



MEMORANDUM

Date: May 02, 2024

From: George Kastanis, MS
Quality Assurance Branch (QAB)
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: The file: STN 125814/0

Subject: Review of Lot Release Protocol (LRP) Template for Pneumococcal 21-valent Conjugate Vaccine included in STN 125814/0

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

Applicant: Merck Sharp & Dohme LLC

Product: Pneumococcal 21-valent Conjugate Vaccine
Trade Name: CAPVAXIVE

Summary: The LRP template for Pneumococcal 21-valent Conjugate Vaccine submitted in amendment 125814/0.25 on April 22, 2024, is acceptable for use.

1 General Information

1.1 CMC Review Identifiers and Dates

1.1.1 Biologics License Application STN: 125814/0

1.1.2 Submission received by CBER: October 18, 2023

1.1.3 Review completed: May 02, 2024

1.1.4 Material Reviewed: BLA 125814/0

1.1.5 Related Master File, INDs and BLAs: STN 125814/0

2 Review

2.1 Documents Reviewed

The LRP template for Pneumococcal 21-valent Conjugate Vaccine submitted on November 17, 2023, in supplement 125814/0.2

The LRP template for Pneumococcal 21-valent Conjugate Vaccine submitted on April 22, 2024, in supplement 125814/0.25

The Drug Product release specifications for Pneumococcal 21-valent Conjugate Vaccine submitted on April 22, 2024, in supplement 125814/0.25

2.2 Review

An LRP template was not provided with the initial BLA submission on October 18, 2023. An IR was sent on November 14, 2023, asking Merck Sharp & Dohme LLC, to submit the LRP template.

A response was submitted on November 17, 2023, in amendment 125814/0.2 with the LRP template. The LRP template was reviewed by OCBQ/DBSQC, OCBQ/DMPQ/PRB and OVR/DBPAP with comments to provide serotype 8 information to the “Conjugated Saccharide Content” table, as it was not present in the table. An IR was sent to Merck Sharp & Dohme LLC on April 19, 2024.

A response was submitted on April 22, 2024, in amendment 125814/0.25. This revised LRP template was reviewed by OCBQ/DBSQC, OCBQ/DMPQ/PRB and OVR/DBPAP with no comments.

3 Conclusions

The lot release protocol template for Pneumococcal 21-valent Conjugate Vaccine submitted in amendment 125814/0.25 on April 22, 2024, is acceptable for use. This template may be used for future lot release submissions.