DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	11/26/2018-12/7/2018*
	FEI NUMBER 3014943990

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lisa A. Bruce, Branch Manager

FIRM NAME	STREET ADDRESS
Geneva Woods Pharmacy	501 W International Airport Rd Ste 4
CITY, STATE, ZIP CODE, COUNTRY Anchorage, AK 99518-1106	TYPE ESTABLISHMENT INSPECTED Producer of 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 OBSERVED:

OBSERVATION 1

Personnel engaged in aseptic processing were observed with exposed hands and exposed hair.

Specifically, your Pharmacy Technician was observed to have exposed hands in the ISO 5 zone. An example includes, but is not limited to, the instance that occurred on the date listed below.

11/27/2018—During sterile drug compounding procedures, your Pharmacy Technician (b) (6) entered the ISO 7 Compounding Room with ungloved hands. He proceeded to don sterile gloves under the ISO 5 "Hood #1" with ungloved hands exposed in this ISO 5 zone.

OBSERVATION 2

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, current sterile gowning components can expose hair and operators touch gowning on the floor. Examples include, but are not limited to, the items listed below.

A.) 11/26/2018—During (b) (4) facility cleaning procedures located in the ISO 7 Compounding Room that (b) (4), your Pharmacy Technician (b) (6) had hair exposed from her bouffant cap.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephanie A Slater, Drug Specialist	X Stephanie A Slater Drug Specialist Signed By: Stephanie A. Slater -S Date Signed: 12-07-2018 14:54:01	12/7/2018

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B.) On 11/27/2018, your Pharmacy Technician (b) (6) allowed the legs portion of his coveralls to touch the floor during sterile gowning procedures and entered the ISO 7 Compounding Room. He was observed assisting another Pharmacy Technician with sterile drug procedures on this date.

OBSERVATION 3

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, your facility is designed with an ISO 7 classified Compounding Room that is directly adjacent to two (2) non-classified "(b) (4) ". These (b) (4) are used daily by your Pharmacy Technicians to (b) (4) .

OBSERVATION 4

Disinfecting agents and used in the ISO 5 classified aseptic processing areas were not sterile.

Specifically, your firm uses a non-sterile cleaning agent called, "(b) (4) " to clean glass surfaces of the hood sash in the ISO 5 classified hoods; the surfaces of repeater pump equipment; and the surfaces of (b) (4) pump equipment. Your firm's written procedures and cleaning logs dated from August 2018 to November 2018 indicate that "(b) (4) " is used (b) (4) to clean ISO 5 hoods. Additionally, there was no evaluation of safety and effectiveness of "(b) (4) " completed by your firm.

OBSERVATION 5

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

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Specifically, your vendor's reports for ISO 7 cleanroom classifications showed multiple environmental excursions that failed to meet required specifications. Approximately two of three (2 of 3) microbial excursions occurred during the year 2018 during your vendor's cleanroom certification activities, which were not addressed and/or followed-up by your firm. Examples included, but are not limited to, the items listed below.

A.) ISO7 Compounding Room
Viable air sampling failed in September 2018. "Non-sporulating fungi" was identified by the cleanroom vendor's contract laboratory. Your firm did not follow up to this September 2018 viable air failure.

B.) ISO7 Ante Room
Viable air sampling failed in October 2017. "Gram positive rods" and "other fungi" were identified by the cleanroom vendor's contract laboratory. Your firm did not follow up to this October 2017 viable air failure.

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, your firm does not have data to support a contact time of (b) (4) for the use of (b) (4) (b) (4).

OBSERVATION 7
You had inadequate HEPA filter airflow over the area to which sterile product was exposed.

Specifically, smoke studies and media fills appeared inadequate and/or had results that did not meet specifications. Examples include, but are not limited to, the items listed below.

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A.) ISO 5 Hoods located in ISO 7 Compounding Room

1.) Your cleanroom certification vendor documented that there was air turbulence during smoke studies of the ISO 5 classified (b) (4) flow hoods listed below.

- SN# (b) (4) (also termed BSC) and SN# (b) (4) (also termed Hood #2) located in the ISO 7 Compounding Room in October 2017;
- SN# (b) (4) (also termed Hood #2) located in the ISO 7 Compounding Room in January 2018;
- SN# (b) (4) (also termed BSC) and SN# (b) (4) (also termed Hood #2) located in the ISO 7 Compounding Room in March 2018;
- SN# (b) (4) (also termed BSC) and SN# (b) (4) (also termed Hood #2) located in the ISO 7 Compounding Room in September 2018.

Your firm did not follow up to these smoke studies results that documented turbulent air flow inside these ISO 5 Hoods.

2.) Smoke studies dated March 27, 2018 and September 25, 2018 were not conducted during dynamic conditions that fully simulate normal operating conditions of sterile drug production.

B.) Media Fills

1.) There were two (2) back to back failures dated in December 2016 for Pharmacy Technician (b) (6) with incomplete follow-up and re-qualification immediately after. Her media fill records are missing for the first quarter of year 2017.

2.) Media fill records for multiple Pharmacy Technicians, dated 2016 to 2018, failed to show that operators performed the aseptic processes to fully simulate normal and/or worst-case operating conditions of sterile drug production.

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*DATES OF INSPECTION

11/26/2018(Mon), 11/27/2018(Tue), 11/28/2018(Wed), 11/29/2018(Thu), 12/05/2018(Wed), 12/07/2018(Fri)

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