DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	10/28/2025-11/5/2025* FEI NUMBER 3004137354

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Militza (nmi) Manzano Miranda, Senior VP of Operations

FIRM NAME	STREET ADDRESS
MOM Enterprises, LLC	1001 Canal Blvd Unit C
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Richmond, CA 94804-3524	Own Label Distributor

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

You did not follow written procedures for the requirements to review and investigate a product complaint.

Specifically, a review of your firm's consumer complaint records dated October 2024 through October 2025 indicates that two consumer complaints that meet the criteria for Serious Adverse Event (SAE) per your firm's written procedures were not reported. Your firm's updated SOP entitled "Consumer Complaints Handling and Reporting of Dietary Supplements" Document #QA-1009, Version #2, Version Date 11/14/2024, Effective Date 11/22/2024 states that "the event is serious and must be reported to FDA when the patient outcome is… Other Serious (Important Medical Events)… Examples include: Having choked, stopped breathing, turned blue, and or/intervention occurred for breathing to resume after consuming one of the Mommy's Bliss's Dietary Supplement".

An analysis of your firm's customer complaint records dated October 2024 through October 2025 indicates that your firm received at least 17 complaints of infants choking after consuming one of your firm's products, meeting the definition of an SAE based on your firm's SOP #QA-1009. Of these 17 complaints, two were not reported to the U.S. Food and Drug Administration (FDA):

Complaint #	Date Received	Complaint	Product	Lot/EXP
(b) (4)	11/10/2024	"Baby didn't do well with product. Made him choke."	Gripe Water Original	Unknown
	12/11/2024	"The second time I tried giving this to my baby the plastic tip came off and fell into my baby's mouth along	Organic Vitamin D Drops	Unknown

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EMPLOYEE(S) SIGNATURE
Hanna S Louvau, Investigator

X Hanna S Louvau
Investigator
Signed By: Hanna S. Louvau -S
Date Signed: 11-05-2025
13:11:54

DATE ISSUED
11/5/2025

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		with all the oil in the bottle – choking my baby."		

This is a repeat observation from the previous inspection(s) conducted on 09/27/2024 (written observation).

OBSERVATION 2

You did not establish product specifications for identity, strength, composition and limits on contamination.

Specifically, according to your written procedures entitled "Quality Unit Responsibilities" Document #QA-1019, Version #02, Version Date 01/20/2025, Effective Date 01/24/2025, your quality team is responsible for approving final product formulation and shall "establish product specifications in alignment with FDA requirements and product claims" and "ensure products meet identity, purity, strength, and composition" for dietary supplements produced at contract manufacturers under your own label brand, Mommy's Bliss.

Your firm did not establish specifications, or use scientifically valid methods of analysis, for the following finished dietary supplements that contain botanical dietary ingredients:

Identity Testing of Finished Dietary Supplements with Botanicals

- Your firm relies on (b) (4) analysis as the method of identity testing for finished dietary supplements containing botanical ingredients including Gripe Water Original, Gripe Water Nighttime, Gripe Water PaciGel, Bedtime PaciGel, and Baby Bedtime Drops. Gripe Water Original, Gripe Water Nighttime, and Baby Bedtime Drops are multi-component liquid blend products comprised of (b) (4) (b) (4) Gripe Water PaciGel and Bedtime PaciGel are multi-ingredient gel products comprised of various botanical ingredients.
- Your firm relies on (b) (4) analysis for identity testing of Bedtime PaciGel, which is not a scientifically valid method of analysis for identity testing of dietary supplements containing botanical ingredients.

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Strength Testing of Finished Dietary Supplements with Botanicals

- Your firm relies on (b) (4) for strength testing of botanical dietary ingredients in Gripe Water Original, Gripe Water Nighttime, and Bedtime PaciGel. These are multi-component liquid or gel dietary supplements intended for use by infants which make label claims related to amount per serving for individual botanical dietary ingredients. Your Director of Quality and Regulatory explained that (b) (4) your contract manufacturer conducts (b) (4) analysis on in-process (b) (4) botanical extracts to confirm botanical presence in the (b) (4) which is then used in the finished dietary supplements. You explained that you are developing qualitative (b) (4) analysis methods for analyzing finished Gripe Water Original and Gripe Water Nighttime (b) (4) however, you do not have analytical methods for other finished dietary supplements with botanical dietary ingredients and do not have quantitative methods for any finished botanical dietary supplement.

