DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556 orabioinspectionalcorrespondence@fda.hhs.gov	8/7/2023-8/16/2023* FEI NUMBER 3004051669

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kristine Marchant, Vice President & General Manager

FIRM NAME	STREET ADDRESS
Emergent Biosolutions LLC	50/90 Shawmut Rd
CITY, STATE, ZIP CODE, COUNTRY Canton, MA 02021-1409	TYPE ESTABLISHMENT INSPECTED Licensed Biological 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

Records associated with investigations into deviations of drug substance manufacturing and within the retention period for such records, were not made readily available for authorized inspection.

Specifically, the security camera footage from the manufacturing floor utilized by your firm during manufacturing investigations to make root cause determinations and risk assessments associated with deviations that occurred during ACAM2000 bulk drug substance manufacturing is not maintained and available for review. We were therefore unable to verify the information provided in the camera footage to confirm that it supports the root cause identified in the investigations. For example,

A. Deviation-003818 was initiated on 05Apr2022 as (b) (4) contact time was documented as 1 minute in the (b) (4) cleaning log of clean room P104 and the associated written procedure, SOP040696 v19.0 requires a (b) (4) contact time. The investigation summary and conclusion section of the deviation report stated that the manufacturing supervisor reviewed the camera security system and found that the recorded contact time was mistakenly written. The associated video footage was not available for review.
B. Deviation-003941 was initiated to investigate mold recoveries from clean room P110A samples collected on 13Apr2022. The investigation report, INV043779 v 1.0 provided a list of manufacturing operations that occurred on 13Apr2022 by reviewing the video footage from the same day. The information collected from the video footage was used for root cause analysis. The associated video footage was not available for review.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Unnee Ranjan, Investigator Lewis K Antwi, Investigator Shafiq Ahadi, Investigator X Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 08-16-2023 14:33:50	8/16/2023

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OBSERVATION 2

Aseptic Process Simulation studies do not simulate routine aseptic manufacturing operations.

Specifically, the sterilization process for (b) (4) followed during routine manufacturing of ACAM2000 P10 viral process is not simulated during media fill studies. For media fill studies, (b) (4) (b) (4) sterilization cycle, which requires an (b) (4) mode, is used. However, the sterilization process for routine manufacturing utilizes a (b) (4) (b) (4) sterilization cycle, which requires a (b) (4) mode. Based on Change Control - 000012, closed on 20Jul2022, your firm eliminated the (b) (4) (b) (4) cycle of (b) (4) during routine manufacturing. There is no data to ensure that the sterilization process followed for commercial batches is the worst case compared to sterilization process used for aseptic processing simulations.

***DATES OF INSPECTION**

8/07/2023(Mon), 8/09/2023(Wed), 8/10/2023(Thu), 8/11/2023(Fri), 8/14/2023(Mon), 8/15/2023(Tue), 8/16/2023(Wed)

X Unnee Ranjan
Investigator
Signed By: 2001565336
Date Signed: 08-16-2023 14:34:22

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Unnee Ranjan, Investigator Lewis K Antwi, Investigator Shafiq Ahadi, Investigator	X Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 08-16-2023 14:33:50	8/16/2023

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."