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

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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 #2 (Amendment 21)

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: Based on my Primary Review memorandum, my two Addendum Review memos and the outcome of the inspections, DMPQ recommends approval of this BLA if no other reviewers have any issues.

Telecons:
None

Summary
I have reviewed Amendment 21 Question 38 only since that is the question in the amendment that is applicable to DMPQ and I found it to be acceptable. Based on my Primary Review memorandum and my two Addendum Review memos, DMPQ recommends approval of this BLA if no other reviewers have any issues. The pre-license inspection for the (b)(4) drug substance facility was waived and the pre-license inspection for the Pfizer ---(b)(4)--- drug product facility was performed by the Product Office and TeamBio ----(b)(4)---- and was classified as VAI.

Review:
On 29 August 2014 an information request was sent to Pfizer. One of the questions, Question 38, was from DMPQ. The remaining questions were from the other review offices. Amendment 21 (STN 125549 / 0/21) was received on 24 Sep 2014 and the response from Pfizer for Question 38 was reviewed and found to be acceptable.

The IR question submitted by FDA is in **bold** font followed by Pfizer's response.

QUESTION 38
In Section 3.2.S.2.2 entitled, Description of Manufacturing Process and Process Controls - Filling, Storage and Transportation, subsection 3.2.S.2.2.2 entitled, -------(b)(4)-------- Storage you state that, ----------(b)(4)---------- Please submit information on the ----(b)(4)----; specifically, equipment description, equipment qualification and ---(b)(4)--- validation.

RESPONSE 38
Table 1 compares the types of ---(b)(4)--- used for the ---(b)(4)--- of MnB ------(b)(4)------. As per the information shown in Table 1, they have been deemed functionally equivalent. The re

1 page redacted (b)(4)

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

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

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Review Comment: I reviewed Figure 2 and found it to be acceptable. ----------
----------(b)(4)----------

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

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Literature References
None

SUPPORTING DOCUMENTATION
New or Replaced Supporting Documentation
033-VD-QF-03288-B (1.0) Qualification Report: ----------(b)(4)----------, New

Previously submitted supporting documentation
Section 3.2.S.2.2 Filling, Storage and Transportation, sequence 0002

Number: 033-VD-QF-03288-B (1.0) Qualification: ----------(b)(4)----------

Review Comment: I reviewed the qualification report and found it to be acceptable. The ----------(b)(4)------ has been acceptably qualified.

This qualification showed that the ---(b)(4)--- from ----------(b)(4)---------- conforms to the intended use and can be used for ----------(b)(4)----------. The equipment is released for GMP operation.

The ----(b)(4)---- was procured new. The operator's requirements were summarized in a user requirement and formed the basis for this first qualification. The qualification was performed according to Qualification Programme (033-VD-QF-03288-P) and concluded successfully. This

Qualification Report describes the results of the Design, Installation, Function and Performance Qualifications of the ---(b)(4)---.

1.1.1 Brief description of the equipment

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

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

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

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

Design Qualification (DQ)
The DQ documented the checking that the intended design is suitable for the corresponding purpose. The DQ was performed concomitant in the procurement process according to SOP 033-AABE-00455 “Process: Procurement of Technical Goods in BO”. The DQ was concluded on 28.10.2009.

Installation Qualification (IQ)
The IQ documented the review of the installation being executed according to the approved specifications and design and the valid guidelines. The IQ was performed according to SOP 033-AA-QF-01221 “Performance of the Installation Qualification”. The IQ was concluded on 25.11.2009.

The IQ comprised the following activities:

- Review of completeness of the ACTUAL parts and check for damage
- Review of completeness of the documentation/certificates
- Designation as “Not for GMP”
- IQ for equipment, instruments and special components
- IQ for media connections
- Review of P&I diagram
- IQ for measuring circles
- IQ for electrical engineering components

- Check of marking and labelling of components
- Content check of the documentation/certificates
- Setting up of a logbook
- First entry of calibration in the IPS
- Review of the requirement specification for observance of the execution as required

Operational Qualification (OQ)
The OQ documented the verification that the ---(b)(4)--- operates as it is installed within the range required.

The Table below shows the tests performed as part of the OQ.

Test item
----------(b)(4)----------
----------(b)(4)----------
(b)(4)
----------(b)(4)----------
----------(b)(4)----------

This test intends to demonstrate the correct function of the appliance during a --(b)(4)-- process.

Acceptance criteria
----------(b)(4)----------.
----------(b)(4)----------.
----------(b)(4)----------.

Result
Check of ------(b)(4)-------
----------(b)(4)---------- the acceptance criterion was met.

Check of ----------(b)(4)----------
----------(b)(4)---------- the acceptance criterion was ------(b)(4)-------.

Check of the ----------(b)(4)----------
----------(b)(4)---------- and the acceptance criterion was ------(b)(4)-----.

Conclusion
The qualification demonstrated that the ----------(b)(4)---------- conforms to the purpose intended and can be used for ----------

----------(b)(4)----------. The appliance is released for GMP operation.

Quality assurance measures
Monitoring
----------(b)(4)----------.

Calibration and maintenance
No measures for maintenance are to be taken. The intervals for calibration were included in the SAP system. The corresponding orders are prepared automatically.

Maintenance of qualified status
Periodic review
The item for qualification was categorized according to SOP 033-VA-QF-00795 and is excluded from periodic review because:

- It is not categorized as a computerized system
- It is a self-contained system and
- All the functions and maintenance of the appliance status are covered by the maintenance and calibration activities.

Deviations, dealing with malfunctions and problem elimination
All malfunctions and problem elimination are documented in the logbook/equipment file. Quality-relevant malfunctions and deviations in operation are dealt with according to SOP 033-VA-QM-00714 “Deviation Management”.

QM documents
The Operating Instructions 033-100-0498 “----------(b)(4)----------” have already been prepared.