

System Info - 119947 SMITH, MICHAEL J 12-Feb-2010 16:45:43 SMITHM

RECORD OF TELEPHONE CONVERSATION

Submission Type: Original Application Submission ID: 125324/0 Office: OVR

Product:

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Applicant:

Wyeth Pharmaceuticals Inc.

Telecon Date/Time: 07-JAN-2010 02:01 PM

Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

Information Request

Author: MICHAEL SMITH

Telecon Summary:

E-mail: Initial version of CMC PMC's sent to Wyeth for review and initial comments from Wyeth

FDA Participants: Julie Vaillancourt and Mike Smith

Non-FDA Participants: Carmel Devlin and Jack Love

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

*E-mail:*

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**From:** Love Jack [mailto:LOVEJ@wyeth.com]  
**Sent:** Thursday, January 07, 2010 2:01 PM  
**To:** Vaillancourt, Julianne; Smith, Michael (CBER)  
**Cc:** Devlin Carmel  
**Subject:** RE: CMC PMC's

Mike,

Can you send me the Word version of this so that it will facilitate my follow-on commitment letter? We are reviewing these now, and I can tell you that the spec for ---(b)(4)- is too high and we would already have a lot in failure on stability that is in the commercial lots designated for the US market. We have agreed to (b)(4)% with Canada and the EU, which is pretty close to the (b)(4)% in your letter.

The majority look fine. In my note to the BLA, I stated that we would need a follow-up meeting with CBER in the first quarter of 2010 to develop a plan for additional assay validation. In these commitments from CBER, there are a number of validation requirements including items we had not previously discussed. These generally look acceptable, but does this include all of the post-approval validation requirements from Rajesh such that we will not need the follow-up meeting in the next few months? Also, I should have the responses to the request you sent on Dec 16th by tomorrow.

After we review the rest in more detail, what is the best approach, to call you and Julie and go over any concerns?

Jack

>>> "Smith, Michael (CBER)" <Michael.Smith2@fda.hhs.gov> 1/7/2010 11:06 AM >>>

Jack and Carmel,

I attached the CMC PMC's as a PDF, please review this list and contact us if you identify anything requiring clarification. We request that you submit an amendment to your BLA with your written agreement to fulfill these commitments, each of which should be stated individually.

Thanks,

Mike

<<Wyeth 125324PMC\_DBPAP\_DPQ final.pdf>>

Mike Smith, Ph.D.  
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Regulatory Project Manager  
Division of Vaccines and Related Products Applications  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research  
U.S. Food and Drug Administration

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Below is the content of the attachment contained in the initial E-mail to Wyeth:



**FOOD AND DRUG ADMINISTRATION**  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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MEMORANDUM

**Date:** January 7, 2010

**To:** Jack Love, Ph.D, Assistant Vice President,  
Vaccine Regulatory Affairs,  
Wyeth Pharmaceuticals Inc

Carmel Devlin, Director,  
Vaccine Regulatory Affairs,  
Wyeth Pharmaceuticals Inc.

**From:** Mike Smith, Ph.D., Regulatory Coordinator, Division of Vaccines and  
Related Products Applications (DVRPA), Office of Vaccines and  
Research and Review (OVRR)

Julienne Vaillancourt, R.Ph., M.P.H., BLA Chair  
DVRPA, OVRR

**Subject:** BLA 125324: CMC Postmarketing Commitments

**Cc:** Norman Baylor, Ph.D., Director, OVRR  
Marion Gruber, Ph.D., Deputy Director, OVRR  
John Cipollo, Ph.D., Primary CMC Reviewer, Laboratory of Bacterial  
Polysaccharides (LBP), Division of Bacterial, Parasitic and  
Allergenic Products (DBPAP), OVRR  
Willie Vann, Ph.D., CMC Reviewer and Chief, LBP, DBPAP  
Milan Blake, Ph.D., Director DBPAP, OVRR  
Rajesh Gupta, Ph.D., Deputy Director, Division of Product Quality  
(DPQ), OVRR  
William McCormick, Ph.D., Director, DPQ, OVRR

Provided below is a complete list of the expected CMC postmarketing commitments pending licensure of Prevnar 13. These PMCs pertain to various CMC issues, which were identified during the course of the review of your BLA and are indicated as italicized sub-headings below. The draft PMCs listed below are a result of communications with you to date. Please review this list and contact us, if you identify anything requiring clarification. We request that you submit an amendment to your BLA with your written agreement to fulfill these commitments, each of which should be stated individually.

**CMC Post Marketing Commitments for Prevnar 13**

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5 pages determined not to be releasable: (b)(4)