DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

COPY

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 303-236-3000 Fax: 303-236-3100 Industry Information: www.fda.gov/oc/industry	09/20,21,22,23,24 & 27,28,29/2021
	FEI NUMBER 3015144909

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Joseph W. Bagan, Chief Executive Officer

FIRM NAME	STREET ADDRESS
STAQ Pharma, Inc.	14135 E 42nd Avenue, Suite 50
CITY, STATE AND ZIP CODE Denver, CO 80239-5214	TYPE OF ESTABLISHMENT INSPECTED 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) (WE) OBSERVED:

Observation 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

A) The firm failed to recertify the ISO 5 LFH (b)(4) and ISO 7 (b)(4) Room (b)(4) after the LFH was moved from the (b)(4) to the (b)(4) of the ISO 7 room during the Smoke Study conducted on 09/17/2020. The firm has been producing aseptically filled (b)(4)) syringes from 09/17/2020 to the present with the ISO 5 LFH (b)(4) located on the (b)(4) of (b)(4) Room (b)(4).
B) The Nonviable (b)(4) and (b)(4) Viable air samplers inside the ISO 5 LFH (b)(4) were not in operation while conducting the Dynamic Smoke Study on 09/17/2020.

Observation 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

There is no environmental monitoring, including but not limited to, the following ancillary equipment located inside the ISO 5 Laminar Flow Hood (LFH (b)(4)), which is located in (b)(4) Room (b)(4):

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Darren S. Brown/Investigator John A. Gonzalez/Investigator	09/29/2021

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A) Non-viable (b) (4)) and viable (b) (4)) hoses feeding into the LFH through the (b) (4)
B) Power cord from (b) (4) (pump located in ISO 7 (b) (4) Room (b) (4)) connected to the (b) (4) Electrical Outlet (inside the LFH)
C) Protruding screw caps of the (b) (4)
D) IV Hanging Bar and IV hooks
E) (b) (4)) L shaped bar that supports the Fill Bag (Fill Bag stand)

Observation 3

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the following product reporting period as required by Section 503B(b)(2)(A) of the FD&C Act.

Specifically, the following products were compounded and not identified on your report dated in:
June 2021 Product Report:

- Buffered Lidocaine 10 mg/mL
- Desmopressin Acetate 1.5 mg/mL Nasal Spray

December 2020 Product Report:

- Phenylephrine 100 mcg/mL
- Ropivacaine HCl 2 mg/mL

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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 judgement, 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."

USFDA
9/24/2021