DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	6/23/2025-6/26/2025
	FEI NUMBER 3012047188

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Gregory J. Fluet, COO and Site Head

FIRM NAME	STREET ADDRESS
Ferring Microbiome Inc.	2660 Patton Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Roseville, MN 55113-1136	Live Biotherapeutics 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

A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary, has not been established.

Specifically, your global procedure, (b) (4) *00000596, Non-Conformance and Recall Management*, version 4.0, 31Jan2023, defines the requirements for you firm to assess critical situations and conduct product recalls, as necessary. (b) (4) *00000596* requires your firm to establish an effective system for the recall of non-conforming product to include preparing written procedures and evaluating that system at least (b) (4) either by assessing a real recall or performing a (b) (4) recall. On 26Jun2025, your firm's Quality Site Head stated that you did not have a procedure in place to conduct recall activities, nor have you performed a (b) (4) recall since you began commercial manufacturing of Rebyota. From 02May2022 through (b) (4) your firm has distributed (b) (4) of the finished drug product, Rebyota, into (b) (4).

X Laurel A Beer
Investigator
Signed By: 0014345915
Date Signed: 06-26-2025 16:56:01

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Laurel A Beer, Investigator Scott T Ballard, Investigator X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 06-26-2025 16:55:10	6/26/2025

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."