DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	2/23/2026-2/27/2026
	FEI NUMBER 1628196

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Mohan Rao Manam, Chief of Operations

FIRM NAME	STREET ADDRESS
Brio Pharmaceuticals Inc	10863 Rockley Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77099-3405	Prescription 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 I OBSERVED:

OBSERVATION 1

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

Specifically,

1) Failure to provide required cGMP training
Your firm did not provide current Good Manufacturing Practice (cGMP) training to employees in 2024 and 2025. According to Section 5.10.1 of SOP-HR-002, CC#25-0139, annual cGMP training is required for all employees, including temporary workers.
2) Inconsistent application of quarantine and approved material labels
Quarantine tags and QA-approved labels are not applied uniformly to material containers and pallets. According to Section 5.1.6.1 of SOP-PR-016, CC#25-0141, quarantine tags must be attached to each pallet or individual container. According to Section 5.7.4 of SOP-QA-116, CC#25-0139, approved labels (printed on (b) (4) paper) must be affixed to each component container and to each pallet for other materials.
During the facility walkthrough on February 23, 2025, not all material containers or pallets in quarantine rooms (b) (4) and (b) (4) had quarantine tags, and not all material containers/pallets in excipient room (b) (4) had QA-approved labels.

OBSERVATION 2

The written stability testing program is not followed.

Specifically,

Your firm has not performed temperature mapping studies for the (b) (4) stability chamber (Serial Number

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EMPLOYEE(S) SIGNATURE
Timothy H Vo, Investigator

Timothy H Vo
Investigator
Signed By: 2003265410
Date Signed: 02-27-2026
10:26:44
X

DATE ISSUED
2/27/2026

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(b) (4)) and the (b) (4) stability chamber (Serial Number (b) (4)). These stability chambers are used to perform stability studies for (b) (4) and (b) (4) Solution.

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X Timothy H Vo
Investigator
Signed By: 2003265410
Date Signed: 02-27-2026
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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."