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 oradevices1firmresponse@fda.hhs.gov	8/12/2024-8/15/2024
	FEI NUMBER 3013942511

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin C. Gillespie, President/CEO

FIRM NAME	STREET ADDRESS
Isopure Corp.	11851 Plantside Dr
CITY, STATE, ZIP CODE, COUNTRY Louisville, KY 40299-6328	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, reviewed Customer Service Report (CSR) forms did not include required documentation of MDR determination. Additionally, CSR forms were found to routinely exhibit empty data fields.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Shannon A Gregory, Investigator

X Shannon A Gregory
Investigator
Signed By: Shannon A. Gregory - S
Date Signed: 08-15-2024 13:57:30

DATE ISSUED
8/15/2024

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FIRM NAME Isopure Corp.	STREET ADDRESS 11851 Plantside Dr
CITY, STATE, ZIP CODE, COUNTRY Louisville, KY 40299-6328	TYPE ESTABLISHMENT INSPECTED Manufacturer

Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Shannon A Gregory, Investigator	X Shannon A Gregory Investigator Signed By: Shannon A. Gregory - S Date Signed: 08-15-2024 13:57:30	8/15/2024

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."