DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	5/27/2026-5/28/2026
	FEI NUMBER 3015200642

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Jared K. Miller, Co-Owner, Chief Technical Officer

FIRM NAME	STREET ADDRESS
Babyation Inc.	11777 Lackland Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63146-4234	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

Reworked product was not adequately verified to ensure it meets applicable acceptance criteria and regulatory requirements.

Specifically, Babyation Inc manufactures and distributes (b) (4), which are FDA Class II medical devices. Babyation employed Company (b) (4) as the contract manufacturer of (b) (4) (b) (4) for the (b) (4). Functions of the (b) (4) include regulation of the (b) (4) via (b) (4) of the (b) (4) Per the risk analysis, this (b) (4) reduces probability of harm to the patient from (b) (4) and (b) (4)

Per Quality Agreement with Company (b) (4) Company (b) (4) was required to certify the units were manufactured in accordance with cGMP's per CFR 820, and under a QMS certified to ISO 9001, ISO 13485, or to similar quality system.

Company (b) (4) provided a certificate of conformance (CoC) with manufactured (b) (4) lot noting that the units were assembled, visually inspected and tested (as required by the customer) to meet all customer specifications.

Per nonconformance PR-00082 (dated on or about December 2022) identified that the (b) (4) were

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edward E Lockwood, Investigator	X Edward E Lockwood Investigator Signed By: EDWARD E. LOCKWOOD -S Date Signed: 05-28-2026 10:21:39	5/28/2026

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failing after a change in the (b) (4) design. Babyation Inc employed Company (b) (4) to rework (b) (4) defective (b) (4) .

The rework was completed on or about April 2023. Company (b) (4) certified:

- (b) (4) was (b) (4)
- Assembly was visually inspected
- Assembly was tested for (b) (4) between (b) (4)
- material was handled under (b) (4) safe procedures.

Company (b) (4) Certificate of Conformance noted "*Conformance to standards outside criteria is not implied.*"

The rework did not certify or verify:

A. The (b) (4) were reworked in accordance with cGMP's per CFR 820, and under a QMS certified to ISO 9001, ISO 13485, or to similar quality system. For example, there is no documentation Company (b) (4) (b) (4) process was validated

B. Company (b) (4) testing was limited to a (b) (4) (b) (4)) test between (b) (4) and a visual inspection. There is no documentation that the reworked (b) (4) were tested against the full scope of customer acceptance criteria

As of 5/28/2026 approximately (b) (4) remain in inventory available for use. No hold or quarantine has been placed on the remaining inventory. Approximately (b) (4) have been used for the assembly of distributed (b) (4) .

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Annotations to Observations

Observation 1: Promised to correct

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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."