DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556 oradevices1firmresponse@fda.hhs.gov	6/10/2024-6/12/2024 FEI NUMBER 3022579801

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Maria Gabriela Salvador, CEO

FIRM NAME	STREET ADDRESS
Maternova, Inc.	10 Davol Sq Ste 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Providence, RI 02903-4752	Importer

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, the firm's Complaints and Feedback procedure, SOP QA00_1, Rev 01, effective 4/21/2019, does not adequately describe the process for investigating complaints and evaluating for Medical Device Reporting. Complaint record F03, pertaining to the (b) (4) , did not include the date the complaint was received, the associated lot code or UDI, the complainant's contact information, details of the complaint, and adequate documentation of the investigation or justification why no investigation was necessary. Additionally, the complaint did not include a reportability determination. In September 2023, the firm imported (b) (4) and offered them for sale in the U.S.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sara M Onyango, Investigator

X Sara M Onyango
Investigator
Signed By: Sara M. Onyango -S
Date Signed: 06-12-2024
14:10:15

DATE ISSUED
6/12/2024

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Annotations to Observations

Observation 1: Promised to correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sara M Onyango, Investigator	X Sara M Onyango Investigator Signed By: Sara M. Onyango -S Date Signed: 06-12-2024 14:10:15	6/12/2024

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."