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	2/23/2021-3/3/2021*
	FEI NUMBER 3007500366

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Erik J. Nelson, Owner and Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
First Pharma Associates LLC dba Riverpoint Pharmacy	1802 N Monroe St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Spokane, WA 99205-4528	Producer of non-sterile drug products

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

You produced highly potent drugs without providing adequate cleaning of utensils to prevent cross-contamination.

Specifically,

On 02/24/21, I observed an employee perform compounding of multiple lots of non-sterile hazardous human drug products, some of which utilized product-contact metal (b) (4) stir axels that were cleaned with only and expired (b) (4) solution between lots of different products. The first hazardous compounded drug product lot manufactured at your firm on (b) (4) was Estradiol 0.5mg/Estriol 0.5mg/gm vaginal cream, lot 02242021@1, during which a metal stir axel was used in the blending of the in-process ointment and was in contact with the product throughout the blending process. The stir axel was cleaned using only a bottle of (b) (4) solution, lot # (b) (4) with the expiration date of 10/19. The same day, your firm manufactured Estriol vaginal cream 2mg/0.5mg, lot 02242021@3 in the same hazardous compounding room using potentially the same stir axel.

*DATES OF INSPECTION

2/23/2021(Tue), 2/24/2021(Wed), 2/26/2021(Fri), 3/01/2021(Mon), 3/03/2021(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christopher R Czajka, Investigator Nathaniel B Phillips-Sylvain, Investigator	X Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed: 03-03-2021 12:56:23	3/3/2021

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X Nathaniel B Phillips-Sylvain
Investigator
Signed By: Nathaniel B. Phillips-sylvain -S
Date Signed: 03-03-2021 13:11:58

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Christopher R Czajka, Investigator Nathaniel B Phillips-Sylvain, Investigator	X Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed: 03-03-2021 12:56:23	3/3/2021

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."