Telecon - PVP for Menveo, August 10, 2009 - Menveo

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RECORD OF TELEPHONE CONVERSATION

Submission Type: Original Application Submission ID: 125300/0 Office: OVRR
Product:
Meningococcal ACWY Conjugate Vaccine
Applicant:
Novartis Vaccines and Diagnostics, Inc.
Telecon Date/Time: 10-AUG-2009 09:49 AM Initiated by FDA? Yes
Telephone Number:
Communication Categorie(s):
1. Advice
2. Information Request
Author: CARA FIORE
Telecon Summary:
PVP for Menveo; See EDR for details
FDA Participants:
Non-FDA Participants:
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:
From: Fiore, Cara
Sent: Monday, August 10, 2009 9:49 AM
To: 'christopher.webster@novartis.com'
Cc: Valenti, Elizabeth
Subject: PVP for Menveo
Hi Chris,
Please see comments below for your pharmacovigilance plan.

In general, we concur with the use of a self-controlled case series method for evaluating post-marketing adverse events after MenACWY. When you submit your protocol for CBER review, please address the following comments:

1. Please propose clinically meaningful (recognizing power constraints) endpoints/criteria for evaluating each EOI and EOI grouping (e.g., the lower bound of the 95% confidence interval for relative incidence (risk/control interval) is $\leq$ 1.00).
2. Please clarify your plans for analyzing individual EOIs within an EOI group (e.g., encephalitis within the new onset neurological events grouping).
3. Please specify the timeframe for risk and control intervals for each EOI.
4. Please clarify the risk interval duration definition (e.g., time from vaccination to onset of the first symptom related to the specific EOI).

5. Please comment on how a new suspected EOI (i.e., not included in the initial protocol) could be evaluated using the same study framework.
6. Please comment on how you would evaluate safety in ages outside of the inclusion criterion age range of 11-19 years if the Advisory Committee on Immunization Practices expands the recommended age for routinely receiving meningococcal conjugate vaccine.
7. Please propose a deadline for submission of the final study report.
8. Please provide interim study reports at least annually within each annual periodic adverse experience report (PAER) until the final study report is submitted to CBER.
9. Please specify procedures and thresholds for early analysis and reporting to CBER (e.g., for a serious unexpected adverse event with a high relative incidence).

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