DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER United States Food and Drug Administration (U.S FDA) 10 Waterview Blvd, 3rd Floor Parsippany, NJ, 07054 (973) 331-4900	DATE(S) OF INSPECTION 03/16/2026-03/27/2026* FEI NUMBER 2244819
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Michael A. Redfern, VP of Operations/Site Lead	
TO: FIRM NAME Bentley Laboratories LLC	STREET ADDRESS 111 Fieldcrest Ave
CITY, STATE, ZIP CODE, COUNTRY Edison, New Jersey, 08837-3622, US	TYPE ESTABLISHMENT INSPECTED OTC 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:

MATERIALS SYSTEM

OBSERVATION 1

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals. Specifically,

1) Only FTIR identification test is performed on each shipment of each incoming lot of the following ingredients used in manufacturing OTC drug products and the following specific identification tests are not conducted:

   a. Limit of (b) (4) testing is not conducted on incoming shipments of (b) (4) which is used to manufacture OTC drug products including, but not limited to, (b) (4) (b) (4), Lot # (b) (4) (Exp: (b) (4)).

   b. (b) (4) and (b) (4) limit testing is not conducted on incoming shipments of (b) (4) USP, (b) (4) USP, and (b) (4) (b) (4), USP. (b) (4) (b) (4), and (b) (4) are used to manufacture OTC drug products including, but not limited to, (b) (4) (b) (4) (Lot# (b) (4) Exp: (b) (4)), (b) (4) (Lot# (b) (4), Exp: (b) (4)) and (b) (4) (Lot# (b) (4) , Exp: (b) (4)), respectively.

2) There are no written procedures for qualifying suppliers of raw materials and active pharmaceutical ingredients (APIs). For example, the suppliers for API (b) (4) , and raw materials such as (b) (4) ,

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(b) (4) USP, (b) (4) USP, and (b) (4) USP, used in the manufacturing of OTC drug products, have not been qualified through full Certificate of Analysis testing.

LABORATORY CONTROL SYSTEM

OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications, identity and strength of each active ingredient prior to release. Specifically,

(b) (4) based non-sterile finished OTC drug products and the (b) (4), used in manufacturing OTC drug products, are not routinely tested for *Burkholderia cepacia* (*B. cepacia*). No documented investigations were conducted when *B. cepacia* was identified during (b) (4) testing of your (b) (4) system on the following dates:

- July 3, 2024 ((b) (4))
- November 4, 2024 ((b) (4))
- September 3, 2025 ((b) (4))
- September 8, 2025 ((b) (4))
- October 24, 2025 ((b) (4))

The following OTC drug products were manufactured with (b) (4) on (b) (4), and (b) (4), respectively, and distributed:

- (b) (4), Bulk Lot # (b) (4), Finished Good Lot #(b) (4) (Expiration: (b) (4))
- (b) (4), Bulk Lot # (b) (4), Finished Good Lot #(b) (4) (Expiration: (b) (4))

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OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy, the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed. Specifically,

1) The stability results at (b) (4) °C/(b) (4)% RH for two lots of (b) (4) demonstrated the following OOS results:

Lot #	Time Point	Assay OOS Results (Specification)	Color/Appearance OOS Result (Specification)
Lot (b) (4)	(b) (4)	(b) (4) : 2.44% (Spec: (b) (4) %) (b) (4) : 5.74% (Spec: (b) (4) %)	Color: Gray (Spec: (b) (4)) Appearance: Soft Stick/Cream (Spec: (b) (4))
Lot (b) (4)	(b) (4)	(b) (4) : 2.67% (b) (4) : 6.20% (b) (4) : 4.36%	Color: Gray Appearance: Cream

The investigation (Non-Conformance Report (NCR) # 24-093), initiated on 12/27/2024, for these OOS assay results and appearance failures stated that bulk retains and finished good retains were pulled from pilot to most recent batches and confirmed that all samples showed "minor to major signs of softening". Despite physical degradation observed across multiple batches, only (b) (4) lots of retain samples were submitted for (b) (4) testing and no Assay testing was conducted on any of the retain samples that exhibited softening.

2) NCR # 24-032 was initiated on 04/01/2024 for failed microbial results for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) (Results: >57,000 CFU/g, Specification: TAMC: (b) (4) CFU/g, TYMC (b) (4) CFU/g) for (b) (4) , Lot# (b) (4). The investigation failed to include a documented review of microbial results of (b) (4) used to manufacture the OTC drug product. Additionally, the root cause was identified as the hoses, used to drop the product from the kettles into

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storage (b) (4), may not have been cleaned and sanitized thoroughly; however, the Preventive Action only states that hoses will be labeled to have traceability but does not include actions to ensure adequate cleaning and sanitization of the hoses.

