

System Info - 120489 SMITH, MICHAEL J 18-Feb-2010 16:44:46 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: 18-FEB-2010 12:00 AM

Initiated by FDA? Yes

Telephone Number: 877-213-9444

Communication Category(ies):

Information Request

Author: MICHAEL SMITH

Telecon Summary:

Discussion regarding 1) additional CMC PMC, 2) request for revised Lot Release Protocol and 3) request for CMC specification document that was originally E-mailed to Julie Vaillancourt on 9-30-09, all three items should be submitted to the BLA

FDA Participants: Willie Vann, Tina Roecklein, Colleen Sweeney, and Mike Smith

Non-FDA Participants: Jack Love, Barry Caplan Kathy Kofsky

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

CBER discussed the following with Wyeth: the need for an additional CMC PMC regarding revised specifications, a revised Lot Release Protocol (LRP) for the 10 lots already submitted to CBER, this will also be used on subsequent lots until a another revised LRP is submitted to CBER (expected before the end of March 2010) and a document regarding CMC specifications that was originally E-mailed to Julie

Vaillancourt on 9-30-09. It was agreed upon that all three of these requests will be officially submitted to the BLA as one amendment pre-approval.

Subsequent to the telecon at 11:30, Tina Roecklein E-mailed Jack Love at 12:53 PM, the main points of the E-mail are as follows:

Hi Jack -

Attached are revisions to the additional CMC PMC to tighten specs. Please submit this PMC, the 9/30/09 document, and a copy of the current Lot Release Protocol in one submission. Thanks.

Tina Roecklein, M.S.
Consumer Safety Officer
DBPAP/OVRR/CBER/FDA
Tel: (301) 827-3026
Fax: (301) 402-2776

There was an attachment to the E-mail containing the additional CMC PMC from CBER's perspective:

Wyeth commits to revise the specifications for ^{(b)(4)} [REDACTED] drug substances, and drug product as needed to be the same as those submitted in this amendment. In every case where a specification will be changed at this time, the revised specification will be to a tighter range than currently shown in the BLA. All documentation and specification revisions will be submitted as one or more CBE-0 supplements on or before the end of March 2010. All lots of Prevnar 13 will be released according to the specifications provided in the Lot Release Protocol submitted in this amendment.