

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	DATE(S) OF INSPECTION 6/1/2017-6/6/2017*
	FEI NUMBER 3010375341

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Martin J. Garda , President and Owner

FIRM NAME Garda Rx LLC	STREET ADDRESS 1596 Hancock Ave
CITY, STATE, ZIP CODE, COUNTRY Apollo, PA 15613-8404	TYPE ESTABLISHMENT INSPECTED 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:**

**Insanitary Conditions**

I observed the process of producing non-sterile products at Garda Rx, LLC and found that:

- The (b) (4) counter top used for the production of non-sterile drug products had exposed particle board on a side adjacent to the work surface.
- Visible residues and filth adjacent to the non-sterile production area on places such as:
  - Shelf with non-sterile production equipment.
  - On the balance used for production of non-sterile drug products.
  - In the (b) (4) use for production of non-sterile drug products.

**\*DATES OF INSPECTION**

6/01/2017(Thu),6/02/2017(Fri),6/05/2017(Mon),6/06/2017(Tue)

<b>SEE REVERSE OF THIS PAGE</b>	EMPLOYEE(S) SIGNATURE Juan R Jimenez Garcia, Investigator	DATE ISSUED 6/6/2017
	X Juan R Jimenez Garcia Investigator Signed by: Juan R. Jimenez Garcia -S	