**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: 12-Jun-2014 10:00 AM  Initiated by FDA? Yes

Telephone Number: 866-453-8391

Communication Categorie(s):
1. Other - Discussion of comments in the 11-June-2014 IR

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Telecon Summary:
Summary of discussion between CBER and Pfizer about the 11-June-2014 IR regarding the called-out 820s for combination products

FDA Participants (CBER):
Nancy Waites
Drusilla Burns
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Non-FDA Participants (Pfizer):
Parag Kolhe, MnB DP Development Lead, Pharmaceutical Research and Development, Biotherapeutics
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Zhaowei Jin, Pharmaceutical Research and Development, Biotherapeutics
Maria McCaffery, Quality Operations at ---(b)(4)--- site
Marian McNally, Quality Control Supervisor at ---(b)(4)--- site
Jim Balun, Regulatory CMC Device Lead

Michael Jordan, Regulatory CMC at ---(b)(4)--- site
Sue Leander, MnB Co-Development Team Leader
Claire Roche, Regulatory CMC MnB DP Lead
Katherine Arch-Douglas, Regulatory MnB CMC Lead
Carmel Devlin, MnB Worldwide Regulatory Lead

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

A teleconference was held between CBER and Pfizer to discuss the information request emailed to Pfizer on 11-June-2014 regarding the called-out 820s for combination products. Nancy Waites led the discussion for CBER and Carmel Devlin was the primary spokesperson for Pfizer.

The comments forwarded to Pfizer in the 11-June-2014 IR are provided below followed by a summary of the discussion of each comment. A new information request was made by CBER during the t-con and is included below as item #6.

1. *In the e-mail from Carmen Devlin to Michael Smith of May 28, 2014, Pfizer indicated that it would be submitting the following three documents to the BLA regarding the agency request for risk management and use risk assessments:*

   a. *Prevnar 13 user compliant data analysis report*
   b. *Risk Management Plan*
   c. *Risk Management Summary Report*

   *It will not be necessary to submit those documents to the BLA since the summary information that you provide in the BLA as well as documentation that will be reviewed on inspection is expected to cover most aspects of these issues. The only additional information that will be needed in the BLA at this time is indicated below.*

   Discussion: CBER stated that the information submitted to the application in Section 3.2.P.2.4.7 provided a summary of the steps Pfizer was performing to ensure they were complying with the called-out 820s for combination products. Pfizer stated that they will continue working on the documents listed above and complete them by the dates proposed in their 28 May 2014 e-mail; however, Pfizer agreed not submit the documents to the application, but instead make them available upon request if needed.

2. *Please submit to the BLA any Extractable/Leachable (E/L) studies or data that you may have for the container/closure.*

Discussion: CBER was unclear what E/L data needed to be submitted since extractable studies have been performed on the stoppers and leachable studies are on-going for final product manufactured at (b)(4). Per Pfizer, the drug product manufactured at (b)(4) is equivalent to the commercial drug product manufactured at ----(b)(4)----. It is filled in the same syringes and uses the same stopper as the commercial drug product. Pfizer noted that information for the (b)(4) stability studies is provided in the application in Section 3.2.P.2.4. The application also includes 24 months of stability data and a comparison between the ----------(b)(4)---------- drug product. Pfizer stated that the E/L information that was proposed to be submitted in October would have consisted of the information currently in the application with an additional testing time point and a written summary of the E/L testing. Since no new information for E/L would have been submitted in October, it was agreed that Pfizer did not need to submit the E/L summary and CBER would review the information already submitted to the application.

3. *Please submit the method validation studies for your container closure integrity test (CCIT) performed on the final product syringes. This would include a description of the positive and negative controls used, sensitivity of the ----------(b)(4)--- test, description of test parameters, etc.*

See discussion after item #5.

4. *Please submit testing validation for the CCIT performed on the filled syringes.*

See discussion after item #5.

5. *Pfizer proposes to use CCIT testing in lieu of sterility testing during stability. Please indicate if the ---(b)(4)--- test was validated using product filled syringes. If product filled syringes were not used for method validation, please provide a comparison between what was used to validate the test method and the product filled syringe. Lastly, please provide your rationale for the equivalence between the two.*

Discussion for items 3, 4 and 5: Pfizer previously provided a high-level summary of the CCIT. CBER requested more detailed information for the method validation of the testing performed. Pfizer noted that information on CCIT was submitted to the application in Section 3.2.P.5.2 and Section 3.2.P.5.3 (testing validation and verification reports), but they would submit an additional Method Validation summary for CCIT, which would likely cover the additional topics CBER inquired about. CBER agreed to review the information currently in the application, along with the additional report to be submitted, and let Pfizer know if any more information is need.

Pfizer stated that CCIT using the ---(b)(4)--- method has been performed on syringes filled with final product.

6. *Please provide a description of the functionality testing performed on the syringes.*

Discussion: Pfizer indicated that the description of the functionality testing performed on the syringes is included in the application in the "Design and Development" section. CBER stated the information in the section would be reviewed.