



Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125814/0

From: Salil K Ghosh, Ph.D., LAC/DBSQC/OCBQ/CBER

Through: Maryna Eichelberger, Ph.D
Division Director, DBSQC/OCBQ/CBER/CBER
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Acting Division Director, DBSQC/OCBQ/CBER

Sponsor: Merck Sharp & Dohme (MSD) LLC.

Subject: Review of Analytical Methods used for Pneumococcal 21-valent
Conjugate Vaccine (V116) (CAPAXIVE) drug substance and drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of CAPAXIVE were reviewed by Seth T Schulte (LMIVTS), Anil Choudhary (LBVI), and Salil K Ghosh (LAC). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their qualifications reviewed for CAPAXIVE were found to be adequate for their intended use.