DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 ORAPHARM1_RESPONSES@fda.hhs.gov	3/7/2022-3/18/2022*
	FEI NUMBER 3012283530

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Neil P. McGarvey, PharmD, Owner	
FIRM NAME Arnold Professional Pharmacy	STREET ADDRESS 1460 Ritchie Hwy Ste 103
CITY, STATE, ZIP CODE, COUNTRY Arnold, MD 21012-2704	TYPE ESTABLISHMENT INSPECTED 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

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

Specifically, amoxicillin, ceftazidime, and cefuroxime were produced in the "general compounding room" where non-beta-lactam containing products are also produced. There are no dedicated spaces, decontamination steps or controls in place to prevent cross-contamination following production of beta-lactam products in the "general compounding room". For example, on March 2, 2022, "MILES SOLUTION" (Rx (b) (6)), which contains amoxicillin, was produced using a non-dedicated graduated cylinder. Similarly, on January 10, 2022, "AMOXICILLIN 100MG/ML SUSP ANHYD" (Rx (b) (4)) and on January 26, 2022, "AMOXICILLIN 50MG CAPSULES" (Rx (b) (4)) were produced using a non-dedicated (b) (4) . Non-beta-lactam products were subsequently produced and released for distribution using the same non-dedicated equipment.

OBSERVATION 2

Non-microbial contamination was observed in your production area.

Specifically,

A. Two areas of black-brown discoloration of unknown source were observed on a ceiling tile in the "general compounding room" on March 9, 2022. The first area measured approximately six inches by one-fourth inch, and the second area measured approximately four inches by one-half inch. The ceiling tile was above a shelf containing closed containers of active pharmaceutical ingredients and other ingredients. The containers are not cleaned off prior to being placed in the hood for use in production operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sena G Dissmeyer, Investigator Roseline N Boateng, Investigator Natasha Gupta, Investigator	X Sena G Dissmeyer Investiga or Signed By: Sena G. Dissmeyer -S Date Signed: 03-19-2022 1 :10:01	3/18/2022

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B. There is no assurance that your cleaning process removes products and cleaning agent residue from your reusable glassware and utensils. Liquid hand soap and "(b) (4)" household liquid detergent were used to clean utensils and equipment for production at your facility. Examples include but not limited to the following:

- On March 7, 2022, your Pharmacy Technician (b) (6)) used a liquid hand soap to clean spatulas, capsule machine parts, and (b) (4) used in production operations.
- On March 8, 2022, (b) (6) used a household liquid detergent, "(b) (4)", to clean similar equipment and utensils routinely used in the production of non-hazardous non-sterile drug products.

Reusable glassware and utensils were utilized in, but not limited to, the production of the following:

- On March 7, 2022, "NALTREXONE 4.5MG CAPSULES" (Rx (b) (6)) was produced using a (b) (4) , and the capsule machine with capsule size (b) (4) change parts.
- On March 8, 2022, "CISAPRIDE 6MG CAPSULES" (Rx (b) (6)) was produced using a (b) (4) (b) (4) , and the capsule machine with capsule size (b) (4) change parts.

Moreover, on March 7 and 8, 2022, visible residue was observed on spatulas store in the designated clean area, following washing and air drying.

OBSERVATION 3

You use equipment in production of drug products that have difficult to clean surfaces.

Specifically, chipped/broken spatulas were observed on March 7 and 8, 2022, in the drying rack in the "general compounding room", creating a difficult to clean surface and a possible source for contamination. Spatulas are non-dedicated utensils that are used in production of various drug products such as creams and ointments.

***DATES OF INSPECTION**

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3/07/2022(Mon), 3/08/2022(Tue), 3/09/2022(Wed), 3/10/2022(Thu), 3/11/2022(Fri), 3/18/2022(Fri)

X Roseline N Boateng
Investigator
Signed By: Roseline N. Boateng -S3
Date Signed: 03-18-2022 14:10:37

X Natasha Gupta
Investigator
Signed By: 2003395695
Date Signed: 03-18-2022 14:11:20

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EMPLOYEE(S) SIGNATURE
Sena G Dissmeyer, Investigator
Roseline N Boateng, Investigator
Natasha Gupta, Investigator

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Investigator
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Date Signed: 03-19-2022
1 :10:01

DATE ISSUED
3/18/2022

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."