



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

## MEMORANDUM

### DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

**To:** The file STN 125819/0

**From:** Kouassi Ayikoe, Ph.D., LAC/DBSQC/OCBQ/CBER

**Through** Kenneth S. Phillips, Ph.D., Chief LAC/DBSQC/OCBQ/CBER

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**Product:** PENMENYV (Meningococcal Groups A, B, C, W and Y Vaccine)

**Applicant:** GlaxoSmithKline Biologicals SA

**Subject:** Analytical Methods for the Lot Release of (b) (4) Drug Product.

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**Recommendation:** Approval

#### Executive Summary:

The following analytical methods used for lot release of PENMENYV (Meningococcal Groups A, B, C, W and Y Vaccine) (b) (4) drug product (DP) from GlaxoSmithKline (GSK) Biologicals SA, and the associated validations or qualifications, were reviewed:

1. (b) (4)

[REDACTED]

**Conclusion**

The analytical methods and their validations and/or qualifications reviewed for PENMENVY (b) (4) from GSK Biologicals, were found to be adequate for their intended use in lot release testing.

**Abbreviations:**

RV- Recombinant vaccine

Kd - Distribution coefficient

PS - Polysaccharide

MenA PS - MenA Polysaccharide (Simplified as MenA)

OMV - Outer Membrane Vesicle.

(b) (4)

FB - Final Bulk

**Background**

MenABCWY RV is for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis*. It is a combination of a vial of lyophilized Meningococcal Groups A, C, W, and Y component (MenACWY Lyo) and a pre-filled syringe of Meningococcal Group B liquid component (MenB Liquid). The lyophilized part is reconstituted with the liquid to 0.5 mL for an intramuscular administration. MenACWY Lyo and MenB are both drug products (DP) with the same amounts of antigens as found in the licensed Menveo vaccine (STN 125300) and Bexsero vaccine (STN 125546) respectively.

MenACWY Lyo DP contains the same antigens in the same amount as the licensed Menveo vaccine (STN 125300) but in a fully lyophilized form: MenA-CRM, MenC-CRM, MenW-CRM and MenY-CRM, derived from MenA, MenC, MenW, and MenY polysaccharides (PS) respectively conjugated to CRM197, a *Corynebacterium diphtheriae* toxin mutant. The MenB Liquid DP has the same formulation as the licensed Bexsero. The specifications for DP and components (DS) are the same as found in the two approved vaccines.

**Information Reviewed**

Information in sections of the original submission that describes control of DS and DP (3.2.S.4 and 3.2.P.5, respectively), including analytical procedures for DP, and validation of these analytical procedures, was reviewed. Additional information in amendments was also reviewed.

**Review Narrative**

(b) (4)

