Record of Telephone Conversation, August 18, 2014 - TRUMENBA

Submission Type: BLA
Submission ID: 125549/0
Office: OVRR
Product: Meningococcal Group B Vaccine
Applicant: Wyeth Pharmaceuticals Inc.
Telecon Date/Time: 18-Aug-2014 10:12 AM
Initiated by FDA? Yes
Telephone Number: Communication Categorie(s): 1. Advice
Author: MICHAEL SMITH
Telecon Summary: Advice provided to the sponsor regarding REACTOG and REACTGEN data sets.
FDA Participants: None
Non-FDA Participants: None
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body: See e-mail below:

From: Smith, Michael (CBER)
Sent: Monday, August 18, 2014 10:12 AM
To: Devlin, Carmel; 'Boyce, Donna'
Cc: Garnett, Theodore; Naik, Ramachandra; Burns, Drusilla L.
Subject: RE: STN 125549/0 IR regarding statistical analyses on safety and immunogenicity

Carmel and Donna,

The explanation provided in your e-mail below sufficiently clarified our information request (IR) regarding the REACTOG and REACTGEN data sets. Therefore, we do not need you to provide additional datasets at this time. Please submit your responses to our 8/8/14 IR's in an amendment to your BLA and include the information provided in your e-mail below in your response to our item 1.

Regards,
Mike

From: Boyce, Donna [mailto:Donna.Boyce@pfizer.com]
Sent: Monday, August 11, 2014 2:10 PM
To: Naik, Ramachandra
Cc: Edwards, Elizabeth; Devlin, Carmel; Smith, Michael (CBER); Garnett, Theodore
Subject: RE: STN 125549/0 IR regarding statistical analyses on safety and immunogenicity

Dear Ramachandra,
Pfizer requests clarification regarding CBER's Question 1 in the August 8th Information Request.
Our specific question is provided below. CBER's written feedback is requested or we would be happy to discuss via teleconference at CBER's convenience.
Thanks
Donna

1. **The SAS datasets REACTGEN and REACTOG were not submitted for each individual study. Please submit these datasets for statistical analyses.**

Pfizer seeks clarification on the request for both REACTGEN and REACTOG reactogenicity datasets for individual studies, in consideration of the naming conventions provided below. REACTGEN and REACTOG datasets are each intended to serve the same purpose, which is to represent data for each individual study (and ISS), as follows:

- REACTOG dataset name was used for the first three studies (B1971003, B1971004, B1971005), representing a common data collection standard they shared.
- REACTGEN dataset name was used on the remaining studies per their common standard.
- REACTGEN dataset name was used for the ISS and brings together as one standard. This dataset also features collapsing of individual study's subject daily records.

Due to SAS transport file size requirements by CBER, some individual study REACTGEN datasets are split. The table below summarizes dataset names:

Study	Reactogenicity dataset name	Split due to Size? (Number of files)
B1971003	REACTOG	No
B1971004	REACTOG	No
B1971005	REACTOG	No
B1971010	REACTGE1,2,3,4	Yes (4)
B1971011	REACTGE1,2,3,4,5,6,7	Yes (7)
B1971012	REACTG01 – 11	Yes (11)
B1971042	REACTGEN	No
ISS (all 7)	REACTGEN	No

Can the Agency please clarify the request for reactogenicity datasets, based on the information above? Is the request to provide additional datasets for the three REACTOG studies to feature collapsed daily information, as is found in the REACTGEN datasets?

From: Naik, Ramachandra [mailto:Ramachandra.Naik@fda.hhs.gov]
Sent: Friday, August 8, 2014 2:55 PM
To: Boyce, Donna
Cc: Edwards, Elizabeth; Devlin, Carmel; Smith, Michael (CBER); Garnett, Theodore
Subject: STN 125549/0 IR regarding statistical analyses on safety and immunogenicity

Dear Ms. Boyce,

Attached is an information request regarding statistical analyses on safety and immunogenicity 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
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