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	06/05/2017-06/15/2017
	FEI NUMBER 3002708794

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hoy D. Allen, Jr., President & CEO

FIRM NAME	STREET ADDRESS
Diabetes Corporation of America dba DCA Pharmacy	233 Bedford Way
CITY, STATE, ZIP CODE, COUNTRY Franklin, TN 37064-5527	TYPE ESTABLISHMENT INSPECTED Producer of Sterile 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 (I) (WE) OBSERVED:
-ACH 06/15/17

OBSERVATION 1

Cleaning pads or wipes used in the ISO 5 area are not sterile.

Specifically, the (b) (4) wipes used to clean the LAFH (ISO 5 area) are not sterile.

OBSERVATION 2

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, a lyophilizer is located in the non-hazardous buffer room (ISO 7), adjacent to LAFH (ISO 5), this equipment contains (b) (4) . There are no procedures for external cleaning and disinfection of this equipment. Also, environmental conditions of the non-hazardous buffer room including but not limited to air flow patterns, viable and non-viable particles have not been evaluated during operation of the lyophilizer.

OBSERVATION 3

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically, on 06/05/2017, I observed clean room operator, with initials (b) (4) perform drug product aseptic transfers in the LAFH (ISO 5). The operator did not always disinfect or change gloves after leaving the LAFH to retrieve materials or discard waste. The following lots were produced without glove disinfection/changes:

-T106/PGE-80/LIDO, RX (b) (6), (b) (7)(C), RX (b) (6), (b) (7)(C),
-Phenylepherine/LIDO, RX (b) (6), (b) (7)(C)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Brandon C. Heitmeier, Investigator	06/15/2017

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OBSERVATION 4

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, post production (b) (4) integrity tests performed by your firm have failed to meet the (b) (4) manufacturer's specifications for (b) (4). No investigations were performed and the batches were released for distribution. The following batches all had recorded (b) (4) values below the manufacturer's specification (list is not all inclusive):

-Tri-mix 4 injectable, lot: 060117wc
-Oxytocin nasal spray 40u/ml, lot: 053117bm
-Glutathione 200mg/ml injectable, lot: 022417bm

OBSERVATION 5

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm's batch sizes for injectable drug products range from (b) (4) to (b) (4). However, the last media fill performed only consisted of (b) (4)

***DATES OF INSPECTION**

06/05/2017, 06/06/2017, 06/07/2017, 06/08/2017, 06/15/2017

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Brandon C. Haltmeier, Investigator	08/15/2017