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 Industry Information: www.fda.gov/oc/industry	08/11/2015 - 08/20/2015 FEI NUMBER 3002708794

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hoy D. Allen, CEO

FIRM NAME	STREET ADDRESS
Diabetes Corporation of America	233 Bedford Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Franklin, TN 37064	Producer of Sterile Drug Products

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

Drug product containers and closures were not sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

1) Your firm has not validated your sterilization process for (b) (4) glass vials and stoppers to be used for aseptic processing and packaging of drug products intending to be sterile.

2) Your firm does not depyrogenate glassware to be used for mixing and packaging of drug products intending to be sterile.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

1) Your firm performs surface monitoring (b) (4). (b) (4) and (b) (4) for the (b) (4), (b) (4) (b) (4), and (b) (4) room. Your SOP 3.030, "Environmental Monitoring of the Clean Room Facility," states (b) (4). Neither is adequate as environmental conditions should be monitored every day of production. Furthermore, the last monitoring conducted by your firm was in December 2014.

2) Your firm's aseptic technician's fingertips are monitored (b) (4). Your SOP 3.030, "Environmental Monitoring of the Clean Room Facility," states (b) (4). Personnel monitoring should be conducted every day of production. Furthermore, the last personnel monitoring conducted by your firm was in December 2014.

3) Viable and non-viable monitoring for the aseptic processing area is only conducted (b) (4) by the certification company.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zada L. Giles, Investigator Zada L. Giles Laura L. Staples, Investigator Laura Lee Staples	08/20/2015

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 Industry Information: www.fda.gov/oc/industry	08/11/2015 - 08/20/2015
	FEI NUMBER 3002708794

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hoy D. Allen, CEO

FIRM NAME	STREET ADDRESS
Diabetes Corporation of America	233 Bedford Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Franklin, TN 37064	Producer of Sterile Drug Products

4) Your firm utilizes a (b) (4) to (b) (4) for aseptic processing. No environmental monitoring has been conducted for the (b) (4).

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

1) Your Cleanroom Certification Report dated (b) (4) indicates smoke studies were performed for the aseptic area (b) (4) however, smoke studies were not conducted for the ISO 5 hood. The smoke studies were not video recorded or documented and were not performed in dynamic conditions.

2) Your firm does not continuously monitor pressure in the ISO 5 hood, buffer room, negative pressure room, or ante room. Air pressure is only checked (b) (4) for the (b) (4) The ISO 5 hood gauge is never monitored.

(b) (4)

(b) (4) 8/20/15

This observation should have been removed as it is incorrect

OBSERVATION 4

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

1) Microbial testing is not performed for each lot of drug product purporting to be sterile. Your firm's lots range in volume from (b) (4).

2) Endotoxin testing is not performed for each lot of drug product purporting to be sterile and vials and stoppers are not depyrogenated before use. All drug products your firm produces are made from non-sterile components.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zada L. Giles, Investigator Laura L. Staples, Investigator	08/20/2015

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 Industry Information: www.fda.gov/oc/industry	08/11/2015 - 08/20/2015 FEI NUMBER 3002708794

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hoy D. Allen, CEO

FIRM NAME	STREET ADDRESS
Diabetes Corporation of America	233 Bedford Way
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Franklin, TN 37064	Producer of Sterile Drug Products

OBSERVATION 5

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

Specifically,

1) Your firm's technicians perform media fill qualifications (b) (4). This process is inadequate as it is not representative of typical or the most complex manipulations performed by your firm. Furthermore, the last media fill qualifications were performed (b) (4).

2) Your firm (b) (4) sterilizes testosterone and estradiol pellets. You have not performed validation of this process.

OBSERVATION 6

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

Specifically,

1) The gowning components your firm uses during aseptic processing are not sterile, except for gloves. The hair covers, face masks, and shoe covers are stored in open containers in the ante room. Also, there is no cover for the eyes, eyebrows, and forehead area.

2) Per your firm's SOP 9.100, "Required Garb for Clean Room Facility Access," (b) (4). Your firm allows (b) (4).

OBSERVATION 7

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your firm has not performed stability studies for your sterile products that include ID, potency, degradant, impurity, and other stability indicating parameters. Beyond use dates of greater than 48 hours are given to sterile injectable drugs that do not contain preservatives.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Zada L. Giles, Investigator Laura L. Staples, Investigator	08/20/2015

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 Industry Information: www.fda.gov/oc/industry	08/11/2015 - 08/20/2015
	FEI NUMBER 3002708794

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hoy D. Allen, CEO

FIRM NAME	STREET ADDRESS
Diabetes Corporation of America	233 Bedford Way
CITY, STATE, ZIP CODE, COUNTRY Franklin, TN 37064	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

OBSERVATION 8

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically,

You do not use a sporicide in your ISO 5 hood where aseptic filling takes place. The only product used to clean the ISO 5 hood is sterile (b) (4).

OBSERVATION 9

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,

1) Your firm stores glassware (used in mixing and aseptic filling) in the buffer room (b) (4). Your firm has not conducted any hold time studies to ensure this storage is adequate for the glassware to remain sterilized until use.

2) Your firm produces (b) (4). These (b) (4) are stored in a refrigerator in an unclassified room and (b) (4). Your firm has not conducted any studies to ensure the product remains sterile after (b) (4) (b) (4) and (b) (4) from the (b) (4).

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Zada L. Giles, Investigator Zada L Giles
Laura L. Staples, Investigator Laura Lee Staples

DATE ISSUED
08/20/2015