DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3/30/2026-4/3/2026
	FEI NUMBER 3030898327

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mercedes F. Kweh, CEO and Co-Founder

FIRM NAME	STREET ADDRESS
KweHealth LLC	13800 Tech City Circle, Suite 314
CITY, STATE, ZIP CODE, COUNTRY Alachua, FL 32615-7254	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

HCT/Ps from two or more donors were pooled during manufacturing.

Specifically, since the start of operations in (b) (4), in (b) (4) out of (b) (4) batches, your firm (b) (4) biological material derived from amniotic fluid (exosomes) from (b) (4) donors (b) (4) The manufacturing was performed by your KweHealth, LLC company, and the finished product was distributed by your HydroKarma, LLC company.

a. On September 24, 2025, batch (b) (4), (b) (6), (b) (7)(C) (b) (4) (b) (6), (b) (7)(C) (b) (4) (b) (6), (b) (7)(C) which resulted in lot (b) (4), (b) (6), (b) (7)(C) yielding (b) (4) of HydroKarma ExoPure 50B.

b. On July 23, 2025, batch (b) (4), (b) (6), (b) (7)(C) (b) (4) (b) (6), (b) (7)(C) (b) (4) (b) (6), (b) (7)(C) which resulted in lot (b) (4), (b) (6), (b) (7)(C) yielding (b) (4) of HydroKarma Rejuvenate Serum 70B.

c. On September 25, 2025, batch (b) (4), (b) (6), (b) (7)(C) (b) (4) (b) (6), (b) (7)(C) (b) (4) (b) (6), (b) (7)(C) resulting in lot (b) (4), (b) (6), (b) (7)(C) yielding (b) (4) of HydroKarma ExoPure 140B.

OBSERVATION 2

The eligibility of an HCT/P donor was not documented by a responsible person, based on results of donor screening and donor testing.

A responsible person did not make and document the donor eligibility determination (DED) for donor

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EMPLOYEE(S) SIGNATURE
Steen N Graham, Investigator
Mizanne E Lewis, Investigator

X Steen N Graham Investigator Signed By: Steen N. Graham -S Date Signed: 04-03-2026 14:00:35

DATE ISSUED
4/3/2026

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(b) (6), (b) (7)(C) There is no documentation demonstrating that your Chief Medical Officer reviewed the donor's medical history, donor screening records, and relevant laboratory test results to make the final DED, as required by your SOP. Exosomes derived from amniotic fluid for this donor were used to manufacture Batch (b) (4), (b) (6), (b) (7)(C) on (b) (4), which yielded lots: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C)

OBSERVATION 3

Documentation of equipment maintenance, cleaning, sanitization, and calibration was not maintained.

Specifically, you failed to provide required maintenance and cleaning records for critical equipment, including the biosafety cabinet (BSC), manufacturing area, centrifuge, refrigerator, and freezer.

OBSERVATION 4

Records stored on electronic systems are not backed up.

Quality records stored on electronic systems were not made available for review after multiple requests during the inspection. Four (4) environmental monitoring records with out-of-specification (OOS) results lacked documented investigations.

Your CEO stated that the firm does not currently have access to the software that houses these investigation records, preventing FDA from verifying compliance with applicable regulations and raising serious concerns regarding data integrity and control.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Steen N Graham, Investigator Mizanne E Lewis, Investigator	X Steen N Graham Investigator Signed By: Steen N. Graham -S Date Signed: 04-03-2026 14:00:35	4/3/2026

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Alachua, FL 32615-7254	Manufacturer

X Mizanne E Lewis
Investigator
Signed By: MIZANNE E. LEWIS -S
Date Signed: 04-03-2026 14:01:23

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Steen N Graham, Investigator
Mizanne E Lewis, Investigator

X Steen N Graham
Investigator
Signed By: Steen N. Graham -S
Date Signed: 04-03-2026 14:00:35

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4/3/2026

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."