DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802 ORAPHARM2_RESPONSES@fda.hhs.gov	7/26/2021-8/12/2021* FEI NUMBER 3011688532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Haleigh J. Cawood, Quality Control Manager

FIRM NAME	STREET ADDRESS
Eagle Pharmacy, Inc.	2200 Riverchase Ctr Ste 675
CITY, STATE, ZIP CODE, COUNTRY Hoover, AL 35244-2918	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1. Environmental monitoring surface sampling conducted in the vial filling room (ISO-5) is not taken in the most critical areas where aseptic manipulations occur. According to the Lead Quality Technician, surface samples are collected on the outer most areas of the LAFW (ISO-5); however, according to the Lead Compounding Technician, aseptic manipulations are performed in the center of the LAFW (ISO-5).
2. Your firm's (b) (4) particle counting probe is not placed in an orientation demonstrated to obtain a meaningful sample to monitor non-viable particles during production of your firm's non-dedicated vial filling machine (ISO-5), located in your firm's vial filling machine (ISO-5). According to your firm's Lead Quality Technician, who conducts routine environmental monitoring sampling, the (b) (4) particle counting probe is located greater than (b) (4) from the most critical area, where the greatest potential risk and highest exposure to the sterilized product occurs.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Susan O Oladeji, Investigator June P Page, Investigator Demario L Walls, Investigator	X Demario L Walls Investigator Signed By: Demario L Walls -G3 Date Signed: 08-12-2021 13:14:48	8/12/2021

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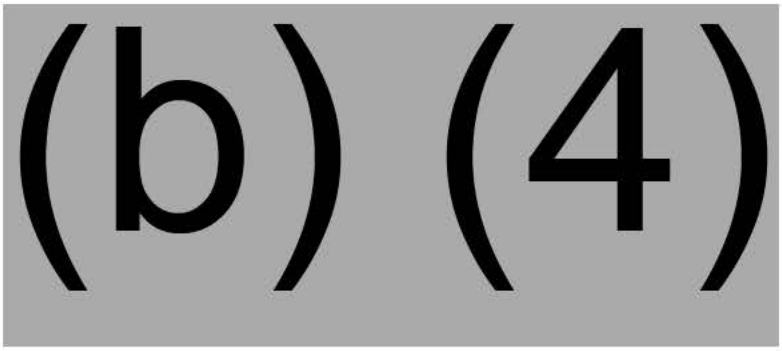
On 7/27/2021, a (b) (4) bin was observed being transferred from the ISO-7 classified area (lab) into the ISO-5 classified area ((b) (4) room) via (b) (4) during the production of Triamcinolone, Lot (b) (4), without being sanitized.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

1. During our review of the smoke study conducted in June 2020, by your firm's 3rd party contractor,
   a. We observed turbulence within the ISO-5 classified area of your firm's (b) (4) vial filling machine. The turbulence is observed at your most critical area of production ((b) (4)) during routine interventions. For example, but not limited to, at approximately:



The vial filling machine is used to (b) (4) drug products at your firm.

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2. Your firm's (b) (4) validation conducted by your 3rd party contractor has not adequately specified a load pattern for your (b) (4) drug product, Triamcinolone, in (b) (4) vials. According to your firm's inventory management software, your firm distributed approximately (b) (4) vials of Triamcinolone Acetonide 50mg and Triamcinolone Acetonide 80mg from 05/18/2018 to 07/31/2021.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

1. The document used to capture your firm's personnel and environmental monitoring results is pre-populated with CFU counts of (b) (4). According to your firm's Lead Quality Technician, they do not contemporaneously document their review of personnel and environmental monitoring plates.
2. Your suspension products (Betamethasone, Dexamethasone, Methylprednisolone, Triamcinolone) do not include a specification for particle size.

OBSERVATION 5

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

Your firm's media fills did not conduct media fill under worst-case, most challenging conditions. For example, but not limited to, prior to this FDA inspection, planned/unplanned interventions were not capture on your firm's batch records. On 08/02/2021, during the media fill, lot (b) (4), at least (b) (4) interventions were observed.

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In addition, on 07/27/2021, during the manufacture of Triamcinolone 50 mg, lot (b) (4) , at least (b) (4) interventions (b) (4)) were observed during a (b) (4) time period. These interventions were not documented on your firm's batch records.

OBSERVATION 6

Deviations from written specifications, sampling plans and test procedures are not recorded.

Specifically,

Your firm's Quality Unit failed to initiate investigations when you deviated from your stability protocols by placing (b) (4) instead of (b) (4) on stability, missing pre-established time points for testing and testing outside of the protocol. Your Quality Control Manager acknowledged that she should have initiated a deviation investigation. Your firm does not have a quality agreement with the laboratory who conducted your stability testing.

*DATES OF INSPECTION

7/26/2021(Mon), 7/27/2021(Tue), 7/28/2021(Wed), 7/29/2021(Thu), 7/30/2021(Fri), 8/02/2021(Mon), 8/03/2021(Tue), 8/04/2021(Wed), 8/05/2021(Thu), 8/06/2021(Fri), 8/09/2021(Mon), 8/10/2021(Tue), 8/11/2021(Wed), 8/12/2021(Thu)

X June P Page
Investigator
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Date Signed: 08-12-2021 13:15:21

X Susan O Oladeji
Investigator
Signed By: Susan O. Oladeji -S
Date Signed: 08-12-2021 13:16:19

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June P Page, Investigator
Demario L Walls, Investigator

X Demario L Walls
Investigator
Signed By: Demario L. Walls -G3
Date Signed: 08-12-2021 13:14:48

DATE ISSUED
8/12/2021

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."