DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	6/1/2016-6/6/2016* FEI NUMBER 3012188803

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kimberly, A Hunter , Vice President of Fulfillment Operations

FIRM NAME	STREET ADDRESS
Enclara Pharmacia Inc	512 Elmwood Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sharon Hill, PA 19079-1014	Producer of 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 OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1. Environmental monitoring of surfaces for microbial contamination is not performed after the completion of sterile operations in the ISO 5 area. Your firm only performs such monitoring on a (b) (4) basis.

2. Technician's gloves are not monitored for microbial contamination after the completion of sterile operations. Glove finger tips are monitored on (b) (4) basis.

3. Environmental monitoring for non-viable particulates and viable air counts is not performed during routine sterile operations. Such monitoring is performed (b) (4)

4. Pressure gauges in the ISO7 clean room and the ISO 8 Ante Room are not continuously monitored for air pressure differential. Instead personnel perform a (b) (4) of the pressure reading and make a record on the Pressure Gauge Log.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Thomas E Friel, Investigator 6/6/2016 X Thomas E Friel Thomas E Friel Investigator Signed by: Thomas E. Friel-S	6/6/2016

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Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

1. (b) (4) [redacted] disinfectant cleaner is not sterilized prior to use in cleaning and disinfect the ISO 5 hood.

2. Non-sterile lint free wipes are used by the firm to clean and disinfect the ISO 5 hood.

OBSERVATION 3

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,
Gowns/coveralls, facemasks, goggles and bouffant hair nets worn by operators working inside ISO 5 zones are not sterile.

***DATES OF INSPECTION**

6/01/2016(Wed),6/06/2016(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Thomas E Friel, Investigator 6/6/2016 X Thomas E Friel Thomas E Friel Investigator Signed by: Thomas E. Friel -S	6/6/2016