



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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125819/0

From: Anil Choudhary, Ph.D., MBA, LBVI/DBSQC/OCBQ

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

Sponsor: GlaxoSmithKline Biologicals

Subject: Suitability of lot-release test methods for PENMENVY (Meningococcal Groups A, B, C, W-135, and Y components and drug product)

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of PENMENVY were reviewed by Brianna R Davis, Simleen Kaur (LMIVTS), Tao Pan, Kouassi Ayikoe (LAC), and Anil Choudhary (LBVI). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their qualifications reviewed for PENMENVY Drug Substances and Drug Products were found to be adequate for their intended use.