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 in that walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically,

On 7/1/19, I observed cracks and chips on the acrylic view screens of the ISO 5 laminar flow hoods located in Room 195, where occurs. The crack in Hood appeared to be inches in length spreading horizontally along the view screen above the sterile compounding work space. A thick and uneven bead of silicone caulk was used to repair the crack on an unknown date—there were no maintenance records for the repair. The crack and uneven caulk surface is not smooth or hard and therefore may be difficult to disinfect and sanitize.

In addition, your ISO 5 cleaning procedure (SOP 4.400 DEN) does not address cleaning the inside of the acrylic view screens and front surfaces, within the ISO 5 laminar air flow space where sterile air contacts and passes as it flows down to the compounding work space. On 7/8/19, I observed the ISO 5 laminar flow hood cleaning process and noted the inside of the front view screen and front surfaces were not cleaned prior to compounding.

The following drugs products were compounded in Hood between 4/15/19 and 7/5/19:
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

ITEM 2

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically, you compound drug products that:

a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or

b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

SEE REVERSE OF THIS PAGE

Zachery L Miller, Investigator

DATE ISSUED 7/18/2019
Examples of compounded drug products that are essentially a copy of one or more approved drugs include:
1) Glycopyrrolate 0.4 mg per 2 mL,
2) Neostigmine methylsulfate 4 mg per 4 mL, and
3) Succinylcholine chloride 140 mg per 7 mL

*DATES OF INSPECTION*
7/01/2019(Mon), 7/02/2019(Tue), 7/03/2019(Wed), 7/08/2019(Mon), 7/09/2019(Tue), 7/12/2019(Fri),
7/15/2019(Mon), 7/16/2019(Tue), 7/17/2019(Wed), 7/18/2019(Thu)