

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Tel: (973) 331-4900 Fax: (973) 331-4969

DATE(S) OF INSPECTION

05/30, 31, 06/01, 06/02, and 07/10/2017

FEI NUMBER

3003348498

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO:

Pramod K. Sharma, Ph.D, Vice President, Quality

FIRM NAME

ImprimisRx NJ

STREET ADDRESS

1705 Route 46 West, suite 6A

CITY, STATE AND ZIP CODE

LedgeWOOD, NJ 07852-9720

TYPE OF ESTABLISHMENT INSPECTED

Producer of 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

The ISO 5 laminar air flow hood was not certified under dynamic conditions.

Specifically, the smoke study performed in (b) (4) of the ISO 5 laminar air flow hood was not conducted with all personnel and containers present. The smoke study was conducted with (b) (4) instead of (b) (4), there was no bulk container present, and (b) (4) did not simulate the filling of product during the (b) (4) video to assess uni-directional air flow under actual conditions.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Jose M. Cayuela

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Jose M. Cayuela, Consumer Safety Officer

DATE ISSUED

07/10/2017