DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/27/2017-3/31/2017
	FEI NUMBER 3003436217

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pramod K. Sharma, Ph.D. , Vice President, Quality

FIRM NAME	STREET ADDRESS
ImprimisRx CA, Inc., dba ImprimisRx	9257 Research Drive
CITY, STATE, ZIP CODE, COUNTRY Irvine, CA 92618-4286	TYPE 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

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

a) It was observed that during product vial filling of Ascorbic Acid P-F 500mg/ml injection lot 03202017@1B in the Clean Room ISO-5 (b) (4) zone, a cart was left sitting for 15-20 minutes between plastic curtains resulting in exposure of the ISO-5 zone to ISO-7 area. Large equipment such as a (b) (4) pump, metal rack, (b) (4) in-process glassware and other supplies were set in the LAFW Hood(b) (4) during use, blocking the movement of first-air passage. Non-viable particle monitoring is placed in the(b) (4) .

b) The smoke studies performed on (b) (4) showed displaced air currents due to the (b) (4) pump. These smoke studies were not performed under normal dynamic conditions with the typical amount of equipment including glassware, racks, or other equipment that block the HEPA air flow. The most recent smoke study on (b) (4) did show some airflow current displaced due to the (b) (4) pump in the hood, but the smoke study was short in duration and did not address this blocked air movement adequately. Corrective actions were not implemented at the firm.

c) The ISO-5 LAFW Hood (b) (4) and Hood (b) (4) have yellow/brown and black stains across the HEPA filters.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Roger F Zabinski, Investigator Theresa Kirkham, Investigator X Roger F Zabinski 3/31/2017 Roger F Zabinski Investigator Signed by: Roger F. Zabinski -S	3/31/2017

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OBSERVATION 2

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

a) The following investigations were not adequate:

- On 03/10/17 the firm received initial notification via telephone of an adverse event due to the intravenous administration of a Curcumin solution. CLR-GEN-IPG-002 entitled "Product Complaint Handling", Version: 1, Authorized By: 11/29/16, states that (b) (4) This adverse event was not documented on complaint or adverse event forms.
- In 2016 and the first quarter of 2017 there have been 69 Quality Related Events (QRE), including ADEs and product quality complaints, including the ADE above. The QRE investigation and documentation process needs to be fortified to include critical information such as the date, prescription (Rx) number, lot number and other pertinent information, for example: incorrect drug, dosage strength, or dosage form. ADEs require complete investigations and corrective actions.

b) (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) employee training files do not include training on the most current complaint procedure.

OBSERVATION 3

The quality control unit lacks authority to fully investigate errors that have occurred.

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Specifically,

In 2016 and the first quarter of 2017 there have been 69 Quality Related Events (QRE), including ADEs and product quality complaints. The pharmacists and pharmacy technicians contribute to the production of the firm and are included in the QA/QRE review. However, your firm lacks a separate Quality Control Unit to implement corrective actions and complete investigations to ensure quality and prevent QREs. For example:

a) There were approximately three customer complaints in the first quarter of 2017, dated 1/10/17, 03/06/17, and 03/15/17, and the corresponding forms, which included investigations, were not reviewed by Quality Assurance (QA), as per CLR-GEN-IPG-002 which states that complaint investigations "(b) (4) " and (b) (4)

b) QRE (b) (4) reviews conducted by pharmacists and pharmacy technicians highlight the need for improvements for training and quality.

3/31/2017

X Theresa Kirkham

Theresa Kirkham
Investigator
Signed by: Theresa Kirkham -S

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