DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	5/25/2021-6/17/2021*
	FEI NUMBER 3016710931

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Anthony R. Schwartz, President

FIRM NAME	STREET ADDRESS
Wells Pharma of Houston LLC	9265 Kirby Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77054-2520	Outsourcing Pharmacy

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:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically, there is no assurance that unidirectional airflow is maintained in the ISO 5 laminar air flow workbenches where sterile, injectable drug products are compounded.

I reviewed the smoke study dated 2/4/2021 for Laminar Air Flow Workbench #EQ-HOU-LAFW-067 and noted that first air was striking the stainless steel shelf inside the ISO 5 hood before sweeping down across aseptic connections and then recirculating beneath the same stainless steel shelf.

*DATES OF INSPECTION

5/25/2021(Tue), 5/26/2021(Wed), 5/27/2021(Thu), 5/28/2021(Fri), 6/02/2021(Wed), 6/03/2021(Thu), 6/04/2021(Fri), 6/07/2021(Mon), 6/08/2021(Tue), 6/15/2021(Tue), 6/17/2021(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Stephen D Brown, Investigator	X Stephen D Brown Investigator Signed By: Stephen D. Brown -S Date Signed: 06-17-2021 11:40:34	6/17/2021

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."