- You did not establish strength specifications for Gripe Water PaciGel, which includes label claims for amount per serving for two botanical dietary ingredients.

Limits on Contamination for Finished Dietary Supplements with Botanicals

☐You did not establish specifications for residual solvents in Baby Bedtime Drops dietary supplement, which is manufactured using 64:1 Elderberry Extract.

This is a repeat observation from the previous inspection(s) conducted on 09/27/2024 (written observation).

OBSERVATION 3

Your quality control personnel approved and released for distribution a batch of dietary supplement that did not meet established product specifications.

Specifically, your firm's written procedure titled "Receiving Finished Products" Document #QA-1008, Version #01, Version Date 03/18/2022, Effective Date 03/25/2022 states that "Quality inspects products and ensures that it meets product specification… COA is reviewed to ensure product testing results meet specifications. If during inspection, a deviation is observed – the following action can be done: (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Hanna S Louvau, Investigator	X Hanna S Louvau Investigator Signed By: Hanna S. Louvau -S Date Signed: 11-05-2025 13:11:54	11/5/2025

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(b) (4)
(b) (4) Additionally, your written procedures entitled "Quality Unit Responsibilities" Document #QA-1019, Version #02, Version Date 01/20/2025, Effective Date 01/24/2025 state that your "Quality Unit shall… Review Certificates of Analysis (COA) and approve product release."

A review of your firm's product specifications entitled "Organic Baby Bedtime Drops + Overnight Immunity Support – 04pk" Version #07, Version Date 09/08/2025, Item (b) (4) and Item (b) (4) indicates the firm established product specifications for Organic Chamomile Flower at (b) (4) Organic Lemon Balm Leaf at (b) (4) Organic Passionflower at (b) (4) and Organic Elderberry Extract 64:1 at (b) (4)

Review of the finished product COAs for "Organic Baby Bedtime Drops (b) (4) and "Organic Baby Bedtime Drops (b) (4) Lot (b) (4)Expiration 09/2027, Manufacture Date 09/09/2025 and COA validation date 09/22/2025 indicate that the specifications for Organic Chamomile Flower at (b) (4) Organic Lemon Balm Leaf at (b) (4) Organic Passionflower at (b) (4) and Organic Elderberry Extract 64:1 at (b) (4) are missing from the record.

Your firm's quality control did not document a disposition of the missing strength specification results upon review of the COA for "Organic Baby Bedtime Drops(b) (4) Lot (b) (4)Expiration 09/2027, Manufacture Date 09/09/2025 and COA validation date 09/22/2025. A review of your "Mommy's Bliss – SOP & Recording Form" revealed that quality checked "yes" for "COA conforms to Product Technical Specification and Acceptance Criteria" with a note for Item (b) (4) that "BPR verified by input" despite the COAs not matching updated product specifications and your quality team not reviewing the BPR as part of a deviation investigation. Your firm's SVP of Operations and Director of Quality and Regulatory explained that Lot (b) (4) was the first batch of Baby Bedtime Drops produced after a reformulation, and that the contract manufacturers COA did not match your firm's updated finished product specification sheet. Your firm hired a consultant to conduct an onsite audit during production of Lot (b) (4)at the contract manufacturer and to review in-process batch production records, and your quality team relied on the results of this audit to release Organic Baby Bedtime Drops Lot(b) (4)without documenting a deviation or disposition decision based on your written procedures. Your firm's quality control personnel released this lot of dietary supplements into interstate commerce.

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***DATES OF INSPECTION**

10/28/2025(Tue), 10/29/2025(Wed), 10/30/2025(Thu), 10/31/2025(Fri), 11/03/2025(Mon), 11/05/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hanna S Louvau, Investigator	X Hanna S Louvau Investigator Signed By: Hanna S. Louvau -S Date Signed: 11-05-2025 13:11:54	DATE ISSUED 11/5/2025

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."