DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	9/18/2023-10/4/2023* FEI NUMBER 3025336457

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph W. Bagan, CEO

FIRM NAME	STREET ADDRESS
STAQ Pharma of Ohio, LLC	255 Phillipi Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbus, OH 43228-1307	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

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically,

Your executed media fill lots (b) (4), and (b) (4) all performed in (b) (4), were compounded and then filled using a (b) (4) mL fill volume in (b) (4) mL syringe size configuration. This does not replicate your actual commercial batch production configuration of (b) (4) mL fill volume in 10 mL syringes for Phenylephrine HCL (1000 mcg / 10 mL), lot (b) (4), manufactured on (b) (4) Expiration date 12/24/2023. Your firm currently compounds no commercial product filled into (b) (4) mL syringes and only fills into 10 mL syringes. Batch size for media fill and commercial lots both yield approximately (b) (4) units; however, the total volume filled for media fill lots is approximately (b) (4) whereas commercial lots is approximately (b) (4).

OBSERVATION 2

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

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Andrew J Barrowcliff, Investigator	X Andrew J Barrowcliff Investigator Signed By: Andrew J. Barrowcliff - S Date Signed: 10-04-2023 11:58:58	10/4/2023

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Joseph W. Bagan, CEO	
FIRM NAME STAQ Pharma of Ohio, LLC	STREET ADDRESS 255 Phillipi Rd
CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43228-1307	TYPE ESTABLISHMENT INSPECTED Outsourcing facility

The location of your viable and nonviable particle sample collection points inside your ISO-5 (b) (4) Laminar Flow Hood in room (b) (4) is inadequate as they are situated directly adjacent to the HEPA air filter grate at the back of the hood. Samples collected evaluate only the air flowing immediately out of the HEPA filter, not air that is representative of the operational sterile filling area where (b) (4) aseptic filling manipulations are being conducted.

***DATES OF INSPECTION**

9/18/2023(Mon), 9/19/2023(Tue), 9/20/2023(Wed), 9/22/2023(Fri), 9/25/2023(Mon), 9/26/2023(Tue), 9/27/2023(Wed), 9/29/2023(Fri), 10/02/2023(Mon), 10/04/2023(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Andrew J Barrowcliff, Investigator X Andrew J Barrowcliff Investigator Signed By: Andrew J. Barrowcliff - S Date Signed: 10-04-2023 11:58:58	10/4/2023

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."