DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772	1/17/2017-3/14/2017* FEI NUMBER 3005472652

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Erik K. Mayes , Pharmacist in Charge	
FIRM NAME Spoonamore Drug Co Inc	STREET ADDRESS 4014 Dutchmans Ln
CITY, STATE, ZIP CODE, COUNTRY Louisville, KY 40207-4715	TYPE ESTABLISHMENT INSPECTED Pharmacy Compounder

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

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Your firm produces products intended for intrathecal use from non-sterile active ingredients that are not controlled for endotoxin level. In addition, your firm does not test final product to ensure the product is within allowable limits for bacterial endotoxins.

OBSERVATION 2

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

Specifically, your smoke studies for ISO 5 hood, serial number (b) (4), test report (b) (4) and for ISO 5 hood, serial number (b) (4), test report (b) (4), performed on (b) (4), are inadequate in that they failed to demonstrate unidirectional airflow studies (smoke studies) under dynamic conditions to determine how the movement of air and personnel during aseptic operations could pose risk to products

OBSERVATION 3

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Michael P Sheehan, Investigator	3/14/2017 X Michael P Sheehan Michael P Sheehan Investigator Signed by: Michael P. Sheehan -S	3/14/2017

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Procedures for the cleaning and maintenance of equipment are deficient regarding inspection of the equipment for cleanliness immediately before use.

Specifically, Your firm uses non-sterile wipes in your sterile compounding area. For example, non-sterile wipes are used when cleaning the ISO 5 hood, cleaning of equipment in both the ISO 7 and ISO 8 areas, (b) (4) and by employees during hand washing activities in the ISO 8 area.

***DATES OF INSPECTION**

1/17/2017(Tue),1/18/2017(Wed),1/19/2017(Thu),1/20/2017(Fri),1/25/2017(Wed),1/26/2017(Thu),1/31/2017(Tue),2/02/2017(Thu),2/03/2017(Fri),2/09/2017(Thu),3/14/2017(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Michael P Sheehan, Investigator	3/14/2017 X Michael P Sheehan Michael P Sheehan Investigator Signed by: Michael P. Sheehan -S	3/14/2017