

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

CBER/OCBQ/Division of Manufacturing and Product Quality
10903 New Hampshire Avenue, Silver Spring, MD 20993
Lead Insp.: Sharmila Shrestha
Telephone: 240-402-6065

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

April 17-18, 2025; April 21-24, 2025

FEI NUMBER

3022984544

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Paul Bullock, Chief Manufacturing Officer

FIRM NAME

Replimune, Inc.

STREET ADDRESS

33 New York Ave.

CITY, STATE AND ZIP CODE

Framingham, MA 01701

TYPE OF ESTABLISHMENT INSPECTED

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) (WE) OBSERVED:

1. Investigations are not closed in a timely manner as required by the SOP "1161-0007: Deviation Management" that states (b) (4) are to be completed within (b) (4) from the observed date. 25% of 660 deviations, including some critical deviations, were not closed within (b) (4)

2. Quality agreements are deficient in that they do not accurately specify the services provided by the supplier. Specifically,

- The quality agreement for a contracted storage site does not include provisions for (b) (4)
- The quality agreement for a contracted testing laboratory does not specify the (b) (4)

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Sharmila Shrestha
Wei Wang
Carla Lorenzo
Bo Liang

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Sharmila Shrestha, Biological Reviewer
Wei Wang, Microbiologist
Carla Lorenzo, CSO
Bo Liang, Staff Fellow | Guo-Chiuan Hung, Biologist

DATE ISSUED

04/24/2025

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 judgement, 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."