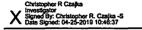
		LTH AND HUMAN SERVICE UG ADMINISTRATION	ES		
DISTRICT ADDRESS AND PHO			DATE(S) OF INSPECTION		
(C. C. C	th Ave SE Suite 210		8/28/2018-4/25/2019*		
Bothell, WA 98021			FEI NUMBER 3014549846		
(425)302-0340 Fax: (425)302-0404		331.31	2010		
NAME AND TITLE OF INDIVIDU	AL TO WHOM REPORT ISSUED				
Amy A. Frost, Pharmacist-in-Charge					
FIRM NAME	spore.	STREET ADDRESS	220 250 N L 254		
다 하는 이 생활되면 하게 되었다면 내 이 경상을 잃으면 하면 하는 아무리를 하는 것이 되었다면 하는 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그 그			1120 Kensington Ave Unit E		
			nding Pharmacy		
observations, and do observation, or have action with the FDA	observations made by the FDA representative(not represent a final Agency determination re- implemented, or plan to implement, corrective representative(s) during the inspection or sub- stact FDA at the phone number and address ab	garding your compliance. If a cation in response to an obs mit this information to FDA	you have an objection re ervation, you may discu	garding an ss the objection or	
OBSERVATION	etion of your firm we observed: DN 1 ded to render final product sterile w	vas not adequate to ac	complish sterilizat	tion.	
 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 beyonduse 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 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 Christopher R Czajka, Inves Andrew K Haack, Generic Dru Amendments (GDUFA)		Andrew K Haack Generic Drug User Fee Generic Drug User Fee Generic Grup User Signed Dr. Andrew K. Haack -3 Date Signed: 04-25-2018 10-48-05	DATE ISSUED 4/25/2019	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OBSERVATION	ONS	PAGE 1 of 2 PAGES	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 8/28/2018-4/25/2019* FEI NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 3014549846 (425)302-0340 Fax: (425)302-0404 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 TYPE ESTABLISHMENT INSPECTED Missoula, MT 59801-5619 Compounding Pharmacy



SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE

Christopher R Czajka, Investigator Andrew K Haack, Generic Drug User Fee Amendments (GDUFA)

Andrew K Heack Generic Drug User Fee Amendments (GDUFA) Signed By: Andrew K. Heack -S Date Signed: 04-25-2019 10:40:00 DATE ISSUED 4/25/2019

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INSPECTIONAL OBSERVATIONS

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