DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	3/26/2019-4/5/2019* FEI NUMBER 3014877770

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Roy C. Anderson, Owner and CEO

FIRM NAME	STREET ADDRESS
Anderson Compounding Pharmacy, Inc. DBA Anderson Compounding Pharmacy	Attn: Cleve Anderson, 310 Bluff City Hwy
CITY, STATE, ZIP CODE, COUNTRY Bristol, TN 37620-4602	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Human and Veterinarian 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 WE OBSERVED:

OBSERVATION 1

The ISO 5 classified aseptic processing areas had difficult to clean and visibly dirty equipment or surface.

Specifically, on 03/26/2019, we observed the following in your firm's ISO 5 classified areas, where aseptic human and veterinarian drug production take place, including, but are not limited to:

A. Inside your firm's Laminar Air Flow Hoods (LAFH) (ISO 5 classified):
   1. Visible discoloration that appears to be rust was observed inside your firm's LAFH (ISO 5 classified), S/N: (b) (4) ;
   2. Visible discoloration that appears to be residue buildup was observed on your firm's LAFH (ISO 5 classified), S/N: (b) (4) , where the workbench meets the HEPA screen;
   3. Paint was observed, and confirmed by your firm's technician that performs aseptic processing, on the inside of the LAFHs (ISO 5 classified) (S/N: (b) (4) & S/N: (b) (4)), appearing to cover areas where discoloration resembling what appeared to be rust was observed; and
   4. Cracks were observed, and confirmed by your firm's technician that performs aseptic processing, on the sides of your firm's (b) (4) walls of the LAFHs (ISO 5 classified) (S/N: (b) (4) & S/N: (b) (4)); and on the top of the LAFH (ISO 5 classified) (S/N: (b) (4)).

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Bristol, TN 37620-4602	Producer of Sterile and Non-Sterile Human and Veterinarian Drugs

Your Quality Control Director reported the following drugs listed in the table below were aseptically produced in your facility over the past 6 months. According to your firm's Lab Director, these drugs have a beyond use date (BUD) ≤ 180 days, including, but are not limited to:

Drug Name
Atropine 0.01% Eye Drops
Autologous Serum 20% Solution
Cyclosporin 2% Eye Drops
Dexamethasone 24mg/mL Otic Injection
DMSO 60mL/Heparin 1mL/Sodium Bicarb 60mL/Solu-Cortef 100mg Bladder Irrigation
Estradiol Cypionate 10mg/mL Injection
Estrone 5mg/mL Oil Injection
Gentamicin Irrigation Sol (Multiple Strengths)
HCG Injections (Multiple Strengths)
Heparin Products (Multiple Strengths)
LIPO-VITE Injection
Methylcobalamin 1mg/mL Injection
Morphine 5mg/3mL Inhalation Solution
Papaverine 30mg/mL
Penicillin G 100,000/mL Ophthalmic Drop

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Phenylephrine HCl 1mg/mL Injection
Potassium Chloride 40meq Per 100mL Solution in Sterile Syringe
Prostaglandin Injections (Multiple Strengths)
Sermorelin Acetate 907.5 mcg/mL
Strept-24mg Dexam-10mg/mL Otic Injection
Testosterone Cypionate 250mg/mL Injection
Vitamin D3 200,000iu/mL Oil Injection

OBSERVATION 2

Non-microbial contamination was observed in your production area.

Specifically, in your firm's Buffer Room (ISO 5 classified), including, but are not limited to:

A. Visible discoloration that appears to be rust was observed around the nuts and bolts, located on the top of your firm's entry door separating the AnteRoom (ISO 7 classified) from your firm's Buffer Room (ISO 5 classified);
B. Visible discoloration that appears to be rust was observed around the nut, located on the outside of your firm's LAFHs (ISO 5 classified), S/N: (b) (4) ;
C. Visible discoloration was observed on your firm's HEPA filters, located on the ceiling above your firm's (b) (4) ;
D. Visible discoloration that appears to be residue buildup was observed on your firm's light fixtures, located above your firm's LAFHs (ISO 5 classified) (S/N: (b) (4) & S/N: (b) (4));
E. What appeared to be packaging tape was observed on your firm's ceiling. The packaging tape was adhered to a fallen light fixture and an adjacent ceiling tile; and

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F. Caulking was observed on the ceiling of your firm's Buffer Room (ISO 5 classified). The caulking is not smooth and not easily cleanable.

Your Quality Control Director reported the following drugs listed in the table below were aseptically produced in your facility over the past 6 months. According to your firm's Lab Director, these drugs have a beyond use date (BUD) $\leq$ 180 days, including, but are not limited to:

Drug Name
Atropine 0.01% Eye Drops
Autologous Serum 20% Solution
Cyclosporin 2% Eye Drops
Dexamethasone 24mg/mL Otic Injection
DMSO 60mL/Heparin 1mL/Sodium Bicarb 60mL/Solu-Cortef 100mg Bladder Irrigation
Estradiol Cypionate 10mg/mL Injection
Estrone 5mg/mL Oil Injection
Gentamicin Irrigation Sol (Multiple Strengths)
HCG Injections (Multiple Strengths)
Heparin Products (Multiple Strengths)
LIPO-VITE Injection
Methylcobalamin 1mg/mL Injection
Morphine 5mg/3mL Inhalation Solution

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Papaverine 30mg/mL
Penicillin G 100,000/mL Ophthalmic Drop
Phenylephrine HCl 1mg/mL Injection
Potassium Chloride 40meq Per 100mL Solution in Sterile Syringe
Prostaglandin Injections (Multiple Strengths)
Sermorelin Acetate 907.5 mcg/mL
Strept-24mg Dexam-10mg/mL Otic Injection
Testosterone Cypionate 250mg/mL Injection
Vitamin D3 200,000iu/mL Oil Injection

OBSERVATION 3

Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically, gaps were observed on the ceiling of your firm's Buffer Room (ISO 5 classified). For example, but are not limited to:

A. Gaps were observed in your firm's light fixture:
   1. Ranging from approximately 0"-1/2" wide and 48" long was observed, located directly above your firm's Biological Safety Cabinet (BSC) (ISO 5 classified), where your firm aseptically produces hazardous sterile drug products.
   2. Ranging from approximately 2-3" wide was observed, located directly above your firm's LAFH (ISO 5 classified), S/N: (b) (4) .

B. Gaps were observed in your firm's ceiling tiles:
   1. A gap <1/4" wide was observed on the ceiling above your firm's (b) (4)

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OBSERVATION 4

You produced hazardous drugs without providing adequate containment to prevent cross-contamination.

Specifically, your firm did not provide documentation supporting smoke studies were performed under dynamic conditions during the routine certification of your ISO 5 classified areas.

*DATES OF INSPECTION

3/26/2019(Tue), 3/27/2019(Wed), 3/28/2019(Thu), 3/29/2019(Fri), 4/01/2019(Mon), 4/02/2019(Tue), 4/03/2019(Wed), 4/04/2019(Thu), 4/05/2019(Fri)

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