firm does not keep production hoods and adjacent areas utilized for the preparation of drug products intended to be sterilized clean and sanitary. Room(b) (4) (ISO-8 classified) is utilized for the production of veterinary and human drugs intended to be sterilized. The following observations were made regarding room(b) (4) on 3/15/2022:

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	Leanna M Slarsky, Investigator Sean R Marcsisin, Investigator Kristina L Conroy, Investigator	X Kristina L Conroy Investigator Signed By: Kristina L. Conroy -S Date Signed: 03-24-2022 14:39:58	3/24/2022

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- The firm utilizes (b) (4) containment hoods within room (b) (4) for production activities (hoods (b) (4) (b) (4)). On 3/15/2022, the hoods were inspected and noted to have unknown brown and white powdery residue located on the ceilings of the hoods (directly above production activities) and on the (b) (4) (b) (4) grates. Additionally, unknown crystalline residue, powder, and what appeared to be rust was noted on the metal edge of the glass sashes (facing towards the production area). Firm management was able to wipe the noted material from the hood. The hoods were observed being utilized to produce multiple drug products to include Tri-Mix (PGE1/Papaverine/Phentolamine) aqueous Injection lot 000-03858168 (human drug, Hood (b) (4)), Pentosan Polysulfate Sodium 250 mg/mL Injection lot 000-03853271 (veterinary drug, Hood (b) (4)), and Flumethasone 0.5 mg/mL Injection lot 000-03853272 (veterinary drug, Hood (b) (4)).

- Two metal plates located between production hoods were noted to have an unknown black discoloration and the wall adjacent to the metal plates was also noted to be discolored with unknown black spots.

- The floor within room (b) (4) appeared textured and unclean areas were noted in the grooves of the textured floor.

- On 3/15/2022, the floor seam separating the unclassified area from the ISO-8 ante room (b) (4) (entry into non-hazardous sterile filling and packaging area) was noted to have unknown grime and dirt in the floor seam. Carts with aseptic filling and packaging supplies and personnel cross the noted seam while entering the sterile filling and packaging area. Similar dirt and grime was also noted in the floor seam between the unclassified area and the ISO-8 production room (b) (4)

OBSERVATION 2

Personnel moved rapidly in the vicinity of open sterile units, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 classified aseptic processing area.

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Specifically,

On 3/18/2022, during observation of sterile filling and packaging operations in room (b) (4) (filling and packaging room for sterile hazardous veterinary drugs) for the veterinary drug product Tacrolimus 0.02% lot 000-03864365, an aseptic operator was observed capping bottles of drug product in an ISO-5 biological safety cabinet (BSC). The operator was then observed to toss/throw the bottles, which hit the back surface of the BSC and landed in a large pile in the back corner of the hood. The actions were being conducted adjacent to open bottles of drug product. When the operator completed bottle-capping activities, the operator was observed to reach his entire arm into the hood and scoop the pile of drug product into a plastic bin. The noted operator also works in the non-hazardous sterilize filling and packaging area and has produced human drug products such as Papaverine/Phentolamine Aqueous 30 mg/1 mg Injection solution lot 000-03797482 (which failed sterility testing at the firm's contract testing laboratory, 1 of (b) (4) drug product lots that failed sterility testing documented for various products from 2021-2022).

OBSERVATION 3

You had inadequate HEPA filter airflow over the area to which sterile product was exposed.

Specifically,

In November 2021, the firm had a contractor perform room re-certification activities of the non-hazardous sterile cleanroom suite (ISO-7 buffer rooms (b) (4)) which included HEPA filter leak scan testing. The ceiling HEPA filter in room (b) (4) failed during the as-found testing. Firm management was unaware of the failed HEPA leak scan result; as to the exact date the HEPA filter damage occurred and has not assessed the HEPA filter failure impact on drug product filling and packaging operations in room (b) (4). Between June 2021 and November 2021, the firm has produced (b) (4) drug product lots in room (b) (4) intended to be sterile.

OBSERVATION 4

Personnel engaged in aseptic processing were observed with exposed hair.

