

System Info - 119760 SMITH, MICHAEL J 08-Feb-2010 14:47:54 SMITHM

RECORD OF TELEPHONE CONVERSATION

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

Product:

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Applicant:

Wyeth Pharmaceuticals Inc.

Telecon Date/Time: 08-FEB-2010 01:58 PM

Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

Information Request

Author: MICHAEL SMITH

Telecon Summary:

E-mail: Revised CMC PMC's sent to Wyeth for review

FDA Participants: Julie Vaillancourt and Mike Smith

Non-FDA Participants: Jack Love and Carmel Devlin

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

E-mail:

From: Smith, Michael (CBER)
Sent: Monday, February 08, 2010 1:58 PM
To: 'Love Jack'; Devlin Carmel
Cc: Vaillancourt, Julianne
Subject: RE: Revised CMC PMC's

Jack and Carmel,

I attached the revised CMC PMC's, 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

- There is a MS Word version attached to the PDF version.



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PMC's 2-8-10 fi...

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Regulatory Project Manager
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Word version of attached document:



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

Date: February 8, 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 Project Manager,
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: Revised CMC Postmarketing Commitments

Cc:

Norman Baylor, Ph.D., Director, OVRR
Marion Gruber, Ph.D., Deputy Director, OVRR
Philip Krause, M.D., Associate Director for Medical Policy and Vaccine
Safety
Erik Henschel, Ph.D., Associate Director for Management and Scientific
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John Cipollo, Ph.D., Primary CMC Reviewer, Laboratory of Bacterial
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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
Tina Roecklein, Regulatory Coordinator, DBPAP

Karen Campbell, Regulatory Coordinator, DPQ

CMC Post Marketing Commitments for Prevnar 13

Provided below is a revised list of the expected CMC postmarketing commitments, based on the January 22, 2010, face-to-face meeting with you, pending licensure of Prevnar 13. 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.

(b)(4)



Pages 1 through 9 redacted for the following reasons:

(b)(4)