Record of Telephone Conversation, July 10, 2014 - GARDASIL 9

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125508/0 Office: OVRR

Product: Human Papillomavirus 9-valent Vaccine, Recombinant

Applicant: Merck Sharp & Dohme Corp.

Telecon Date/Time: 10-Jul-2014 04:00 PM Initiated by FDA? Yes

Telephone Number: 800-857-9860

Communication Categories: 1. Advice
2. Information Request

Author: JEREMY WALLY

Telecon Summary: Discussion of Autoclave Validation Developmental Data and Performance Qualification Protocols

FDA Participants: Jeremy Wally, Marion Michaelis, Laura Montague

Non-FDA Participants: Navdip Ghai, Cathy Hoath, William M. Rankin, William H. Dodge, Allison L. Fischer, David Boscher, John T. Krincek, Sean Fadden

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body: A telecon was requested by DMPQ and the following issues were discussed:

- Regarding developmental studies completed in -----(b)(4)-----,
  - Merck confirm that mock BIs were not used.
  - In the table of results for the (b)(4) Load Pattern (page 24 of 70), it states in the rationale that “no data collected by logger” but data for this logger is presented in the table. Merck clarified that this is a typographical error (see email below).

- Merck confirmed that studies 9-3604B-P26 and 9-3604B-P27 for the (b)(4) Load Pattern were conducted using -(b)(4)- and that ---(b)(4)--- ----------(b)(4)---------- (see email below).

- Regarding the protocols for the PQ studies planned in ----------(b)(4)----------,

- Merck provide a justification for the evaluation criterion for validation -----(b)(4)----- cycles (----------(b)(4)----------) and stated that this is based upon ----------(b)(4)----------. DMPQ found the justification to be acceptable.

- Merck provided a justification of the differences in the lists of required initial validation studies planned that are planned to be conducted in --------(b)(4)--------, as it appears that a less comprehensive set of studies are planned to be conducted in ----(b)(4)----, stating that the difference were based upon the commitment in their previous PQ protocols to perform additional runs in ----(b)(4)---- compared to what was planned in ----(b)(4)----. DMPQ stated that their current plan is acceptable.

- DMPQ stated that we have had further discussions, both internally and externally within FDA, regarding the need to perform cycles with ----------(b)(4)---------- and have determined that this is no longer required. Merck stated that since they are set-up to run the -----(b)(4)---------- they plan to run them. DMPQ agreed with this plan and noted that the complete autoclave cycle in the production SOP should match the cycle used during validation. Merck acknowledged this comment.

  The following email was received after the telecon:

  From: Ghai, Navdip [mailto:navdip.ghai@merck.com]
  Sent: Friday, July 11, 2014 3:57 PM
  To: Wally, Jeremy; Montague, Laura; Michaelis, Marion
  Subject: BLA 125508/00

  Hello everyone,

  We have prepared responses to the two questions that were not fully answered during our teleconference yesterday. Please see attached document.

  To summarize;

  1. The note about “no data collected for logger” in the table on page 24 was a typographical error. Data was collected and data summary sheet from the specific logger is attached to the response.

  2. Studies 9-3604B-P26 and 9-3604B-P27 were --(b)(4)-- studies. There were fewer test locations in the second study since a different configuration of a ----(b)(4)---- needed to be tested. Load diagram with test locations for both studies is attached to the response.

Please expect the attached response to also come to you through the gateway by early next week.

Have a pleasant weekend.

Regards,
Navdip Ghai
Regulatory Affairs, Vaccines CMC
(215)652-4170
WP37A-104

Attachment: