(System Info - 284017 SMITH MICHAEL 08/18/2014 16:48:05 SMITHM)

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125549/0 Office: OVRR

Product:
Meningococcal Group B Vaccine

Applicant:
Wyeth Pharmaceuticals Inc.

Telecon Date/Time: 18-Aug-2014 11:45 AM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request
2. Other - Facilities IR

Author: MICHAEL SMITH

Telecon Summary:
IR regarding facilities issues

FDA Participants: Mike Smith, Drusilla Burns, Ted Garnet and Ram Naik

Non-FDA Participants: Carmel Devlin

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

See e-mail below:

From: Smith, Michael (CBER)
Sent: Monday, August 18, 2014 11:45 AM
To: Devlin, Carmel (Carmel.Devlin@pfizer.com)
Cc: Burns, Drusilla L.; Garnett, Theodore; Naik, Ramachandra
Subject: STN 125549.0: Information request regarding facility questions

Carmel,

The review team has the attached information requests (IR's) regarding facility questions, please confirm receipt.

Regards,

Mike

Mike Smith, Ph.D.
CDR, U.S. Public Health Service
Regulatory Project Manager
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
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See contents of attached PDF below:

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
OFFICE OF VACCINES RESEARCH AND REVIEW
DIVISION OF VACCINES AND RELATED PRODUCT APPLICATIONS

Date: August 18, 2014

Pages: 3

To: Carmel Devlin
Senior Director, Worldwide Regulatory Strategy
Pfizer Inc.
Authorized Agent for: Wyeth Pharmaceuticals Inc.
401 N. Middletown Road
Pearl River, NY 10965
Telephone: (485) 602-5537 Fax: (485) 602-4139

From: Division of Vaccines and Related Products Applications
Office of Vaccines Research and Review
Point of Contact: CDR Mike Smith, Ph.D.
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10903 New Hampshire Ave., White Oak Bldg. 71
Silver Spring, MD 2993-0002
Telephone: (301) 796-2640 Fax: (301) 595-1124

STN#: 125549/0

Product: Meningococcal Group B Vaccine

Subject: CBER information request regarding the review of facilities information

The following comment pertains to the document located under eCTD section 3.2.S.6 entitled, “Container Closure System”.

1. You state on page 4 in subsection 3.2.S.6.3 “Suitability and/or Safety of the Container Closure System” that “The ----------(b)(4)---------- was tested by ----------(b)(4)- detection, which demonstrated that these (b)(4) are capable of withstanding anticipated ---(b)(4)--- conditions without compromise to container closure integrity”. Please clarify when this test was performed on the --(b)(4)-- for the bioburden controlled ------(b)(4)------. Specifically, was the test performed prior to the ---(b)(4)--- cycling challenges you performed or was it performed after the cycles?

The following comment pertains to the document located under eCTD section 3.2.S.2.5 entitled, “Process Validation and or Evaluation– (-(b)(4)-) Qualification and Validation”.

2. In Table 3.2.S.2.5-1 “(b)(4) Qualification Requirements” (page 2 in subsection 3.2.S.2.5.1. “(b)(4) Qualification”) you indicate the ----------(b)(4)---------- undergo a ----------(b)(4)---------- process. You do not provide information on the ----------(b)(4)----------. Please provide this information or indicate the location of the information within the application.

The following comments pertain to the documents located under eCTD section 3.2.A.1 entitled, “Facilities and Equipment – (b)(4)”.

3. In Table 3.2.A.1-10 “OQ Test Parameter and Acceptance Limits during HVAC Qualifications” (pages 12 and 13 in Section 3.2.A.1.3.3.2. “Validation Summary of HVAC systems”) it appears the acceptance criteria for Microbial Contamination have been switched for ----------(b)(4)---------- area classification. Please clarify the acceptance criteria for the Microbial Contamination.

4. In Table 3.2.A.1-15 “---(b)(4)--- Product-Contacted Equipment used for the Production of

MnB rLP2086 subfamily A and B Drug Substances" (page 22 in subsection 3.2.A.1.4.2 entitled, "Manufacturing Equipment" you indicate the (b)(4) systems are (b)(4). Please indicate if the ------(b)(4)----- used for drug substance manufacturing are shared or dedicated.

5. In subsection 3.2.A.1.5.2 entitled, "Cleaning and Disinfection of Manufacturing Areas" regarding the drug substance manufacturing facility, -(b)(4)-, you describe either a MACO (maximum allowable carryover) or a MAR (maximum allowable residue) for your general approach for setting cleaning acceptance criteria. Please note that we expect alert and action levels to be set based on actual cleaning capabilities so that you will be alerted if your cleaning efficiency starts to deteriorate. Please comment.

In your reply to this information request, we recommend that you restate the item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference. If you have any questions, please contact CDR Mike Smith, Ph.D. at 301-796-2640.