DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	10/16/2023-10/20/2023
	FEI NUMBER 3010683345

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gee Ho Jang, CEO

FIRM NAME	STREET ADDRESS
Aqualex Co., Ltd.	RM 203, 27, Dunchon-daero 457beon-gil, Jungwon-gu
CITY, STATE, ZIP CODE, COUNTRY Seongnam-si, Gyeonggi-do, 13219 Korea (the Republic of)	TYPE ESTABLISHMENT INSPECTED Drug and Cosmetic Manufacturer

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

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

Specifically,

A. Your cleaning procedures described in SOP number HSOP-H-001 for your manufacturing equipment have never been validated. Your manufacturing equipment is used to manufacture both (b) (4) drug products and cosmetic products.

B. Your firm lacks procedures for good documentation practices and for issuance of GMP records in production and the laboratory. QC Analysts freely print out analytical forms related to chemical and microbiological finished product and (b) (4) testing with no QA oversight or reconciliation. In addition, your production employees are able to freely print out official GMP records related to production area temperature monitoring and differential pressure monitoring. Your Production employees shred these documents when any errors are made and they then re-print new forms without QA oversight. Numerous completed forms, including production area temperature monitoring and differential pressure monitoring forms, were observed in the basket for documents waiting to be shredded in a production office.

C. Your firm lacks a procedure for qualification of manufacturing equipment. In addition, you have not qualified the equipment used in the manufacturing of you(b) (4) drug product.

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	Wayne D Mcgrath, Investigator X Wayne D Mcgrath Investigator Signed By: 2001897192 Date Signed: 10-20-2023 14:43:20	10/20/2023

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OBSERVATION 2

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your firm lacks a procedure for performing stability studies on your (b) (4) drug product. In addition, you stated you have never performed a stability study on your (b) (4) drug product at 25°C and 60% relative humidity conditions to demonstrate the product retains its quality attributes throughout the (b) (4) labeled expiry.

OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

A. Your firm does not perform growth promotion testing or use positive controls during analyses on the media used for (b) (4) and finished product (b) (4) total microbial count testing. In addition, after incubation, media appeared to be dried out as evidenced by the media peeling away from the edges of the plates and having cracks in it on multiple occasions.

B. You have not validated your method for determination of total microbial count in (b) (4) samples.

C. Your firm does not perform representative sampling of received raw materials used in the manufacturing of your (b) (4) drug product. Your firm collects (b) (4) gram sample from the (b) (4)

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(b) (4) container when receiving raw materials, including APIs, independent of the amount of containers received. For example, on 03 August 2023, your firm received (b) (4) drums of API (b) (4) (b) (4) sample from (b) (4) drum was collected for raw material testing.

OBSERVATION 4

The (b) (4) system contains defects that could contribute to the contamination of drug products.

Specifically,

Your (b) (4) system contains an approximately 10 feet long dead leg, part of which contains (b) (4) This (b) (4) is used for product formulation, including the formulation of your (b) (4) drug product. In addition, you identified results exceeding your limit of (b) (4) cfu/mL in (b) (4) samples collected on 21 December 2022 (result (b) (4) cfu/mL) and 26 January 2023 (result (b) (4) cfu/mL) from (b) (4) in the production area. You took no action for these excursions. You perform total microbial count testing on the (b) (4) system (b) (4)

OBSERVATION 5

Established sampling plans, test procedures and laboratory control mechanisms are not documented at the time of performance.

Specifically,

Your QC chemistry and microbiology laboratory employees stated they routinely record analytical results for raw materials, finished drug products, and (b) (4) samples on temporary, non-official paper and then later record the results on the official forms. The employees stated the paper containing the original results (raw data) is discarded after copying the results to the official form. In addition, your QC chemistry and microbiology laboratory employees do not document sample preparation steps, calculations, or notes related to the analysis.

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OBSERVATION 6

Records are not kept for the cleaning and sanitizing of equipment.

Specifically,

Your firm does not maintain records of cleaning performed on the equipment used to manufacture your (b) (4) drug product. You record cleaning activities on a dry erase board which is erased after each batch.

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