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 cleaning and disinfecting the room and equipment to produce aseptic conditions.

Your firm utilizes several different disinfectants in the ISO 5 areas of which two, (b) (4), are non-sterile.

*DATES OF INSPECTION
9/01/2016(Thu), 9/02/2016(Fri), 9/07/2016(Wed), 9/09/2016(Fri), 9/14/2016(Wed)