

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Food & Drug Administration 22215 26th Ave S E Suite 210 Bothell, WA. 98021 425-302-0340 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 04/09-12/2019, 04/15-16/2019
	FEI NUMBER 3002759569

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Piper J. Machamer, General Manager

FIRM NAME Geneva Woods Pharmacy, Inc. dba Geneva Woods Pharmacy	STREET ADDRESS 501 W. International Airport Road, Suite 20
CITY, STATE AND ZIP CODE Anchorage, AK. 99518	TYPE OF 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 (I) (WE) OBSERVED:

OBSERVATION 1

Beta-lactam drugs were produced without providing adequate containment, cleaning of work surfaces, utensils/equipment and personnel to prevent cross-contamination.

Specifically, between 04/10/2017-04/09/2019, your pharmacy produced (b) (4) beta-lactam drug products in your non-hazardous area on work surfaces also used for the production of non-beta lactam products.

- a) Your pharmacy cleans work surfaces ((b) (4)) in your non-hazardous area with (b) (4) (b) (4)
- b) Your pharmacy does not have dedicated equipment for beta-lactam and non-beta lactam products. Production equipment is shared between both beta-lactam and non-beta lactam products.
- c) Equipment used to produce beta-lactam products is cleaned with (b) (4) and rinsed with distilled water. Following cleaning, this equipment is used for any non-hazardous product, including a non-beta lactam product.

OBSERVATION 2

Hazardous drugs were produced without providing adequate cleaning of utensils/equipment to prevent cross-contamination.

Your pharmacy produces approximately (b) (4) different drug products in your hazardous room and approximately (b) (4) patient-specific prescriptions per day. Specifically, between 04/12/2018 to 04/12/2019, your pharmacy produced (b) (4) testosterone prescriptions from the Active Pharmaceutical Ingredient (API) testosterone and (b) (4) progesterone prescriptions from the API progesterone.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kristin M. Abaonza -S <small>Digitally signed by Kristin M. Abaonza -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001597849, cn=Kristin M. Abaonza -S Date: 2019.04.16 12:43:07 -07'00'</small>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Kristin M. Abaonza, Investigator	DATE ISSUED 04/16/2019
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- a) Your pharmacy does not have dedicated equipment for hazardous drugs. Production equipment is shared between the (b) (4) products produced in your hazardous room. Dirty equipment (used to produce hazardous drug products) is cleaned with (b) (4) and distilled water.

Add Continuation Page

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