

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax: (781) 587-7556		DATE(S) OF INSPECTION 2/1/2016-2/19/2016*  FEI NUMBER 3011859261			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Derick B. Anderson , Owner					
FIRM NAME Anderson Holdings Inc.		STREET ADDRESS 129 Main Street			
CITY, STATE, ZIP CODE, COUNTRY Nashua, NH 03060-2718		TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products			
<p>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.</p>					
<p><b>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</b></p> <p><b>OBSERVATION 1</b></p> <p>Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.</p> <p>Specifically,</p> <p>A. The firm's cleaning process involves the full opening of the front panel of the ISO 5 glove box for cleaning at the beginning and end of each day of use. During the cleaning process, the aseptic processing area inside the glove box is exposed to non-sterile gowning worn by firm operators as well as air in the surrounding ISO 8 room. There has been no evaluation of the impact the opening of the ISO 5 glove box may have on the quality of sterile drug products.</p> <p>B. The firm uses non-sterile solutions (e.g. Process LpH st, Vesphene IIse, and Sporicidin) for the cleaning and disinfecting of surfaces in the ISO 5 glove box.</p> <p>C. Two of the cleaning agents used by the firm require dilution prior to use (Process LpH st and Vesphene IIse). The firm does not document the preparation of the cleaning agents. The firm uses distilled water for the dilution of the cleaning agents.</p> <p>D. The firm's cleaning log does not document which cleaning agents were used for the daily and monthly cleanings of the ISO 5 glove box and ISO 8 room.</p> <p>E. The firm uses non-sterile non-shedding wipes to clean and disinfect the interior of the ISO 5 glove box.</p>					
<p><b>OBSERVATION 2</b></p> <p>Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.</p>					
<b>SEE REVERSE OF THIS PAGE</b>		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"> EMPLOYEE(S) SIGNATURE  Stacey S Degarmo, Investigator  John P Mistler, Investigator  Dien N Nguyen, Investigator </td> <td style="width: 40%; text-align: right; vertical-align: bottom;"> <div style="display: flex; justify-content: space-between;"> <div> X Stacey S Degarmo  Investigator  Signed by: Stacey S. Degarmo -S </div> <div style="text-align: right;"> 2/19/2016  DATE ISSUED  2/19/2016 </div> </div> </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Stacey S Degarmo, Investigator John P Mistler, Investigator Dien N Nguyen, Investigator	<div style="display: flex; justify-content: space-between;"> <div> X Stacey S Degarmo  Investigator  Signed by: Stacey S. Degarmo -S </div> <div style="text-align: right;"> 2/19/2016  DATE ISSUED  2/19/2016 </div> </div>
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Specifically,

- A. The firm conducts volumetric viable air sampling and surface contact monitoring of the ISO classified areas on a monthly basis. There is no routine monitoring of the processing area of the ISO 5 glove box during each occurrence of aseptic operations, which are conducted approximately three to four days each week.
- B. The firm conducts personnel monitoring (fingertip plating) only at the time of semi-annual media fills. There is no personnel monitoring following routine sterile processing. The firm does not currently adhere to the fingertip sampling frequency specified in their procedure (initially weekly for three weeks then every other week).
- C. The firm documents the air pressure of the ISO 8 room once each day. There is no continuous monitoring of the pressure differentials for the ISO 5 glove box to ensure the maintenance of appropriate pressure during aseptic operations.
- D. The firm failed assess the potential impact of positive low level viable air monitoring results at the work table in the ISO 8 clean room on 11/27/15, 12/14/15, and 12/18/15. The firm uses the work table for the preparation of drug products prior to aseptic filtration in the ISO 5 glove box. No corrective actions were implemented outside of routine scheduled cleanings following the positive results. The bacterial isolates were not sent out for identification. To date, the firm has not considered these results during their ongoing evaluation of the Cyclosporin 2% ophthalmic solution sterility failure for Lot #121415-28, which was prepared on 12/14/15.

**OBSERVATION 3**

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

- A. The firm's procedures require sterility and bacterial endotoxin testing for batches of sterile drug products consisting of 25 or more units or multi-dose vials. The firm does not require bacterial endotoxin testing for batches of sterile drug products comprised of less than 25 units.

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B. The firm does not have data to support sterility assurance of prepared sterile drug products for the duration of the extended beyond use dates assigned to the products.

#### **OBSERVATION 4**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established , written and followed .

Specifically,

A. The firm's procedure for the dry heat oven is inadequate for the following reasons:

- 1) The procedure does not address the validation of the dry heat sterilization or depyrogenation cycles allowed by the firm.
- 2) The procedure allows for a 90 day clean hold time for depyrogenated glassware and utensils. The firm does not have data to support the 90 day clean hold time allowed.

B. Firm personnel stated that semi-annual media fill simulations are required for personnel conducting aseptic operations. There is no written procedure that covers the firm's media fill simulation process or requirements.

C. The firm media fill simulation does not represent the most challenging or stressful condition. For example, the firm failed to include the use of reusable glassware during the semi-annual media fill.

D. The firm uses Logged Formula Worksheets to document depyrogenation cycles. The worksheets fail to document what equipment and/or components were included in the cycle load. The documentation records do not include equipment printouts for the depyrogenation cycles to ensure the time and temperature specifications for the cycles were met.

#### **OBSERVATION 5**

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

Specifically,

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The firm does not require the gowning worn by personnel performing operations in the ISO 5 glove box to be sterile, with the exception of sterile gloves. The following non-sterile items are used when firm personnel gown for sterile operations: disposable gown, bouffant, beard cover (when applicable), face mask, and shoe covers. There is no requirement for sterile gowning during the cleaning of the glove box in which the entire front panel is opened and the operator reaches into the aseptic processing area to clean the walls and work surfaces of the ISO 5 glove box.

**OBSERVATION 6**

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

The alternate test method (Rapid ScanRDI Microbial Detection) used by the firm in place of USP <71> sterility testing has not been validated for use with the sterile drug products produced by the firm. For example, the firm used the Rapid ScanRDI Microbial Detection results in lieu of sterility testing results for the 250 mL (50 vial) batch of Tri-Mix 30-1-10, Lot #101515-01.

**OBSERVATION 7**

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

The firm failed to investigate two instances of potency results above the allowed 90-110% for Quad Mix 20/0.8mg/8.3/160mcg/mL from the potency over time testing conducted on Lot #100215-26. The potency analysis on 11/6/15 revealed a potency of 0.896 mg/mL (112%) for the phentolamine mesylate component of the product. The potency analysis on 12/1/15 revealed a potency of 186 mcg/mL (116%) for the atropine sulfate component of the product.

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**OBSERVATION 8**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

The firm does not conduct routine potency testing for prepared sterile drug products prior to release.

**\*DATES OF INSPECTION**

2/01/2016(Mon), 2/02/2016(Tue), 2/04/2016(Thu), 2/11/2016(Thu), 2/19/2016(Fri)  
2/19/2016
2/19/2016

X Dien N Nguyen

Dien N Nguyen  
Investigator  
Signed by: Dien N. Nguyen -S

X John P Mistler

John P Mistler  
Investigator  
Signed by: John Mistler -S

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