3) An Out of Specification (OOS) for (b) (4), Batch #(b) (4), Exp Date: (b) (4), Fill Date: (b) (4) was received for (b) (4) (Result: 5.96; Specification: (b) (4)) at (b) (4) at (b) (4) °C/(b) (4)%RH. There was no investigation or documented review of the formulation or (b) (4) system to identify the underlying root cause for the (b) (4) drift (b) (4) the original specification. Following the OOS result at (b) (4) stability testing, the (b) (4) specification range was broadened to (b) (4) without scientific justification.

OBSERVATION 4

The suitability of all testing methods is not verified under actual conditions of use. Specifically,

Failure to ensure that the approved contract laboratory has performed method suitability of compendial methods USP <61> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: MICROBIAL ENUMERATION TESTS and USP <62> MICROBIOLOGICAL EXAMINATION OF NONSTERILE PRODUCTS: TESTS FOR SPECIFIED MICROORGANISMS, used for the testing of Total Aerobic Microbial Count (TAMC), Total Yeast and Mold Count (TYMC), and tests for specified microorganisms such as *Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus*, and *Salmonella*, respectively. For example, no method suitability was conducted for (b) (4) OTC Drug Products which have a (b) (4) (b) (4), (b) (4) in the formulation.

OBSERVATION 5

The written stability program for drug products does not include reliable, meaningful, and specific test methods. Specifically,

Failure to ensure that the approved contract laboratory, which conducts stability testing for (b) (4) (b) (4) OTC Drug Products, has performed validation of the in-house method for Assay tests and has conducted forced degradation studies to demonstrate the Assay method is stability indicating.

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OBSERVATION 6

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Specifically,

1) Electronic data stored within the (b) (4) computer used to operate the FTIR (b) (4) Software, used for identification testing of raw materials used in the manufacturing of OTC dug products, is not protected against possible deletion or modification. The raw data/spectra are saved on the (b) (4) after analysis; on 03/17/2026, we observed that the delete function on (b) (4) is not disabled, and we observed deleted spectra in the recycle bin. Additionally, the software does not have an audit trail to track the creation, modification, and deletion of data.

2) There is no assurance that all analytical data on the standalone (b) (4) pH meters, used to test raw materials, in-process samples, and finished OTC drug products are retained. On 03/17/2026, we observed a flashing error message on pH Meter #(b) (4) which stated "(b) (4) (b) (4). The data from the pH meters are not backed up. In addition, results from the two pH Meters (#(b) (4) and #(b) (4)) are not printed out, and no second person verification is conducted at time of testing. Additionally, we observed that the "delete" option on the pH meters are not disabled.

3) The (b) (4) weigh balances (IDs: (b) (4)), used to conduct (b) (4) measurements for in-process bulk batches and finished OTC drug products, lack adequate controls to ensure complete and accurate data capture. The balances do not have the ability to save data electronically and no permanent record of the original instrument reading is maintained. All weight measurements are manually transcribed by an analyst onto (b) (4) and there are no procedures requiring second person verification of results at time of testing.

4) The (b) (4) (IDs: (b) (4)), used in (b) (4) testing of bulk batches used in finished OTC drug products, lack adequate controls to prevent loss and ensure data integrity. The (b) (4) do not have the ability to save data electronically and analysts can clear or delete test data. Additionally, all (b) (4) measurements are manually transcribed by an analyst onto CMS and there are no procedures requiring second person verification of results at time of testing.

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PRODUCTION SYSTEM

OBSERVATION 7

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically,

1) Changes to manufacturing processes were implemented without undergoing a revalidation to ensure its reproducibility. For example, Customer Concern Communication Report (CCCR # 24-013) was initiated on 02/22/2024 when the customer expressed concerns with bulk manufactured material (b) (4) (b) (4) having a grainy appearance. An evaluation of finished goods and bulk retains was conducted and it was determined that samples showed some variance of grainy appearance. After a review of the validated process, a decision was made that a new process/re-phasing was necessary. The new phasing consisted of (b) (4) as opposed to the validated procedure which included the (b) (4) (b) (4) The change in manufacturing process was implemented on 04/26/2024 without a Change Control per SOP QA-002c "Change Control System" and without re-validation. The following batches of (b) (4) were manufactured and released after the change in manufacturing process:
   - Lot # (b) (4) Expiration: (b) (4)
   - Lot # (b) (4), Expiration: (b) (4)
   - Lot # (b) (4), Expiration: (b) (4)
   - Lot # (b) (4), Expiration: (b) (4)

2) The process validation (PV) for (b) (4), Formula (b) (4) (Protocol No: PV-006-2024, Approved: 12/26/2024) was not completed in accordance with procedure #VA-001a "Validation Master Plan" which requires a process to be validated using (b) (4) batches. (b) (4) bulk batches ((b) (4), (b) (4)) were manufactured; however, validation batch #(b) (4) did not proceed to the filling and assembly stage. Additionally, the (b) (4) PV batches were not placed on stability studies.

