DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20903

MEMORANDUM

Date: July 28, 2014

From: Anil Choudhary, Ph.D., MBA.
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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 # 125549/0**

Subject: **Review of Analytical Procedures for Drug Substance and Drug Product of Biologics License Application for Meningococcal Group B Vaccine**

Through: Muhammad Shahabuddin, Ph.D., HFM-680, LBVI, DBSQC/OCBQ/CBER/FDA
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Cc: Michael Smith, Ph.D., Lead RPM, DVRPA/ OVRR
Drusilla Burns, Ph.D., Chair, BLA Review Committee, DBPAP/OVRR

Applicant: Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.

Product: Trumenba- Meningococcal Group B Vaccine

1 General Information

1.1 CMC Review Identifiers and Dates

1.1.1 Biologics License Application (BLA) Submission Tracking Number (STN) #: 125549

1.1.2 Submission received by CBER: May 29, 2014

1.1.3 Review completed: July 28, 2014

1.1.4 Material Reviewed

Original BLA: Amendments 2, comprised the rolling BLA submissions.

The following general module sections of the BLA were reviewed: M3 CMC, Quality

1.1.5 Related Master File, INDs and BLAs:

- Master File (b)(4), Master File (b)(4), Master File (b)(4) and Master File (b)(4)
- IND 13812: *Neisseria meningitidis* Serogroup B Recombinant Lipoprotein (rLP2086; subfamily A and B; E. coli) Vaccine with Aluminum Phosphate

2 Executive Summary:

The assay method SOP13496 is properly validated for its intended use for Identity Test of bivalent rLP2086 drug product and ----------(b)(4)----------.

3 Review

3.1 Documents Reviewed

1. Validation Plan and Report Summary for Identity of MnB bivalent rLP 2086 Drug Product (Section 3.2.P.5.3) by --(b)(4)--.
2. Validation Plan and Report Summary for Identity of MNB RLP 2086 ----------(b)(4)---------- (Section 3.2.S.4.2 and 3.2.S.4.3, MnB ----(b)(4)------) by ---(b)(4)---.
3. Document Number: SOP-13496- ---(b)(4)--- assay for identification of ----------(b)(4)---------- in vaccine materials and formulations.

3.2 Method Overview

The SOP-13496 describes the method for identification of the MnB ---------(b)(4)----------, namely, ----------(b)(4)----------, in ----------(b)(4)----------. This method is an immunoassay, wherein ----------(b)(4)----------

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----------(b)(4)----------

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3.3 Review of Validation of Identity (ID) Assay for -(b)(4)- DP

The validation of the assay method-SOP 13496, was performed in conformance with ----(b)(4)---- guidelines, for establishing the "Identity" of the MnB rLP2086. The (b)(4) guidelines require the assessment of the specificity parameter only for validation of a method used for Identity (ID) of drug ---(b)(4)---/ product. In the ID validation document submitted by sponsor, specificity was assessed along with the robustness of the assay method. In the experimental design to assess ID, type specific antibodies for -------(b)(4)------- for ----------(b)(4)---------- were used along with ----------(b)(4)----------.

The negative controls used were of ----------
----------(b)(4)----------
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----------(b)(4)----------
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----------(b)(4)----------

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----------(b)(4)----------

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3.4 Conclusions

The method SOP 13496 has been validated for demonstrating the Identity of the bivalent rLP2086 drug product and its ------(b)(4)-------. The specificity and robustness parameters were evaluated and all the specifications were met satisfactorily. The method is suitable for the intended purpose and the results are acceptable to DBSQC. The assay method is approvable.