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	09/08/2014 - 09/22/2014 FEI NUMBER 3004969894

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: DANNY BARNES, PHARMD, RPH, President

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

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Investigations into sterility failures of products formulated by your facility were not thoroughly reviewed and evaluated to determine the root cause of the event and to identify and implement appropriate corrections to prevent reoccurrence. For instance:

i. Iohexol 300mg/ml, lot 82857-LG 15704: The root cause analysis identified potential sources of contamination to include: product wrappers, alcohol wipes, and pre-sterilized vials. However, no evaluation of the current process for decontaminating these articles was addressed or implemented.

ii. Betamethasone Sodium Phosphate (PF) 8mg/ml inj., lot 73729-LG21569: The root cause analysis of the identified potential sources for the contaminant found did not result in the firm implementing a corrective action to prevent reoccurrence. There was no environmental monitoring conducted at the time the lot was aseptically processed.

iii.Potassium Phosphate PF (150mM/50ml) inj., lot 81464-LG22806: The root caluse analysis of the identified potential sources of contamination did not result in the firm implementing a corrective action to prevent reoccurrence.

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OBSERVATION 2

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

Complaint investigations were not conducted to determine the product related events that could have resulted in the adverse drug experiences reported, and to determine the corrective actions to prevent reoccurrence. In addition, these reports were not further evaluated to determine if the events were reportable under the Medwatch program. For instance:

1. (b) entry dated 3/10/2014 - report of reaction experienced with Hydroxyprogesterone Caproate
2. Internal Adverse Drug Monitoring Report dated 2/19/14 - report of reaction experienced with Testosterone Topical Gel
3. Internal Adverse Drug Monitoring Report dated 6/17/14 - report of reactions experienced with lidocaine/magnesium injection kit
4. Internal Adverse Drug Monitoring Report dated 2/7/14 - report of reactions experienced with Methylfolate, Glutathione , Lidocaine, and Methylcobalamin injections.
5. Internal Adverse Drug Monitoring Report dated 4/15/14 - multiple reports of severe reactions experienced tith Hydroxyprogesterone Caproate Injections.

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OBSERVATION 3

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

Specifically,

The microbial sampling of personnel gowning is only assessed through (b) (4) personnel gowning qualification and not routinely during active processing of sterile products.

OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate standards and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

1.There is no training procedure for employees to perform 100% visual inspection checks of sterile drug products. Currently operators are only trained on the established procedure which does ~~not~~ describe the defect categories that may appear in the finished product. BSC 9/22/14

2. There has been no established procedures or methods employed to evaluate the effectiveness of preservatives used in finished sterile products, such as Hydroxyprogesterone Caproate Injection.

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OBSERVATION 5

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

OBSERVATION 6

The written stability testing program is not followed.

Your current procedures governing stability testing of sterile drug products, DOC No.: 8.001, has not been executed for any sterile drug products formulated to support labeled expiration date (Beyond Use Dates= 30,45 60,90, 180 days) and storage conditions.

OBSERVATION 7

There is a lack of written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and testing of labeling and packaging materials.

OBSERVATION ~~6~~ 8 BSC 9/22/14

The labels of your outsourcing facility's drug products do not include the information required by section 503B (a)(10)(A) &(B).

Specifically,

1. The statements, "This is a compounded drug," "Not for resale," and "Office use only" are not on your drug product labels.
2. Your drug product labels do not include a list of inactive ingredients, identified by established name and the quantity or proportion of each ingredient nor does it appear on the containers from which individual units of the drug are removed for dispensing or for administration.

3. The containers from which individual units of the drug are removed for dispensing or for

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administration do not contain information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

Examples of drug product labels and containers with these deficiencies include the following:

" Sodium Phosphate Injection 150mM/50ml, Phosphorus 200mEq/50ml Sodium – Corrected + verified 9/22/14, BSC
" NADH Injection 10mg/ml
" Potassium Chloride Injection 2mEq/ml
" Avastin (Bevacizumab) 2.5mg/0.1ml Soln – Corrected + verified 9/22/14, BSC
" TriMix Injectable 75/2.5/25 per 4.3 mL
" Dexamethasone Sodium Phosphate Injectable 24 mg/mL, 5 mL
" Heparin 40,000 U/19 ml, Lidocaine HCl 2%, Sodium Bicarbonate 8.4% Bladder Irrigation 38 mL

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