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: 08-Aug-2014 02:55 PM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request

Author: RAMACHANDRA NAIK

Telecon Summary:
IR regarding statistical analyses on safety and immunogenicity

FDA Participants: Ramachandra S. Naik

Non-FDA Participants: Ms. Donna Boyce

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

E-mail message and attachment below.

From:	Naik, Ramachandra
To:	"Donna.Boyce@pfizer.com"
Cc:	"Betsy.Edwards@pfizer.com"; "Devlin, Carmel (Carmel.Devlin@pfizer.com)"; Smith, Michael (CBER); Garnett, Theodore
Subject:	STN 125549/0 IR regarding statistical analyses on safety and immunogenicity
Date:	Friday, August 08, 2014 2:55:00 PM
Attachments:	STN 125549-0 IR regarding statistical analysis on safety and Immunogenicity.pdf

Dear Ms. Boyce,

Attached is an information request regarding statistical analyses on safety and immunogenicity that supports your BLA for Meningococcal Group B Vaccine (STN 125549/0).
Please confirm the receipt of this IR and provide us an estimated target date for your response.

Thanks,

Ramachandra S Naik, PhD
Primary Reviewer
Food and Drug Administration
CBER/OVRR/DVRPA/RRB3
HFM-475
10903 New Hampshire Avenue
Building 71, Room 3045
Silver Spring, MD 20993
Phone: (301) 796-2640

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

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

Date: August 8, 2014

Pages: 2

To: Ms. Donna Boyce
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Authorized Agent for: Wyeth Pharmaceuticals Inc.
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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: Ramachandra S. Naik, Ph.D.
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Silver Spring, MD 20993-0002
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STN#: 125549/0

Product: Meningococcal Group B Vaccine

Subject: CBER's comments and request for additional information regarding statistical analysis on safety and immunogenicity

We have the following comments regarding statistical analysis on safety and immunogenicity.

Regarding statistical analysis on safety:

1. The SAS datasets REACTGEN and REACTOG were not submitted for each individual study. Please submit these datasets for statistical analyses.

2. Per AE data set submitted under the Integrated Summary of Safety, CBER's statistician found that a total of 2386 subjects had at least one AE event. This number, however, is inconsistent with the total number of 1855 reported in the last column in Table 18 of the 2.7.4 Summary Clinical Safety, page 106. Please comment and clarify.

Regarding statistical analysis on immunogenicity (B1971011):

3. The evaluable immunogenicity population was defined in the CSR (page 78) specifically for testing the primary hypothesis and for some exploratory analyses related to immunogenicity of the bivalent rLP2086 vaccine. However, some evaluable subjects after dose 2, who had the post-Vaccination 2 blood drawn within 28-42 days after Vaccination 2 (Visit 3) and "had valid and determinate assay results for the proposed analysis," were not included in the evaluable immunogenicity population for the pre-defined secondary statistical analysis. Please clarify.

   Also, please address the following comments:

   a. Define a post-Vaccination 2 evaluable immunogenicity population,
   b. Provide a summary table showing the disposition of subjects for this population, and
   c. Provide a summary of the statistical analysis results for this population, showing proportions of subjects achieving four-fold rise in hSBA titers and achieving hSBA titers greater than or equal to LLOQ, for all 4 primary MnB test strains.

In your reply to this information request, we recommend that you restate each 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 Ramachandra S. Naik, Ph.D., at 301-796-2640.