

# Vaccines, Blood & Biologics Addendum Review Memo - TRUMENBA

## Memorandum

**Food and Drug Administration  
Center for Biologics Evaluation and Research  
Office of Compliance and Biologics Quality  
Division of Manufacturing and Product Quality**

**To: 125549/0 Meningococcal Group B Vaccine**

Drusilla Burns, PhD, Committee Chair, CBER/OVRR/DBPAP

Michael Smith, DVRPA, RPM

**Cc: Review Committee Members**

Margaret C Bash, DBPAP, Consultant Reviewer Product

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**From:** Nancy Waites, CMC Facility Reviewer, OCBQ/DMPQ

**Through:** Carolyn Renshaw, Branch Chief, OCBQ/DMPQ/B1

**Through:** John Eltermann, Div Dir, DMPQ/OCBQ

**Subject:** Addendum Review Memo

**Indication:** Active immunization to prevent invasive meningococcal disease caused by N. meningitides serogroup B in individuals aged 10 through 25 years.

**Applicant:** Wyeth Pharmaceuticals Inc. US License # 0003

**Facility Sites:** -----(b)(4)-----

Pfizer -(b)(4)- Pharmaceuticals -----(b)(4)-----

**Addendum Review Memo Due Date Goal:** 03 Oct 2014

**Final Action Due Date:** 16 Feb 2015

**Recommendation:** DMPQ provisionally recommends approval of the application based on the contents of the application and amendments submitted through the date of this

memo and the acceptable status of the inspectional compliance of the facilities. Final recommendation will be provided pending the review of the future submission of an amendment for an outstanding IR request.

**Telecons:**

None

**Summary**

I have reviewed the amendments that are applicable to DMPQ's review of the application and I find them to be acceptable.

**Review:**

The following is a list of the information requests sent out over the course of the Primary Review of the BLA along with a list of the resulting amendments. The review of the BLA was managed under PUDUFA V "The Program".

<b>IR Date</b>	<b>Amendment Number</b>	<b>Amendment Receipt Date</b>	<b>Review Result</b>
11 Jun 2014	Amendment 5	23 Jun 2014	Acceptable
18 Aug 2014	Amendment 19	29 Aug 2014	Acceptable
29 Aug 2014	Amendment *	*	*

\*At the time this review memorandum was written, the last IR response was not received from Pfizer. The last IR will be reviewed in a separate Addendum Review memorandum.

The reviews of these amendments are attached to this addendum review memo as appendices.

**List of Appendices**

- Appendix 1 – Review of Amendment 5 - Responses to Information Request Dated 11 Jun 2014
- Appendix 2 - Review of Amendment 19 - Responses to Information Request Dated 18 Aug 2014