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FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 8

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product. Specifically,

1) Cleaning Validation (CV) conducted for (b) (4), Formula (b) (4) (Protocol No: PV-006-2024, Approved: 12/26/2024) is deficient for the following reasons:

   a. (b) (4) bulk batches ((b) (4)) were manufactured but only (b) (4) were filled and assembled. Validation batch #(b) (4) did not proceed to the filling and assembly stage; as a result, swab samples for detergent and API residue and microbial burden samples were not collected from product contact areas of the filling and assembly equipment for (b) (4) batches in accordance with the firm's procedure #VA-001a "Validation Master Plan" which requires CV to be conducted through (b) (4) product changeovers.

   b. During the CV, the following results from swab analyses which exceeded specification for residuals of actives (Specification: (b) (4)) were received and no investigations were conducted:

PV Batch No.	Location	Result (ppm/swab)
(b) (4)		(b) (4): 14.66
		(b) (4): 13.26
		(b) (4): 48.08
		(b) (4): 12.31
		(b) (4): 16.78
		(b) (4): 16.83
		(b) (4): 75.30
		(b) (4): 28.17
		(b) (4): 28.20

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(b) (4)	(b) (4) : 79.38 (b) (4) : 392.28 (b) (4) : 131.48 (b) (4) : 130.69
	(b) (4) : 22.13
	(b) (4) : 41.21 (b) (4) : 10.36 (b) (4) : 11.68

Additionally, no swab samples were collected for detergent and API residue and microbial burden of product contact surfaces of the bulk manufacturing Kettle and (b) (4) Pump for batch (b) (4) .

c. The CV Protocol No: PV-006-2024 states "the equipment used during the manufacture, filling, and packaging…will be sampled …at locations with product contact and perceived of being difficult to clean" areas; however, the protocol does not define the hardest-to-clean areas of the manufacturing Kettle and Filling Hopper and there is no documentation of what areas were swabbed during the CV. Additionally, SOP CS-009f "Cleaning and Sanitization of Manufacturing, Filling Equipment and Parts" prescribes contact time to be maintained with each cleaning and sanitizing agent; however, there is no documentation to show contact time for cleaning agents used during the CV.

2) Procedure SOP CS-009f "Cleaning and Sanitization of Manufacturing, Filling Equipment and Parts" requires the hopper and parts to (b) (4) ; additionally, the procedure requires all parts (b) (4) . During a walkthrough on 03/17/2026, it was observed that there is no documentation to show contact time maintained with cleaning and sanitizing agents used as prescribed in the procedure during routine cleaning.

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QUALITY SYSTEM

OBSERVATION 9

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed. Specifically,

1) No investigation was initiated when the contract testing laboratory did not perform species identification on two Colony Forming Units of Gram-negative rods recovered on 08/07/2023 from (b) (4) of the (b) (4) (b) (4) system.

2) Retain samples were not assessed in response to a Customer Concern Communication Report (CCCR # 23-025) initiated on 10/04/2023 for (b) (4), Formula: (b) (4); the customer ((b) (4)) received complaints from clients of severe allergic reactions linked to lot numbers (b) (4) and (b) (4). The investigation failed to include a documented review of retain samples of the (b) (4) lots as required by SOP QA-034c "Customer Concern Communication (CCCR)" which states that preliminary investigations should include evaluations of retain samples.

3) No investigation was initiated to investigate low percentage yields for the following bulk batches of (b) (4) (b) (4) which were summarized as achieving the following yields in the Annual Product Review (APR) (Approved 04/23/2024):

   a. Batch (b) (4) (manufactured (b) (4)) achieved a 94.11% yield
   b. Batch (b) (4) (manufactured (b) (4)) achieved a 94.64% yield

   The APR states that the allowable theoretical yield for any given OTC drug product will be between (b) (4)% and (b) (4)%.

***DATES OF INSPECTION**
03/16/2026 (Mon), 03/17/2026 (Tue), 03/18/2026 (Wed), 03/19/2026 (Thu), 03/23/2026 (Mon), 03/25/2026 (Wed), 03/26/2026 (Thu), 03/27/2026 (Fri) (8 Days)

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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."