DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	9/19/2017-9/28/2017* FEI NUMBER 3008563008

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Phanesh Koneru, PhD, LLM, President & CEO

FIRM NAME	STREET ADDRESS
Exela Pharma Sciences LLC	1245 Blowing Rock Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lenoir, NC 28645-3618	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 I OBSERVED:

OBSERVATION 1

There was a failure to handle and store components and drug product containers at all times in a manner to prevent contamination.

Specifically,

a) Your firm cannot ensure that materials, products, and/or samples are kept at a controlled room temperature.
   1. Your firm currently transports raw materials and finished product between their (b) (4) facilities via a company truck that is not temperature controlled.
   2. Your firm currently transports raw material samples and finished product samples between their (b) (4) facilities via employees' personal vehicles. Your firm does not have a standard practice and/or procedure specifying who can transport manufacturing materials and products (in Ziploc bags) and does not maintain records for time in transport. Additionally, these samples are placed in a Ziploc bag with a label on the bag, without any seal to secure the samples in the Ziploc bag during transport.
   3. Your firm cannot ensure that microbiology samples are maintained at controlled room temperature. Your firm monitors temperature using one temperature probe in the microbiology laboratory, which consists of (b) (4) rooms without a door. Microbiology samples are located in (b) (4) and the temperature probe is located in back room on the (b) (4)

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b) Your firm is unable to ensure the integrity of all materials and components stored in the microbiology laboratory, as microbiology laboratory temperatures exceeded the upper temperature storage requirement of (b) (4) C for (b) (4) in March, April, May, and July 2017. Moreover, the specifications for temperature in the microbiology laboratory, which are (b) (4) C, have a higher upper limit than materials and components stored in the lab.

OBSERVATION 2

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

Specifically,

a) Your firm did not certify that the ISO-classification of the ISO-classified areas are met under dynamic conditions prior to the release and distribution of the following lots of Sodium Bicarbonate Injection 84mg/mL (1mEq/mL), 50mL vials:
   1. Lot #BMHG1709, compounded/filled 7/24/17, released/distributed 8/15/17
   2. Lot #BMHH1701, compounded/filled 8/15/17, released/distributed 9/26/17

b) Your firm monitors pressure differentials via the (b) (4) Magnehelic gauges for the (b) (4) of the (b) (4) (ISO 5 area) before and after production, but not during production.

OBSERVATION 3

Routine checking of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, your firm does not challenge the (b) (4) system that verifies lot numbers/expiration dates and barcodes, prior to use of the system. Currently, your firm (b) (4) the (b) (4) system, (b) (4) packaging and labeling operation, (b) (4) to ensure that it will pass if a label with the correct lot number, expiration date, and barcode is read. However, no challenge is conducted to ensure that the system can detect if there is a label with an incorrect lot number, expiration date, and/or barcode. Your firm only challenges the (b) (4) system at the time of its original qualification, on 1/4/14, when it was (b) (4) facility.

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OBSERVATION 4

The results of the examination of the packaged and labeled products were not documented in the batch production or control records.

Specifically, operators on the packaging and labeling line do 100% visual examination of vial labels and QA personnel do 100% visual inspection of carton labels and for the presence of the vial in the carton prior to closing the carton. However, the results of these inspections are not recorded in the batch record or elsewhere.

OBSERVATION 5

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

a) Your firm has not validated the electronic system used to create labels.
   1. Your firm is creating labels through the (b) (4) which is installed on an undetermined number of computers at Exela.
   2. On 9/20/17, I observed PDF labels for Sodium Bicarbonate Injection, 84mg/mL (1mEq/mL), 50mL vials, generated in (b) (4) being stored on a (b) (4) (b) (4)
   3. Access to this folder could not be determined, as your firm changed the location, name, and permissions of 503B Labels folder during the inspection without documenting this change.

b) Your firm does not define a specified maximum timeframe, either in practice or in procedure, that labels can remain in the QA Office/Staging Area, which is not temperature controlled, prior to their utilization in packaging and labeling operations.

OBSERVATION 6

The labels of your outsourcing facility's drug products are deficient.

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Specifically, labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A), as the quantity or volume is not on your drug product labels (vials). Currently, the volume is on your drug product containers (cartons). Vial labels for Sodium Bicarbonate Injection, 84mg/mL (1mEq/mL), 50mL vials, do not contain this information.

***DATES OF INSPECTION**

9/19/2017(Tue), 9/20/2017(Wed), 9/21/2017(Thu), 9/22/2017(Fri), 9/25/2017(Mon), 9/26/2017(Tue), 9/27/2017(Wed), 9/28/2017(Thu)

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