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	10/17/2017-11/3/2017* FEI NUMBER 3004488698

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David J. Miller, Pharmacist-In-Charge/Co-owner

FIRM NAME	STREET ADDRESS
Keystone Pharmacy	4021 Cascade Rd SE Ste 50
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Grand Rapids, MI 49546-3720	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 WE OBSERVED:

OBSERVATION 1

You produced highly potent drugs without providing adequate segregation and cleaning of utensils to prevent cross-contamination.

Specifically,

A. There are no defined/labeled areas for storage of "clean" and "unclean" drug production equipment/utensils and the small-sized plastic containers that are reused for repackaging bulk chemical materials. These small containers, along with other drug product production equipment such as capsule filling trays, capsule filling molds, and spatulas/mortars/pestles/spinners, were observed to be stored on portable carts or in/on a 3-compartment sink in the cleaning area of the production room with no identification of "clean" or "unclean" status or any other unique identifier.

B. Bulk chemical materials used in production of hormonal creams/ointments (b) (4) (b) (4) and three excipients are received in large plastic containers and then repackaged into small-sized reusable plastic containers for ease-of-dispensing during production operations. These small containers are not dedicated and there is no method for tracking or identifying what each container previously held after it was cleaned. For example, prescription (b) (6) was produced using testosterone that was repackaged in such a manner, and there is no way to determine what the small container into which the testosterone was repackaged had been previously used for.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Constantin Y Philopoulos, Investigator Charles L Zhou, Investigator	X Constantin Y Philopoulos Investigator Signed By: Constantin M. Philopoulos -S Date Signed: 11-03-2017 15:14:42	11/3/2017

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*DATES OF INSPECTION

10/17/2017(Tue), 10/18/2017(Wed), 10/30/2017(Mon), 11/03/2017(Fri)

X Charles L Zhou
Investigator
Signed By: Charles L. Zhou -S
Date Signed: 11-03-2017 15:15:27

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Constantin Y Philopoulos, Investigator
Charles L Zhou, Investigator

X Constantin Y Philopoulos
Investigator
Signed By: Constantin M. Philopoulos -S
Date Signed: 11-03-2017 15:14:42

DATE ISSUED
11/3/2017

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."