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	8/28/2018-4/25/2019*
	FEI NUMBER 3014549846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amy A. Frost, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Pinnacle Compounding	1120 Kensington Ave Unit E
CITY, STATE, ZIP CODE, COUNTRY Missoula, MT 59801-5619	TYPE ESTABLISHMENT INSPECTED Compounding Pharmacy

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

(b) (4) intended to render final product sterile was not adequate to accomplish sterilization.

Specifically,

a. Your firm failed to conduct (b) (4) testing on (b) (4) used to sterilize Atropine Sulfate 0.01% Sterile Ophthalmic Solution, lot 021219OS1010, manufactured on 02/12/19, with a beyond-use date (BUD) of 180 days.

b. Your firm released products purported to be sterile despite the failure of the (b) (4) used in their production to meet the manufacturer's (b) (4) test specifications. For example:

- Prednisolone/Ketorolac 1%/0.5% Ophthalmic Solution, lot 021319OS1001, manufactured on 02/13/19, with a BUD of 180 days, was released with a (b) (4) testing result of (b) (4) which is below the manufacturer's specification of (b) (4)
- Timolol/Brimonidine/Dozolamide 0.5%/0.2%/2% Ophthalmic Solution, lot 02072019OS1006, manufactured on 02/07/19, with a BUD of 180 days, was released with a (b) (4) testing result of (b) (4) which is below the manufacturer's specification of (b) (4)

*DATES OF INSPECTION

8/28/2018(Tue), 8/29/2018(Wed), 8/30/2018(Thu), 8/31/2018(Fri), 9/04/2018(Tue), 9/05/2018(Wed), 9/06/2018(Thu), 9/07/2018(Fri), 4/17/2019(Wed), 4/18/2019(Thu), 4/25/2019(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christopher R Czajka, Investigator Andrew K Haack, Generic Drug User Fee Amendments (GDUFA)	X Andrew K Haack Generic Drug User Fee Amendments (GDUFA) Signed By: Andrew K. Haack -3 Date Signed: 04-25-2019 10:48:05	4/25/2019

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X Christopher R Czajka
Investigator
Signed By: Christopher R. Czajka -S
Date Signed: 04-25-2019 10:46:37

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Christopher R Czajka, Investigator Andrew K Haack, Generic Drug User Fee Amendments (GDUFA)	X Andrew K Haack Generic Drug User Fee Amendments (GDUFA) Signed By: Andrew K. Haack -S Date Signed: 04-25-2019 10:48:05	DATE ISSUED 4/25/2019