



MEMORANDUM

From: Marie J. Anderson, MS, PhD
Division of Biological Standards and Quality Control (DBSQC)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

To: Biologics License Application Submission Tracking Number 125761

Subject: Lot Release Protocol Template (LRP) for Anthrax Vaccine Adsorbed, Adjuvanted for post-exposure prophylactic vaccine following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial regimen.

Through: Varsha Garnepudi, MS, Branch Chief QAB/DBSQC/CBER/FDA
Maryna Eichelberger, PhD, Director DBSQC/OCBQ/CBER/FDA

Cc: Taruna Khurana, PhD, Chair, DVRPA/OVRR/CBER/FDA
Diana Oram, PhD, RPM, DVRPA/OVRR/CBER/FDA

Applicant: Emergent Product Development Gaithersburg Inc. (Emergent)

Product: Anthrax Vaccine Adsorbed, Adjuvanted

Trade Name: Cyfendus

Summary: The LRP template for Anthrax Vaccine Adsorbed, Adjuvanted submitted in amendment 125761/0.39 on March 20, 2023 is acceptable for use.

1 General Information

1.1 CMC Review Identifiers and Dates

1.1.1 Biologics License Application (BLA) Submission Tracking Number (STN): 125761

1.1.2 Submission received by CBER: April 20, 2022

1.1.3 Review completed: April 19, 2023

1.1.4 Material Reviewed: BLA 125761

1.1.5 Related Master File, INDs and BLAs: BLA 103821

2 Review

2.1 Documents Reviewed

LRP template for Anthrax Vaccine Adsorbed, Adjuvanted submitted on July 26, 2022 in amendment BLA 125761/0.8.

Response and revised LRP template for Anthrax Vaccine Adsorbed, Adjuvanted submitted on October 18, 2022 in amendment BLA 125761/0.23.

Response and revised LRP template for Anthrax Vaccine Adsorbed, Adjuvanted submitted on January 5, 2023 in amendment BLA 125761/0.32.

Response and revised LRP template for Anthrax Vaccine Adsorbed, Adjuvanted submitted on February 14, 2023 in amendment BLA 125761/0.36.

Revised LRP template for Anthrax Vaccine Adsorbed, Adjuvanted submitted on March 20, 2023 in amendment BLA 125761/0.39.

2.2 Review

An IR was sent to Emergent on July 12, 2022 to submit an LRP template. A response was submitted on July 26, 2022 in amendment 125761/0.8. This template was reviewed by OVR/DBPAP, OCBQ/DMPQ/PRB, and OCBQ/DBSQC with comments.

An IR was sent to Emergent on September 27, 2022 to submit a revised LRP template to include the following changes: 1. replacement of tables listing test methods with the appendices that state the release specifications (test parameter, method type, and acceptance criteria) for the drug substance and drug product; 2. maintain the format and contents of the DP ^{(b) (4)} filtrate and relative potency tests as the currently approved LRP template for STN 103821 (Anthrax Vaccine Adsorbed); 3. addition of the sterility results table; 4. use the

proper name of Anthrax Vaccine Adsorbed, Adjuvanted throughout the LRP template. A response and revised LRP template were submitted in amendment 125761/0.23 on October 18, 2022. This template was reviewed by OVR/DBPAP, OCBQ/DMPQ/PRB, and OCBQ/DBSQC with comments from PRB regarding the LRP template format.

An IR was sent to Emergent on December 9, 2022 to submit a revised LRP template regarding the header format and information for submitting LRPs via the enterprise submission gateway. A response and LRP template were submitted in amendment 125761/0.32 on January 5, 2023. This template was reviewed by OCBQ/DMPQ/PRB and OCBQ/DBSQC with comments from PRB regarding the LRP template format.

An IR was sent to Emergent on January 26, 2023 to submit a revised LRP template regarding the header format. A response and LRP template were submitted in amendment 125761/0.36 on February 14, 2023. This template was reviewed by OCBQ/DMPQ/PRB and OCBQ/DBSQC with no comments.

Emergent submitted amendment 125761/0.39 on March 20, 2023 proposing the withdrawal of the (b) (4) facility as a proposed commercial drug product filling and testing site. An LRP template was submitted and reviewed by OCBQ/DBSQC with no comments.

3 Conclusions

The LRP template for Anthrax Vaccine Adsorbed, Adjuvanted submitted in amendment 125761/0.39 on March 20, 2023 is acceptable for use. This template may be used for future lot release submissions.