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: 05-Aug-2014 01:01 PM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):
1. Information Request

Author: RAMACHANDRA NAIK

Telecon Summary:
Information request regarding HPV immunogenicity assay

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

Non-FDA Participants: Donna Boyce

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

See e-mail message and attachment below.

Naik, Ramachandra

Sent:
To:
Cc:
Subject:

I confirm receipt and will get back to you shortly with a target date for our response.

Kind regards
Donna Boyce

From: Naik, Ramachandra [mailto:Ramachandra.Naik@fda.hhs.gov]
Sent: Tuesday, August 5, 2014 1:01 PM
To: Boyce, Donna
Cc: Edwards, Elizabeth; Devlin, Carmel; Smith, Michael (CBER); Garnett, Theodore
Subject: STN 125549/0 IR on HPV Immunogenicity assay

Dear Ms. Boyce,

Attached is an information request regarding the HPV immunogenicity assay 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 5, 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: 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 the HPV immunogenicity assay that was utilized in the Phase 2 concomitant study B1971011

The following comments pertain to the three documents located under section 5.3.1.4 regarding the Human Papilloma Virus competitive Luminex ImmunoAssay (HPV cLIA) validation.

1. Please verify that the HPV immunogenicity assay for the concomitant administration study (B1971011) was version (b)(4) of HPV cLIA rather than version [redacted]

2. Please verify that the only significant difference between HPV cLIA versions (b)(4) is the (b)(4) [redacted]. If other substantive changes exist between the assay versions, please provide relevant qualification reports that support these changes.

3. Please provide an analysis of any trend in the change in HPV immunogenicity assay results over time for the control sample used in HPV cLIA.

4. Please include the period (with dates) in which control samples and samples for the concomitant administration study were assessed.

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 Ramachandra S. Naik, Ph.D., at 301-796-2640.