DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	5/11/2026-5/15/2026
	FEI NUMBER 1000132299

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Susan T. Owen, Executive Vice President	
FIRM NAME Owen Biosciences Inc.	STREET ADDRESS 7053 Revenue Dr
CITY, STATE, ZIP CODE, COUNTRY Baton Rouge, LA 70809-4918	TYPE ESTABLISHMENT INSPECTED contract 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 I OBSERVED:

OBSERVATION 1

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established.

Specifically,

Your firm failed to establish appropriate procedures to prevent objectionable microorganisms in non-sterile OTC drug products manufactured at your firm, specifically failing to test for Burkholderia Cepacia (B. Cepacia) in finished OTC Drug Products and (b) (4) used for manufacturing.

A. B. Cepacia is absent from your microbiological testing panel for the following OTC finished drug products
   - (b) (4)
   - (b) (4)
   - (b) (4)
   - (b) (4)

B. B. Cepacia is absent from your (b) (4) microbiological testing panel

OBSERVATION 2

Written records are not made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically,
For (b) (4), Batch (b) (4) *exp.* (b) (4), an OOS result of 1.1462 was

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brittny C Cargo, Investigator	X Brittny C Cargo Investigator Signed By: Brittny C. Cargo -S Date Signed: 05-15-2026 12:43:13	5/15/2026

obtained during routine QC testing, which was (b) (4) the specification limit of (b) (4) and outside the allowable range of (b) (4) . Your firm did not initiate an OOS investigation at the time the result was obtained. Instead, your firm performed a retest the following day, which yielded a passing result. The batch was subsequently released for distribution without a documented OOS investigation to support product disposition.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Your Quality Unit (QU) failed to fulfill its responsibilities to ensure the firm's quality system was adequate and that all necessary controls were exercised with respect to the identity, strength, quality, and purity of OTC drug products manufactures at your firm, as evidenced by the following:

A. Failure to implement your remediated stability testing program for all marketed OTC drug products including (b) (4) and (b) (4) (b) (4)
B. Failure to ensure cleaning procedures for non-dedicated equipment were validated
C. Failure to ensure process validation was conducted and documented for all marketed OTC Drug products including (b) (4) and (b) (4) (b) (4)
D. Failure to establish a change control procedure **Repeat Observation**
E. Failure to establish an adequate OOS procedure **Repeat Observation**
F. Failure to ensure completeness and accuracy during batch production record review. **Repeat Observation**
G. Failure to establish an adequate Supplier Qualification procedure. Furthermore, your firm was unable to provide supplier qualification documentation for the following raw materials used in

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the manufacture of currently marketed OTC drug products:

- (b) (4) — used in the manufacture of (b) (4) (b) (4)

H. Failure to provide a complete, controlled Master Batch Record (MBR) for the manufacture of (b) (4) and (b) (4)

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X Brittny C Cargo Investigator Signed By: Brittny C. Cargo -S Date Signed: 05-15-2026 12:43:13

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5/15/2026

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."