DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71-5128 Silver Spring, MD 20993-0002 240-402-8906 orabioinspectionalcorrespondence@fda.hhs.gov	9/15/2022-9/23/2022* FEI NUMBER 3011292311

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Carole Resman, CEO LFB Biomanufacturing & Executive Vice President of Production for LFB Group

FIRM NAME	STREET ADDRESS
LFB Biomanufacturing S.A.S.U	Impasse Des Chenes Rouges
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ales, Gard, 30100 France	Biologic Drug Substance

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

Your firm collects samples for bioburden analysis at different stages of manufacturing leading to the production of "FORMULATED DRUG PRODUCT SUBSTANCE" (electronic tracking/stock management system designation: (b) (4) (b) (4), code (b) (4)). The final drug substance/product is itself sampled for bioburden. Bioburden specifications, including for the final drug substance/product, are indicated in your firm's control plan, *Plan de controle pour la purification de l'IPI a la DS entrant dans la fabrication de SEVENFACT (lots commerciaux)*, Document No. 15208. Microbiological results (aerobic bacteria and mold counts) are documented on the form, *Feuille de travail - contamination microbiologique par filtration sur membrane*, Document No. 10046. (b) (4) (b) (4) compared against the required bioburden specifications. If (b) (4) then your firm does not (b) (4) Your firm's QC Laboratory Manager confirmed that (b) (4) (b) (4) if (b) (4), whether (b) (4) or (b) (4) (b) (4)

***DATES OF INSPECTION**
9/15/2022(Thu), 9/16/2022(Fri), 9/19/2022(Mon), 9/20/2022(Tue), 9/21/2022(Wed), 9/22/2022(Thu), 9/23/2022(Fri)

X Gene D Arcy
Investigator - Team Biologics
Signed By: 1300159983
Date Signed: 09-23-2022 06:04:18

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lewis K Antwi, Investigator Gene D Arcy, Investigator - Team Biologics	X Lewis K Antwi Investigator Signed By: 2001796124 Date Signed: 09-23-2022 06:03:18	9/23/2022

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."