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	11/16/2022-12/14/2022* FEI NUMBER 3016710931

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Theaquiata Mitchell, VP of Quality

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 Facility

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

Routine inspection and checking of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, your firm failed to adequately validate the electronic building monitoring system, (b) (4) (b) (4)) prior to use. Your firm uses the system to control, monitor, and record differential pressure, temperature, and relative humidity for the ISO classified along with non-classified areas used in the production of sterile and non-sterile drug products. For example, your firm initially validated the (b) (4) on 3/10/2020 with the revalidation not being approved until 12/15/2021. Your firm's VP of Quality reported following a review of the validation report by your firm's quality unit, a re-validation was required. In my review of the initial documented (b) (4) Validation Report, I found it failed to it failed to include documented differential pressure measuring, monitoring, and recording as part of the system's qualifications, IQ, OQ, and PQ along with providing adequate data in support of the system qualification. your firm's quality unit continued to review and approved differential pressure (b) (4) reports, while the software underwent revalidation for the selected and reviewed months: July 2021, September 2021, and November 2021 resulting in the acceptance, released, and distribution of sterile drug products. A review of your firm's (b) (4) Validation Report dated 12/15/2021 included no approved deviation allowance for the continued system use.

OBSERVATION 2

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 12-1 -2022 09:2 :0	12/14/2022

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Specifically, during a walk-through of your firm's cleanroom and visual inspection of the ISO 8 (b) (4) (b) (4), I observed a gap, approximately 0.5 inches from the bottom of the (b) (4) to the floor in both the controlled non-classified pre-production side and the ISO 7 Cleanroom side of the unit. Your firm failed to ensure the (b) (4) was not a potential source of lower quality air being transferred from the controlled non-classified production prep area into the higher quality air ISO 7 Cleanroom containing (b) (4) LAF units used in the aseptic processing of sterile drug products in the prevention of possible contamination resulting from the gap.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not in writing.

Specifically, your firm's procedures, (b) (4), HOU-QA-050 and Temperature, Humidity and Pressure Monitoring of Classified Areas, HOU-QC-002 used to document your firm's building monitoring systems environment conditions controls and monitoring requirements (differential pressure, temperature, and relative humidity) are inadequate. Your firm's procedure fails to adequately define and document differential pressure specifications, alert, and action limits for your firm's ISO 8 Anteroom, ISO 8 Gowning Room, and ISO 7 Cleanroom, which contain your firm' s (b) (4) LAF units used in processing of aseptic sterile to sterile finished drug transfers along with sterile drug repackaging.

***DATES OF INSPECTION**

11/16/2022(Wed), 11/17/2022(Thu), 11/18/2022(Fri), 11/29/2022(Tue), 11/30/2022(Wed), 12/01/2022(Thu), 12/02/2022(Fri), 12/05/2022(Mon), 12/06/2022(Tue), 12/07/2022(Wed), 12/08/2022(Thu), 12/09/2022(Fri), 12/14/2022(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 12-1 -2022 09:2 :0	12/14/2022

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."