(System Info - 283714 SMITH MICHAEL 08/14/2014 11:44:31 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: 01-Aug-2014 03:39 PM  Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request
2. Other - Req for concept protocol for pregnancy study

Author: MICHAEL SMITH

Telecon Summary:
Request for concept protocol regarding the multi-year pregnancy study

FDA Participants: Mike Smith, Theodore Garnett, Ramachandra Naik and Drusilla Burns

Non-FDA Participants: Donna Boyce, Betsy Edwards and Carmel Devlin,

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

See e-mail below:

**From:** Smith, Michael (CBER)
**Sent:** Friday, August 01, 2014 3:39 PM
**To:** Donna.Boyce@pfizer.com; Betsy.Edwards@pfizer.com; Devlin, Carmel (Carmel.Devlin@pfizer.com)
**Cc:** Garnett, Theodore; Naik, Ramachandra; Burns, Drusilla L.
**Subject:** STN 125549: IR for concept protocol regarding the multi-year pregnancy study

Donna, Betsy and Carmel,

The review team has the attached Information Request (IR) regarding a concept protocol for the multi-year pregnancy study, please confirm receipt of this IR.

I will be on annual leave ----(b)(6)----, please ensure my CBER colleagues that are Cc'ed on this e-mail are included on all e-mails to me during this time frame.

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
Office of Vaccines Research and Review
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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 1, 2014**

**Pages:** **2**

**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.**
**Regulatory Project Manager**
**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 request for concept protocol regarding the multi-year pregnancy study**

The following comment pertain to the Risk Management Plan that is located in module 1.16.

1. You mentioned a Pregnancy Registry will be conducted using electronic healthcare data. We note that on page 66 you wrote "The Sponsor will submit a draft protocol for this multi-year pregnancy study to the FDA within 3 months following bivalent rLP2086 accelerated approval." However, we would like to review this under the BLA, please submit a brief concept protocol for this study in an amendment to the BLA by Friday, August 15, 2014.

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.