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Specifically,

On 3/14/2022, during observation of aseptic filling and packaging operations in the ISO-5 classified area in room (b) (4), a firm operator was noted to have their safety glasses down on their nose which exposed skin and hair (eyebrows) to the ISO-5 environment. The operator was observed producing a veterinary drug intended to be sterile (Protirelin Injection lot 000-03847342, veterinary drug).

OBSERVATION 5

Vermin was observed in an area immediately adjacent to your production area.

Specifically,

What appeared to be insects were noted in multiple areas where drug production components (that are utilized in drug production activities) are stored as exampled below:

- On 03/17/2022 during a walkthrough of the first-floor additional warehouse storage area (unfinished space), a live insect (what appeared to be a centipede) was observed crawling under two pallets in the location designated as (b) (4). The pallets contained item # (b) (4) - white gallon buckets, which was partially unwrapped and exposed to the environment. Item # (b) (4) was utilized (b) (4) times between 02/17/2022 and 03/17/2022 as an API re-pack vessel, production component, and intermediate vessel to store non-sterile drug products. Item # (b) (4) was utilized to repack item (b) (4), doxycycline hyclate powder lot (b) (4), on 3/4/2022, which was utilized in the production of human drug doxycycline oral suspension lot 000-03852523 on 3/15/2022 and veterinary drug product doxycycline fish chew lot 000-03845146 on 3/11/2022. At the time of the walkthrough, insect pest control devices were not observed in the near vicinity of the open pallets. A review of the firm's pest control plan identified no insect pest control devices in the area surrounding (b) (4)

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- On 3/17/2022, a second-story additional warehousing space (unfinished space) contained approximately 50 dead insects of multiple varieties throughout the storage area immediately adjacent to primary packaging components such as medication vials and desiccant sachets. At the time of the walkthrough, insect pest control devices were not observed in any location within this warehousing space. A review of the firm's pest control plan identified no pest control measures within the second-story warehouse space. Items stored in this area include:

Item #	Item description
(b) (4)	Syringe, 3mL, luer lock, clear
	Pump, siphon for 5-gallon pail
	Tube 1oz plastic collapsible + cap #16
	Cap for tube 1/8oz metal collapsible
	Vial, hinged, clear, 3.17oz
	Vial, hinged, clear, 5.23oz
	Desiccant 1gm silica gel
	Tubing, masterflex l/s 24, 50ft
	Spout 20mm opaque yorker

Additionally, the firm has documented the following Quality Events related to identification of suspected insects found in drug product preparations:

Case Number	Drug Product	Lot Number	Complaint Summary
00161544	GABAPE-CAP0008VC	000-03149828	Customer identified a bug-like item inside the bottle containing capsules of medication
00169898	PIMOBE-SUS0054VC	000-03425626	A bug flew into the product during preparation

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00169911	ENRKET-OTI031VC	000-03396306	A fruit fly got into lanolin beaker while packaging the product

OBSERVATION 6

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically,

The firm's contact/dwell time for the (b) (4) disinfectant is (b) (4) as per procedure and the manufacturer's instructions (surface must remain wet). On 3/15/2022, cleaning activities were observed for room (b) (4) to include disinfection of the ISO-5 classified area. An operator was observed to disinfect the ISO-5 hood in the room with (b) (4) disinfectant. The interior surface of the hood remained wet for approximately (b) (4) The operator did not re-wet the ISO-5 surfaces after the surfaces dried. The noted hood is utilized for the production of sterile human and veterinary non-hazardous drugs to include Tri-Mix (PGE1/Papaverine/Phentolamine) Aqueous Injection lot 000-03858168 (human drug) and Protirelin Injection lot 000-03847342 (veterinary drug).

OBSERVATION 7

Microbial contamination was recovered from areas where you produce drugs.

