DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	12/15/2014 - 12/31/2014* FEI NUMBER 3005031360

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ronald M. McGuff, President & CEO

FIRM NAME	STREET ADDRESS
McGuff Compounding Pharmacy Services, Inc.	2921 W Macarthur Blvd Ste 142
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Santa Ana, CA 92704	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

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

Specifically,

A. The firm has not performed suitability testing on all of their drug formulations to demonstrate that the product does not interfere with the sterility test. Examples include:

i. Dexpanthenol 250mg/ml, lot 14K2521, was filled into 30mL multi-dose vials on 10/20/14 and released on 11/4/14. The sterility test was initiated on 10/21/14 and completed on 11/4/14.
ii. Edetate Calcium Disodium 200 mg/ml, lot 14K5601 was filled into 15mL single dose vials on 11/7/14 and released on 12/1/14. The sterility test was initiated on 11/14/14 and completed on 12/1/14.
iii. Taurine 100mg/ml, lot 14L3481 was filled into 30mL multi-dose vials on 11/26/14 and released on 12/10/14. The sterility test was initiated on 11/26/14 and completed on 12/10/14.

B. The inhibition/enhancement test has not been performed to ensure the validity of the (b) (4) Limulus Amebocyte Lysate (LAL) test performed on injectable drug products. Examples include:

i. Dexpanthenol 250mg/ml, lot 14K2521, was filled into 30mL multi-dose vials on 10/20/14 and released on 11/4/14. The LAL test was performed on 11/20/14.
ii. Edetate Calcium Disodium 200 mg/ml, lot 14K5601 was filled into 15mL single dose vials on 11/7/14 and released on 12/1/14. The LAL test was performed on 11/13/14.
iii. Taurine 100mg/ml, lot 14L3481 was filled into 30mL multi-dose vials on 11/26/14 and released on 12/10/14. The LAL test was performed on 12/4/14.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Caryn M. Mcnab, Investigator Sangeeta M. Khurana, Investigator	12/31/2014

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OBSERVATION 2

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

Specifically,

A. The firm does not have data to support the potency of drug products over the labeled shelf life, for example:

   i. Ascorbic Acid Injection preservative free (non-corn) 500 mg/ml, lot 14G4191 was filled into 50ml vials on 7/25/14 and labeled do not use beyond 1/21/15.
   ii. Edetate Calcium Disodium 200 mg/ml, lot 14K5601 was filled into 15 mL single dose vials on 11/7/14 and labeled do not use beyond 5/2/15.
   iii. Dexpanthenol Injection 250 mg/ml, lots 14J1741 (2ml), 14J1742 (5ml), and 14J1743 (10ml) were filled on 9/11/14 and labeled do not use beyond 3/10/15.

B. The firm has not performed any studies on preserved products in multi-dose vials to demonstrate that the preservative is effective at the time of release and that it retains antimicrobial effectiveness over the shelf life of the product. For example:

   i. Dexpanthenol Injection, 250mg/mL, lot 14K2521 was filled into 30mL multiple dose vials on 10/20/14 and labeled do not use beyond 4/18/15.
   ii. Taurine Injection 100mg/ml, lot 14L3481 was filled into 30mL multiple dose vials on 11/26/14 and labeled do not use beyond 5/23/15.

C. The firm has not performed sterility testing at the end of shelf life or a container closure integrity study to demonstrate that the primary container closure system maintains product sterility throughout the shelf life. For example:

   i. Methylcobalamin Injection preservative free 20 mg/ml lot 14L2031 was filled into 2ml vials on 11/19/14 and labeled do not use beyond 5/16/15.
   ii. Edetate Disodium Injection 150 mg/ml lot 14L2611 was filled into 100ml vials on 11/19/14 and labeled do not use beyond 5/16/15.

*** DATES OF INSPECTION:**
12/15/2014(Mon), 12/16/2014(Tue), 12/17/2014(Wed), 12/18/2014(Thu), 12/23/2014(Tue), 12/30/2014(Tue), 12/31/2014(Wed)

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