DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	11/12/2014 - 11/24/2014* FEI NUMBER 3011082190

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kenneth M. Behr, Pharmacist and Owner

FIRM NAME	STREET ADDRESS
National Prescription Services Inc. dba HRI Pharmacy	3S721 West Ave Suite 300
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Warrenville, IL 60555-3254	Producer of non-sterile drugs

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

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

The firm has no evidence that the cleaning procedure for the (b) (4) (b) (4) product contact surfaces is sufficient to prevent cross-contamination. Between capsule batches it is (b) (4) . The firm has no evidence that this process sufficiently removes drug residues before subsequent batches are encapsulated. Also, the (b) (4) is not cleaned before it is replaced (b) (4) . Both Nystatin and Metronidazole are encapsulated, as well as various formulations containing vitamins, minerals, and amino acids.

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,

The firm has no data to support the adequacy of its blending process for encapsulated drug products, which consists of (b) (4) . In addition, the firm has no data on the particle sizes of its powdered drug components. Both Nystatin and Metronidazole are encapsulated.

OBSERVATION 3

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Russell K. Riley, Investigator

DATE ISSUED
11/24/2014

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The firm does not chemically test its drug products: Nystatin capsules and oral suspension, Metronidazole capsules and oral suspension, and Naltrexone topical cream.

OBSERVATION 4

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

Specifically,

The firm has no stability data to support the expiration periods it assigns to drug products. For example:
a. An expiration period of 6 months is applied to Naltrexone 6mg/ml Cream Safflower.
b. An expiration period of 6 months is applied to Nystatin Capsules (500,000 units/capsule).
c. An expiration period of 30 days is applied to Nystatin 200,000 units/ml Oral Suspension.
d. An expiration period of 30 days unrefrigerated or 90 days refrigerated is applied to Metronidazole Benzoate 400mg/5ml Oral Suspension.
e. An expiration period of 6 months is applied to Metronidazole Benzoate 500mg Capsules.

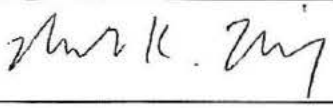
OBSERVATION 5

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically,

The firm does not test drug components for identity. In addition, the firm has made no attempt to establish the reliability of the Certificates of Analysis that it receives with drug components.

*** DATES OF INSPECTION:**
11/12/2014(Wed), 11/17/2014(Mon), 11/18/2014(Tue), 11/20/2014(Thu), 11/24/2014(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Russell K. Riley, Investigator 	11/24/2014