Specifically,

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The firm does not keep production hoods and production areas utilized for the preparation of drug products clean and sanitary. The following examples were noted during the current inspection:

A.Hood (b) (4) in room (b) (4) is utilized in the production of non-hazardous human and veterinary non-sterile drug products. The following observations were made regarding hood (b) (4) and the production hood utilized for non-sterile hazardous drug production during the current inspection:

In February 2022, the firm recalled 297 lots of Twist-A-Dose Transdermal Gel veterinary drug products due to contamination of multiple lots with *Penicillium sp*, *Aspergillus sp, and Cladosporium sp*, mold. Examples of veterinary drug products contaminated with mold includes Methimazole in Lipoderm 2.5 mg/0.05 mL Transdermal Gel Twist-a-dose lot 000-03465399 and Amitriptyline HCl 7.5 mg/0.05 mL Twist-A-Dose Transdermal Gel lot 000-03396931 (produced in hood (b) (4)). The firm's investigation (QEI# 173310) did not identify the source of the contamination; however, the firm had a contract testing laboratory conduct environmental monitoring of the non-sterile production hoods (to include (b) (4)) in December 2021. Mold was recovered from air viable samples taken during the December 2021 sampling. As of the current inspection, the firm had not requested the microbiological identification results from the contract testing laboratory. On 3/18/2022, the microbiological identification results were provided and indicated that *Penicillium sp*, and *Aspergillus sp* mold was recovered from the production hoods. The firm's investigation into the mold contamination of the Twist-A-Dose veterinary drug products (QEI# 173310) is inadequate as the firm has not assessed the impact of the production area mold recoveries in regard to the Twist-A-Dose Transdermal Gel veterinary drug mold contamination nor on other non-sterile drug preparations produced using the same equipment/areas and during the same time frame for potential mold contamination. The firm has not adequately assessed the risk to previously produced drug products, and the firm also has not resolved the contamination risk to animal drug products that continue to be produced without adequate corrective and preventive actions.

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Additionally, the firm has received customer complaints for mold in other non-sterile veterinary drug products produced in other production hoods to include:

Complaint Case#	Drug Product	Lot Number	Production Hood Utilized	Complaint Summary
00166758	OMEPRASUS0061VC - Omeprazole Oral Suspension	000-03359571	(b) (4)	vets office called to report color change to yellow and appearance of what looks like mold in the prep
00178036	ATENOLSUS0064VC - Atenolol Oral Suspension	000-03772714	(b) (4)	owner stated medication has black mold or black particles floating in suspension
00174209	PREDNISUS0729VC – Prednisolone Oral Suspension	000-03488239	(b) (4)	owner calling to report bottle is growing green stuff on the bottle itself and cap and also on top of PIBA.

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B.In October 2021, the firm conducted environmental monitoring of the (b) (4) containment hoods (b) (4) (b) (4)) utilized in room (b) (4) (ISO-8 classified room) which are utilized in the production of hazardous veterinary drug products intended to be sterilized. The firm recovered mold in 2 of the (b) (4) hoods in room (b) (4). The firm did not identify the source nor identity of the mold and did not assess the impact of the mold contamination on drug products produced during this time frame in the affected area to include Tacrolimus Ophthalmic Solution lot 000-03442860.

OBSERVATION 8

ISO-5 classified areas were not certified under worst-case dynamic conditions. Specifically, uni-directional airflow was not verified under operational conditions.

Specifically,

In November 2021, the firm had a contractor perform air pattern analyses (smoke studies) of the non-hazardous sterile cleanroom suite ISO-5 classified areas (in rooms (b) (4)). The ISO-5 classified areas are utilized to fill and package various non-hazardous sterile human and veterinary drugs to include Tri-Mix (PGE1/Papaverine/Phentolamine) Aqueous Injection lot 000-03744413 (human drug) and Tolazoline 100 mg/mL Aqueous Injection lot 000-03574637 (veterinary drug). The smoke studies conducted within the ISO-5 classified areas were inadequate as the studies did not include a complete representation of production activities to include the transfer of starting components and materials into the ISO-5 classified areas, the transfer (b) (4) of in-process products into a sterile hang bag, or open vial staging/set-up in the ISO-5 classified areas.

*DATES OF INSPECTION

3/14/2022(Mon), 3/15/2022(Tue), 3/16/2022(Wed), 3/17/2022(Thu), 3/18/2022(Fri), 3/21/2022(Mon), 3/22/2022(Tue), 3/23/2022(Wed), 3/24/2022(Thu)

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X Leanna M Slarsky
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Kristina L Conroy, Investigator

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DATE ISSUED
3/24/2022

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."