

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a> Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION 03/25-28/2019, 4/2-3/2019, 4/9/19
	FEI NUMBER 3003348498

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO: Pramod K. Sharma, Vice President, Quality**

FIRM NAME <b>ImprimisRx</b>	STREET ADDRESS <b>1705 US Highway 46, Suite 4</b>
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CITY, STATE AND ZIP CODE <b>Ledgewood, NJ 07852</b>	TYPE OF ESTABLISHMENT INSPECTED <b>Producer of Sterile and Non-Sterile Drugs</b>
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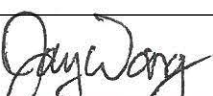
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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

**OBSERVATION 1**

The ISO 7 Filling Room is not adequately constructed to ensure aseptic processing conditions.

Specifically, during the cleaning of the ISO 7 Filling Room, we observed that the ceiling tiles were moving up and down when the technicians were wiping them with a mop. Within the ISO 7 Filling Room, the ISO 5 Laminar Air Flow Hood is used for the filling of sterile ophthalmic and injectable drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Nancy Scheraga, Investigator	DATE ISSUED 4/9/2019
		Jay Wong, Investigator	