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 Industry Information: www.fda.gov/oc/industry	01/12/2015 - 01/16/2015
	FEI NUMBER 3004969894

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Danny Barnes, President

FIRM NAME	STREET ADDRESS
Triangle Compounding	3700 Regency Pkwy Ste 140
CITY, STATE, ZIP CODE, COUNTRY Cary, NC 27518-8696	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

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

Specifically,

1) Your quality unit did not appropriately review the results of the aseptic process simulations for all the sterile processing technicians, dated 10/20/14, 10/23/14, 10/24/14 and 11/10/14, and as delineated in the policy titled Quality Assurance Program, effective 09/03/13.

2) Non-sterile wipes are utilized to clean inside the ISO 5 personal workplace hood area as delineated in standard operating procedure 5.161, Clean Room Routine Maintenance, effective 01/05/15.

3) There is no standard operating procedure delineating the disinfection of the non-viable particle counter device which is placed inside the ISO 5 personal workplace hood area and transported from the ISO 7 and ISO 8 areas.

4) Active air samples for viables are not collected inside the ISO 5 personal workplace hood area as part of the current environmental monitoring program delineated in standard operating procedure 7.110, Environmental Monitoring, effective 10/01/14.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Viviana Matta, Investigator Marie F. Mathews, Investigator	01/16/2015

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OBSERVATION 2

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

Specifically,

1) The firm's stability program lacks evidence that stock solutions that are prepared from non-sterile active pharmaceutical ingredients and (b) (4) (for use as an intermediary ingredient) remain sterile for the duration of the assigned expiration dates. The expiration dates are 90 days for most of the stock solutions. The firm does perform sterility testing on samples of the filled solution after filling. Examples of the formulations that contain an interim stock solution are (b) (4)

OBSERVATION 3

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

Specifically,

Your cleaning practices for critical aseptic work areas, such as the ISO 5 workspace hood and carts adjacent to the workspace, are deficient in that the recommended surface contact times for application of the sporicidals and disinfectants are not always followed.

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	Viviana Matta, Investigator Marie F. Mathews, Investigator	01/16/2015