

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Chicago District Office 550 West Jackson Blvd. 15th Floor Chicago, IL 60661 312-353-5863 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 10/2/17 - 11/13/17 FEI NUMBER 3011707930
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Aileen M. Warren, Pharmacy Manager

FIRM NAME WellRx, LLC dba HomeRx, LLC	STREET ADDRESS 200 East Willow Avenue, Suite 100
CITY, STATE AND ZIP CODE Wheaton, IL 60187	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

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

Observation 1

Non-pharmaceutical grade components are used in the formulation of human non-sterile drug products.

Specifically, non-pharmaceutical grade (b) (4) water was used to produce the following human non-sterile drug products rather than purified USP grade water. Examples include the following:

1. Rx # (b) (6) on 8/21/17 for C-Diphenhydramine 25mg/5ml liquid.
2. Rx # (b) (6) on 7/28/17 for C-Diphenhydramine 25mg/5ml liquid.
3. Rx # (b) (6) on 7/31/17 for C-Scopolamine 0.25mg/0.1ml topical lipoderm.
4. Rx # (b) (6) on 8/17/17 for C-Omeprazole 4mg/ml suspension.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Debra I. Love - S <small>Digital Signature by Debra I. Love 5 DN: cn=US Government, ou=FDA, ou=FDIA, ou=Purple cn=Debra I. Love, 5 0 9 2343 19200280 100 1 1-1300157402 Date: 2017.11.13 12:06:36 -0600</small>	EMPLOYEE(S) NAME AND TITLE <i>(Print or Type)</i> Debra I. Love, Investigator	DATE ISSUED 11/13/2017
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