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	2/22/2016-4/7/2016*
	FEI NUMBER 3002992930

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jacqueline S. Bernard , President and Owner

FIRM NAME	STREET ADDRESS
Wickliffe Pharmaceutical Inc	4340 Georgetown Rd
CITY, STATE, ZIP CODE, COUNTRY Lexington, KY 40511-9115	TYPE ESTABLISHMENT INSPECTED Producer of Veterinary 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 I OBSERVED:

OBSERVATION 1

Reprocessing procedures lack the steps to be taken to insure that reprocessed batches will conform with all established standards, specifications, and characteristics.

Specifically, your firm made a batch of Pentosan Polysulfate 250 mg/mL Injectable, lot 23-12-2014@9, B.U.D. 06-04-2015. This batch was made on 12/23/14. Recall actions were initiated on 1/19/15. This batch had originally passed visual inspection and all testing (sterility testing, date: 12/31/2014 and endotoxin testing date: 1/12/20015) and was released for distribution. A total of (b) (4) of the batch had been shipped on or about 1/13/15 to a DVM customer located in (b) (4), (b) (6) who received the (b) (4) on or about 1/15/15. Records identify that prior to dispensing and distributing, the (b) (4) had been visually inspected by a PharmD at your firm and no visual particulates were noted at that time. On 1/19/15, a PharmD of your firm was visually inspecting in its entirety the remaining Pentosan 250 mg/ml Injectable, lot 23-12-2014@9 on hand at your firm and noticed particulates in several of the vials.Your firm then recalled the (b) (4) that had been distributed. There is no failure investigation to identify what the particulate matter was or the source of the particulate matter. The remaining amount of product on hand of this batch was removed from their original vials and the product was (b) (4) and re-packaged into new vials. The re-packaged product was sent to a laboratory for sterility and endotoxin testing. The sterility results, dated 2/4/15, identifies passing results for sterility and endotoxin testing (both on 1/30/15) of the (b) (4) product. There is no assurance that the (b) (4) process assured that the product was free of particulates.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael P Sheehan, Investigator 4/7/2016 X Michael P Sheehan Michael P Sheehan Investigator Signed by: Michael P. Sheehan -S	4/7/2016

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A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary, has not been established.

Specifically, failure to appropriately handle recalls at your firm. For recalled products Magnesium Sulfate Injectable, lots 05-11-2014@8 and 07-01-2015@1; Cyclosporin A 2% Opthalmic Solution, lot 02-09-2015@3, and Pentosan Polysulfate 250 mg/mL Injectable, lot 23-12-2014@9, deficiencies include one or more of the following: not knowing why the product was recalled, not knowing if all customers were notified, not knowing if the recalled product was returned by all customers, and not knowing the final disposition of recalled product.

***DATES OF INSPECTION**

2/22/2016(Mon),2/23/2016(Tue),2/24/2016(Wed),2/25/2016(Thu),3/09/2016(Wed),3/10/2016(Thu),3/11/2016(Fri),3/21/2016(Mon),3/22/2016(Tue),3/23/2016(Wed),3/24/2016(Thu),4/07/2016(Thu)

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