

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: 07-Aug-2014 08:18 AM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: RAMACHANDRA NAIK

Telecon Summary:

IR for summaries of clinical safety and financial disclosures

FDA Participants: Ramachandra S. Naik

Non-FDA Participants: Ms. Donna Boyce (Pfizer)

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"](mailto:Donna.Boyce@pfizer.com)
Cc: ["Betsy.Edwards@pfizer.com"](mailto:Betsy.Edwards@pfizer.com); ["Devlin, Carmel \(Carmel.Devlin@pfizer.com\)"](mailto:Devlin_Carmel (Carmel.Devlin@pfizer.com)); [Smith, Michael \(CBER\)](#); [Garnett, Theodore](#)
Subject: STN 125549/0 IR on Clinical Safety and Financial disclosures
Date: Thursday, August 07, 2014 8:17:00 AM
Attachments: [STN 125549-0 IR on Summaries of clinical safety and Financial Disclosures.pdf](#)

Dear Ms. Boyce,

Attached is an information request regarding summaries of clinical safety and financial disclosures (FDA form 3455) 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



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

Date: August 7, 2014

Pages: 2

To: Ms. Donna Boyce
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: Ramachandra S. Naik, Ph.D.
Regulatory Project Manager
10903 New Hampshire Ave., White Oak Bldg. 71
Silver Spring, MD 20993-0002
Telephone: (301) 796-2640 Fax: (301) 595-1124

STN#: 125549/0

Product: Meningococcal Group B Vaccine

Subject: CBER request for additional information regarding summaries of clinical safety and financial disclosures

We have the following comments regarding summaries of clinical safety and financial disclosure forms for the clinical investigators.

Regarding summary of clinical safety:

1. Please provide a summary table of AEs and SAEs for subjects who received at least one dose of 120 µg bivalent rLP2086 vaccine (any schedule) in the three studies without control group [B1971003, B1971012, B1971042] [e.g., similar to the format for Summary of Clinical Safety.pdf, Table 18, page 106].
2. Please provide a summary table of AEs and SAEs by Gender – Pooled 7 Studies for subjects who received at least one dose of 120 µg bivalent rLP2086 vaccine (any schedule) [e.g., similar to the format for ISS.pdf, Table 10, page 33].

Regarding study B1971003:

3. Please provide summary tables of safety [solicited AEs, unsolicited (all AEs, immediate, SAEs, newly diagnosed chronic medical conditions)] for study B1971003, categorized by study group, severity, age group 18 to <25 years and 26 to <40 years.

Regarding Financial Disclosures:

4. We note in your Disclosure: Financial Interests and Arrangements of Clinical Investigators form (FDA form 3455) submitted on June 16, 2014, that nine investigators disclosed payments > \$25,000 for miscellaneous expenses. Please further itemize the miscellaneous expenses to include payments for equipment or grant funding for *Neisseria meningitides*-related research, consultations or honoraria related to *N. meningitidis* vaccines.

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.