DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Baltimore District Office 6000 Metro Drive, Suite 101 Baltimore, MD 21215 410-779-5455 Industry Information: www.fda.gov/oc/industry	08/27-31/2018, 09/06-07/2018, 09/12/2018
	FEI NUMBER 3001465817

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: James R. Whitford, Director of Pharmacy

FIRM NAME	STREET ADDRESS
Acarial Health Pharmacy, Inc.	2924 Telestar Ct.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Falls Church, VA 22042	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

1. Non-microbial contamination was observed in your production area. Specifically,

On 08/29/2018, I conducted a walk-through of the clean rooms used for compounding hazardous and non-hazardous sterile drugs. I observed white fiber-like particles on the surface of the (b) (4) [redacted] located in the hazardous clean room. This ISO 5 area is used in the production of sterile hazardous drug products.

2. The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent.

Your firm is not aware of the concentration of the sporicidal agent used, (b) (4) [redacted], and lacks assurance that the concentration applied to ISO 5 surfaces is adequate for use as a sporicidal agent.

3. You used a non-pharmaceutical grade component in the formulation of a drug product. Specifically,

(b) (4) [redacted] is used as an ingredient in non-sterile compounded drug products, such as Sodium Butyrate Enema 11.01mg/ml solution, Naltrexone 4mg/ml suspension, and Methocel (Potassium Sorbate) 2% Gel. Your firm does not monitor the (b) (4) [redacted] nor conduct microbial and/or chemical analysis to ensure it meets USP standards.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Marcus A. Ray, Investigator	09/12/2018