

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1777 Hardee Ave SW Atlanta, GA 30310 (404) 253-1284 Fax: (404) 669-4443	DATE(S) OF INSPECTION 3/23/2026-3/26/2026 FEI NUMBER 1051203
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Maurine McCleskey, QA Specialist

FIRM NAME Newton Laboratories, Inc.	STREET ADDRESS 455 Gees Mill Business Ct Ne
CITY, STATE, ZIP CODE, COUNTRY Conyers, GA 30013-1577	TYPE ESTABLISHMENT INSPECTED Homeopathic Drug 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

The written stability testing program is not followed.

Specifically, your firm has failed to establish and maintain an adequate stability testing program for all of your finished homeopathic drug products, as required by your Stability Standard Operating Procedure NLQA-057 "Stability Testing - Test-Sample Submission" rev 4 effective 5/15/2025, which requires submission of homeopathic drug products for (b) (4) and real time stability studies for (b) (4). The following identified issues state specific deficiencies:

- ☐ You have not placed any stability samples into the stability program since February 2021, following the implementation of Change Control CCLN-2101-1_(b) (4) Caps which changed the container closure system from a (b) (4) cap to a (b) (4) cap for your liquid formulations. This represents a five-year gap in stability testing for products with a modified container closure system.
- ☐ You have not generated any stability data for any of your pellet finished products intended for vulnerable populations, such as:
 (b) (4) (mfg # (b) (4), Lot #s (b) (4))
 (b) (4) (mfg # (b) (4), Lot #s (b) (4))
 o(b) (4) (mfg # (b) (4), Lot #s (b) (4))
- ☐ Between February 2021 to March 2026, your firm manufactured a total of (b) (4) batches across your (b) (4) homeopathic finished drug products that have been released or are intended for release and distribution into U.S. commerce without supporting stability data.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Martin M Kimani, Investigator John D McIntosh, Investigator	John D McIntosh Investigator Signed By: 2004159344 Date Signed: 03-26-2026 07:39:31 X	DATE ISSUED 3/26/2026

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Without an ongoing stability program, you cannot assure that your drug products meet established specifications throughout their shelf life or retain their quality attributes under recommended storage conditions.			
OBSERVATION 2 Complaint procedures are deficient in that they do not include provisions that allow for the review and determination of an investigation by the quality control unit. Specifically, your firm's complaint handling Standard Operating Procedures SOP NLQA-005 "Product-Customer Complaints" Rev 4 effective 04/01/2025 and SOP NLQA-006_ "Product Complaint Investigation" Rev 4 effective 04/01/2025 lacks sufficient detail regarding investigation requirements, root cause analysis procedures, trending analysis, and corrective and preventive action (CAPA) implementation for product quality complaints. For example, Between 2023 and 2025, the firm received 194 complaints regarding leaking bottles affecting at least 15 different batches, including but not limited to (b) (4) (Batch Record# (b) (4)) and (b) (4) (Batch Record# (b) (4)). Leaking/seal complaints increased from 37 in 2023 to 89 in 2024, representing a 140% increase, before decreasing to 68 in 2025. This trend was observable, yet the firm took no investigative action. The firm's response to the leaking bottle complaints consisted solely of replacing the affected product units for consumers without: investigating the underlying cause(s) of the container closure failures, evaluating the impact on affected batch(es) (b) (4) (Batch Record# (b) (4)) and (b) (4) (Batch Record# (b) (4)), assessing whether distributed product poses quality or safety concerns and/or implementing corrective actions to prevent recurrence.			
OBSERVATION 3			
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Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically, your firm has not conducted container closure integrity qualification or validation studies to demonstrate that the (b) (4) bottles with (b) (4) caps adequately protect against contamination, evaporation, or leakage throughout the product shelf life. This applies to all your manufactured homeopathic drugs, including but not limited to (b) (4) (Batch# (b) (4)), (b) (4) (Batch Record# (b) (4)), and (b) (4) (Batch Record# (b) (4)).

This deficiency is particularly concerning given the 194 leaking bottle complaints received between 2023 and 2025 (see Observation [2]) and the absence of stability data for products with this closure system since its implementation in February 2021 (see Observation [1]).

X
Martin M Kimani
Investigator
Signed By: Martin M. Kimani -S
Date Signed: 03-26-2026 07:41:00

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Martin M Kimani, Investigator John D McIntosh, Investigator	John D McIntosh Investigator Signed By: 2004159344 Date Signed: 03-26-2026 07:39:31 X	DATE ISSUED 3/26/2026

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."