DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/DBM, Attn: Dr. Zhihao (Peter) Qiu, Director 10903 New Hampshire Avenue; White Oak Building 22, Room 5112 Silver Spring, MD 20993 (301) 796-6655| Email: OPFBLAInspection483Responses@fda.hhs.gov	08/26/2020-09/04/2020
	FEI NUMBER 1220423

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms Lisa McClintock, Site Head Framingham Biologics Operations

FIRM NAME	STREET ADDRESS
Genzyme Corporation	8 New York Avenue
CITY, STATE, ZIP CODE, COUNTRY Framingham, MA, 01701	TYPE ESTABLISHMENT INSPECTED Drug Substance 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:

Facilities and equipment supporting manufacture are not adequately maintained. Specifically,

a. On September 2, 2020, (b) (4) FB-2880-001 used in sterilization of the (b) (4) filter and bioreactor probes was observed with (b) (4) and (b) (4) residue on the (b) (4) cart. The (b) (4) chamber was also observed in a similar condition. There is no routine inspection of the (b) (4) for cleanliness nor is there a procedure for cleaning.

b. On August 26, 2020, an air return pre-filter located within Downflow Booth DFB1000001 used in raw material weighing, was observed not secured to its mounting. The filter is a pre-filter to the high efficiency filter and subsequent downflow booth ceiling HEPA filter bank.

c. A ceiling air supply diffuser screen in Suite (b) (4) CNC space was observed not secured to its ceiling mount. The cause was an unsecured fastener. Numerous other air supply diffuser screens within the CNC space were observed with similar unsecured fasteners.

Observation 2: Equipment used within the QC Microbiology Laboratory has not been adequately certified and review of logbooks has not been conducted according to procedure. Specifically,

a. Sartorius analytical balance F-16499 has not been certified in determination of the balance minimum weigh amount.

b. Standard operating procedure FBL-SOP-000942, Good Documentation Practices, v6, Effective date 01/09/2020 identifies under section 6.10.9 that functional area review of logbooks is to be conducted within (b) (4) of final entry. The following logbooks located within the bioburden room exceeded the (b) (4) specification:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Wayne E Seifert Ying-Xin Fan	Wayne E. Seifert, Consumer Safety Officer Ying-Xin Fan, Chemist	09/04/2020

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Framingham, MA, 01701	Drug Substance Manufacturer

a. Logbook 2019QCM0219, Equipment I.D.: F-17173, Temperature Log Sheet 2, Water Bath.
b. Logbook 2019QCM0220, Equipment I.D.: F-17174, Temperature Log Sheet 2, Water Bath.
c. Logbook 2019QCM0124, Equipment I.D.: F17174, Dry State Storage Checklist for QCM Water Baths.

N/A WA 09/04/2020

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	Wayne E Seifert Ying-Xin Fan	Wayne E. Seifert, Consumer Safety Officer Ying-Xin Fan, Chemist	09/04/2020