DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	8/13/2018-8/22/2018*
	FEI NUMBER 3004483441

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James L. McCarley, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Cantrell Drug Company	7321 Cantrell Rd
CITY, STATE, ZIP CODE, COUNTRY Little Rock, AR 72207-4144	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

a) The smoke study performed under static conditions on May 29, 2018 to June 1, 2018 within the ISO 7 room 409 showed significant turbulence for HEPA filters S11 and S35. S35 is a new HEPA unit located between filters S10 and S11. In addition, filter S8 in Room 410 which is located between LFH (b)(4) and (b)(4) also showed turbulence. The smoke study did not demonstrate how this turbulence would not affect the ISO 5 environment for LFHs (b)(4) (room 409), (b)(4) and (b)(4) (room 410).

b) The return air vent (R23) located in the ceiling of room 418 by anterooms 416 and 417 does not work properly. The smoke study could not demonstrate sufficiently whether a dead zone is present or not. This design of the ISO 8 room 418 does not assure proper cascading of air from ISO 7 classified rooms.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Claire M Minden, Investigator Bonita S Chester, Investigator	X Claire M Minden Investigator Signed By: Claire M. Minden -S Date Signed: 08-22-2018 11:41:01	8/22/2018

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OBSERVATION 2

Equipment for adequate control over humidity is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, the upper action limit for relative humidity (RH) for your ISO rooms is set at above (b) (4) %. You have no scientific rationale for this limit and your monitoring shows/demonstrates a steady increase since mid-May for the humidity in these areas. For instance, room 409 has maintained RH values of 70%+ since mid-May. In addition, you have not set an alert level for humidity to control/prevent possible growth under these conditions.

OBSERVATION 3

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

Excel spreadsheets used to maintain data for trending data including non-conformances, weight checks and environmental monitoring data do not have adequate controls to prevent manipulation and storage of data.

***DATES OF INSPECTION**

8/13/2018(Mon), 8/14/2018(Tue), 8/15/2018(Wed), 8/16/2018(Thu), 8/17/2018(Fri), 8/20/2018(Mon), 8/22/2018(Wed)

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X Bonita S Chester
Investigator
Signed By: Bonita S. Chester -S
Date Signed: 08-22-2018 11:41:54

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