DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	01/07/2014 - 01/23/2014* FEI NUMBER 1019003

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Krista M. Roberts, Plant Manager

FIRM NAME	STREET ADDRESS
Baxter Healthcare Corporation	911 N Davis Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cleveland, MS 38732-2106	Drug Manufacturer

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

The quality control unit lacks the responsibility and authority to reject all drug products.

Specifically, the firm's QA department approved/released for distribution the following finished drug product lots: (b) (4) - 0.9% Sodium Chloride Irrigation; (b) (4) - Veterinary 0.9% Sodium Chloride Irrigation; (b) (4) - Sterile Water for Irrigation; (b) (4) - Sterile Water for Irrigation; and (b) (4) - 0.9% Sodium Chloride Irrigation. These drug product lots were contained in plastic pour bottles that were manufactured by the firm using the plastic (b) (4) lot # (b) (4) . The firm determined that this lot of (b) (4) was contaminated with (b) (4) by the firm's (b) (4) supplier. The firm knew that the (b) (4) was contaminated with (b) (4) before these plastic pour bottles were manufactured and then filled with these finished drug products.

OBSERVATION 2

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, on 11/02/2012 the firm installed an (b) (4) metal detector on the (b) (4) supply line to address the (b) (4) contamination from the firm's supplier of plastic (b) (4) This (b) (4) is used by the firm to manufacture plastic pour bottles/caps which will be filled with drug products. Also, on 06/19/2013 a (b) (4) metal detector was installed to replace the (b) (4) metal detector installed 11/02/2012. The firm did not perform any type of validation for these critical pieces of equipment.

OBSERVATION 3

Routine calibration and inspection of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, the firm did not calibrate the metal detectors that were installed on 11/02/2012 and 06/19/2013. Also, the firm has no documented calibration/maintenance records for these metal detectors.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Marvin D. Jones, Investigator Thomas O. Morgan, Investigator	01/23/2014

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OBSERVATION 4

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, the firm has not qualified the current (b) (4) supplier used for the manufacturing of plastic pour bottles and caps. The firm has documented two lots of plastic (b) (4) that were received from the firm's (b) (4) supplier that were contaminated with (b) (4) The firm has performed no investigations as to the source of this contamination from the supplier or any testing to determine the exact contents of the contamination. Also, the firm has not performed any on-site audit of the supplier to address the issues of (b) (4) contamination in the plastic (b) (4)

OBSERVATION 5

The quality control unit lacks responsibility to approve all procedures or specifications impacting on the quality and purity of drug products.

Specifically, the firm's QA department did not revise the receiving procedures for plastic (b) (4) to address (b) (4) contamination or set any specifications for (b) (4) contained in the plastic (b) (4)

*** DATES OF INSPECTION:**
01/07/2014(Tue), 01/08/2014(Wed), 01/09/2014(Thu), 01/23/2014(Thu)

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