DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Baltimore District Office 6000 Metro Drive Suite 101 Baltimore, MD 21215 410-779-5455 Industry Information: www.fda.gov/oc/industry	01/12/15, 01/13/15,01/14/15,01/15/15
	FEI NUMBER 3004580127

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Amanda T. Baxter, Pharmacist / Owner

FIRM NAME	STREET ADDRESS
Wood's Pharmacy, Inc., dba The Medicine Shoppe	108 Main Street
CITY, STATE AND ZIP CODE Boones Mill, VA 24065	TYPE OF ESTABLISHMENT INSPECTED Producer of non-sterile drugs

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

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,

The firm does not perform analytical testing to determine finished product potency. For example,

Methimazole (5 mg /0.1 ml, 4mg, 3mg and 2.5 mg/0.1 ml) transdermal gel
Testosterone 1.25 mg / ml transdermal gel
Biestrogen 0.6 and Progesterone 100 / ml transdermal gel
Aspirin 1.25 mg capsules
Ketoprofen 25 mg capsules

Observation 2

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

Specifically,

There is no data that supports the expiration periods assigned to drug products. For example, the following products are assigned 6 months expiration period:

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		Nebil A. Oumer, Investigator Tajah L. Blackburn, Investigator	01/15/2015

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A) Methimazole transdermal gel

B) Testosterone 1.25 mg / ml transdermal gel

C) Biestrogen 0.6 and Progesterone 100 / ml transdermal gel

D) Aspirin 1.25 mg capsules

E) Ketoprofen 25 mg capsules

Observation 3

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Expired chemicals / components used for producing pharmaceutical products were observed on the shelves near the production area on 01/12/2015. For example: Magnesium Stearate NF, expired on 12/02/14, (b) (4) [redacted] expired on 10/17/13, Glucosamine Hydrochloride, USP, expired on 02/28/14 and Promethazine Hydrochloride, USP, expired on 09/06/14. (b) (4) [redacted] is used in Progesterone Capsules, (b) (4) [redacted] is used in Ketoprofen transdermal gels and (b) (4) [redacted] is used in Promethazine transdermal 25 mg /ml gel.

Observation 4

Laboratory records do not include complete records of the periodic calibration of laboratory instruments.

Specifically,

There are no calibration records for the scale ((b) (4) [redacted]) used for weighing chemicals for

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producing pharmaceutical products. This instrument is the only scale in the facility and is used for all weighing activities performed by employees.

Observation 5

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

There is no documentation showing equipment, utensils and other production materials have been cleaned. Additionally, there are no procedures in place to instruct employees to clean equipment such as mortar and pestle, (b) (4) and (b) (4) before producing new pharmaceutical products.

Observation 6

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,

A) Currently, there are no weight checks performed to ensure that capsules contain no less than (b) (4) of the theoretical calculated weight for each unit.

B) There is no data to support ingredients are blended in such a way that a homogenous mixture is achieved. Employee, (b) (6) performs only (b) (4) to ensure that capsules (e.g. Ketoprofen 25 mg, Aspirin 1.25 mg) are filled adequately and gels (e.g. Methimazole, Testosterone 1.25 mg / ml, Biestrogen 0.6 and Progesterone 100 / ml) are the desired consistency.

C) There is no procedure in place or test performed to ensure correct particle size is achieved during production. Currently the employees (b) (4) to determine if the particles are sufficiently ground (components that go

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into capsules and gels).

Observation 7

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

There are no (b) (4) instructions for producing capsules. Additionally, there is no procedure in place for order of (b) (4) to ensure uniform consistency of the final product (capsules).

Observation 8

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,

No identity test is performed for drug product components received by the firm. Furthermore, the firm has not established the reliability of the drug component supplier through validation of the supplier's test results in the Certificate of Analysis.

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