DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DATE(S) OF INSPECTION: 02/10, 11 & 13/2020
FEI NUMBER: 3015826061

TO: Douglas E. Clark, Pharmacist
FIRM NAME: Blount Discount Pharmacy, Inc.
CITY, STATE AND ZIP CODE: Alcoa, TN 37701

TYPE OF ESTABLISHMENT INSPECTED: Non-sterile Drug Product Producer

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) (WE) OBSERVED:

Observation #1
Hazardous and highly potent drugs are produced without providing adequate cleaning of work surfaces, utensils, equipment and/or personnel to prevent cross-contamination.

Specifically, I observed built-up residue on the scale, stained and nicked spatulas, scratched and cloudy glassware used to produce non-sterile drug products. You use these same utensils and equipment to manufacture hazardous drugs and non-hazardous types of drugs including but not limited to hormone, Fluorouracil, and opioid products.

Observation #2
Agents used for cleaning the laminar flow hood and other equipment between products do not include a deactivating agent (e.g. oxidizing agent) to prevent cross-contamination.

Specifically, the cleaning agents I observed used between batches for equipment and the hood were (b) (4) and dish soap only.

Observation #3
Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, you use Sodium Hyaluronate, (b) (4) and (b) (4) as components in hormone creams, cough syrup and suspensions. You do not have adequate documentation to demonstrate these components meet suitability for use in non-sterile drug products.

DATE ISSUED: 02/13/2020

Claire M. Minden
Investigator

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