DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	04/02/2014 - 04/08/2014* FEI NUMBER 3008213711

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Paul R. Elmer, President

FIRM NAME	STREET ADDRESS
Pharmakon Pharmaceuticals	14450 Getz Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Noblesville, IN 46060-3303	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 I OBSERVED:

OBSERVATION 1

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

1. Recall Procedures SOP PL 122 reads in part, "It is the responsibility of the QA department to issue recalls when appropriate." However, incident report 001 indicates your firm was notified NDC 45183-0016-69 (Midazolam) was mislabeled on 3/26/2014 and no recall was issued. The incident report reads in part, (b) (6) called to report label having incorrect concentration of drug. Label had 0.2mg/2ml total dosage 0.4 mg per 2ml. They were wanting 0.1mg/ml. Investigation was performed, label was incorrect should have been 0.2mg/ml". The labels for Midazolam lots E0433735C and E1016227C reads in part, "Midazolam 0.2mg/2ml 0.9% Sodium Chloride Total dosage: 0.4 mg per 2mL".

2. Labeling Printing and Issuance SOP PH127 reads in part, "Templates for all labels are on the (b) (4) only authorized personnel can access the file. Labels are printed in roll quantity by the operator. The operator will sign give labels to a manager or QA personnel for verification of correctness". However, (b) (4) (b) (4) currently being used to store templates and print labels, does not have any audit trail, security access, user role permissions, or user controls to ensure only authorized personnel can access template files.

   The label template for Midazolam 0.2mg/2mL in 0.9% Sodium Chloride 2mL in 3mL syringe NDC 45183-0014-69 was erroneously changed in (b) (4) software by the Clinical Quality Manager to reflect the following, "***Midazolam 0.2mg/2ml 0.9% Sodium Chloride Total dosage: 0.4 mg per 2mL***". The software has no audit trail to verify the date of the change of the Midazolam NDC 45183-0014-69 template. There is no documentation of the verification of the correctness of these labels by a second person.

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Meisha R. Waters, Investigator	04/08/2014

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The formulation, batch record, and label was changed for NDC#45183-0014-69 from Midazolam 0.2mg/2ml in 0.9% Sodium Chloride 2ml in 3ml syringe to Midazolam 0.2mg/mL in 0.9% Sodium Chloride 2ml in 3mL syringe prior to compounding batch E0433736C on 02/04/2014 without review and investigation into the discrepancy.

OBSERVATION 3

The results of the examination of the packaged and labeled products were not documented in the batch production or control records.

Specifically,

There is no documentation of the review of each unit by the pharmacist of finished product after compounding prior to release and distribution. The review of packaged and labeled syringes prior to distribution for Midazolam lots E0433735C, E1016227C, E0433736C, and E60038692C was not documented.

OBSERVATION 4

Examination of packaging and labeling materials for suitability and correctness before packaging operations is not performed and not documented in the batch production records.

Specifically,

Midazolam 0.9% Sodium Chloride Total dosage: 0.4 mg per 2mL NDC#45183-0014-69 lot E1016227C compounded on 01/21/2014 and lot E0433735C compounded on 01/20/2014 were released and distributed with inconsistent labeling. The batch record for Lot E1016227C was reviewed by quality on 01/21/2014 and the pharmacist on 01/23/2014. There is no batch record for lot E0433735C.

The label for lots E0433735C and E1016227C state "***Midazolam 0.2mg/2ml 0.9% Sodium Chloride Total dosage: 0.4 mg per 2mL***". This error was not identified when labels were issued prior to compounding or during review of the batch record by quality personnel or the pharmacist.

* DATES OF INSPECTION:
04/02/2014(Wed), 04/03/2014(Thu), 04/07/2014(Mon), 04/08/2014(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Meisha R. Waters, Investigator	04/08/2014