DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver District Office 6th Ave. and Kipling St., Bldg. 20 Denver, CO 80225 (303) 236-3017 Industry Information: www.fda.gov/oc/industry	09/02/2020-09/16/2020
	FEI NUMBER 3011701621

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kevin M. Borg, PharmD, President and CEO

FIRM NAME	STREET ADDRESS
Potter's House Apothecary, Inc.	21585 N. 77th Ave., #1500
CITY, STATE AND ZIP CODE Peoria, AZ 85382	TYPE OF ESTABLISHMENT INSPECTED producer of sterile and non-sterile drugs

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 (I) (WE) OBSERVED:

OBSERVATION 1
Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

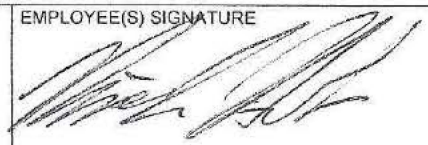
Specifically,

A) On 09/03/2020, I observed an approximately 8x5 inch splatter of reddish-purple substance on the perforated metal (b) (4) and HEPA filter inside the ISO 5 (b) (4) LAFW, model (b) (4), used to produce approximately (b) (4)% of sterile drugs. The residue/staining was present after the technician performed a "deep clean" prior to production, and the firm was unable to determine when the splatter occurred. The firm continued production of sterile drugs inside the ISO 5 LAFW throughout the inspection. I observed production of lot (b) (4).

B) Technicians remove sterile wipes from the manufacturer's packaging and store them on a cart in the ISO 7 buffer room indefinitely. There was no documentation available which detailed how long the wipes were on the cart exposed to the environment within the ISO 7 buffer room. I watched a sterile technician apply sterile (b) (4) (b) (4) to the wipes and use them to sanitize the ISO 5 LAFW work surface and all items introduced into the ISO 5 LAFW during sterile production on 09/03/2020.

C) I observed multiple cracks in the acrylic side and top panels of the ISO 5 LAFW used to produce sterile drugs. The cracks were located where the bolts secured the panels to the stainless steel housing for the HEPA filters.

OBSERVATION 2
Personnel were observed to manually contact a product contact surface while conducting aseptic operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Nicholas L. Hunt, Drug Specialist	09/16/2020

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Specifically, I observed the sterile technician contact the top of an unstoppered vial with a gloved thumb and forefinger at approximately 0945 on 09/03/2020 while attempting to seat a stopper on one vial of Tri-mix, lot 20200903@49. The vial contained (b) (4) finished drug.

OBSERVATION 3
ISO-5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow in the ISO 5 LAFW and ISO 5 BSC used to produce all sterile drugs was not verified under operational conditions:

A) The studies did not use sufficient smoke or duration to visualize unidirectional airflow.

B) The studies did not include a (b) (4) which sterile technicians use to dissolve bulk drug substances in most sterile finished drugs. I observed the technician use a (b) (4) during sterile production in the ISO 5 LAFW on 09/03/2020 and 09/09/2020.

C) The studies did not include items such as vials, sterilizing (b) (4) syringes, and large diluent containers on the primary workspace. I observed the technician place all items needed for production onto the primary workspace during sterile production in the ISO 5 LAFW on 09/03/2020 and 09/09/2020.

D) The studies did not show the interaction between the smoke and the technician. I observed the technician placed their body against the front edge or the worktop throughout sterile production in the ISO 5 LAFW on 09/03/2020 and 09/09/2020.

E) The studies were taken with a close-up view and did not include an examination of the entire workspace. I observed the technician use the entire workspace within the ISO 5 LAFW during sterile production on 09/03/2020 and 09/09/2020.

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	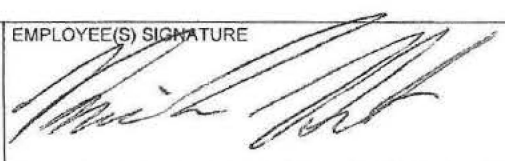	Nicholas L. Hunt, Drug Specialist	09/16/2020

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OBSERVATION 4

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, technicians (b) (4) solutions into vials during media fills, but they do not fill prefilled syringes from vials which is the most significant process for routine sterile production.

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		Nicholas L. Hunt, Drug Specialist	09/16/2020

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 judgement, 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."