

Information Request Email, April 7, 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: 07-Apr-2014 10:13 AM Initiated by FDA? Yes

Telephone Number: Email

Communication Category(ies): 1. Information Request

Author: BHARAT KHURANA

Telecon Summary: Regarding assay performance and validation reports for the assays to quantitate antibody to the diphtheria, tetanus, pertussis and meningococcal antigens.

FDA Participants: Bharat Khurana

Non-FDA Participants: Alison Fisher, Merck

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

The following email was forwarded to the sponsor:

From: Khurana, Bharat

Sent: Monday, April 07, 2014 10:13 AM

To: alison_fisher@merck.com

Subject: STN 125508/0; Information Request #4

Dear Alison:

As we review STN 125508/0, CBER would like to request the following information:

1. Please provide the complete validation reports for the assays to quantitate antibody to the diphtheria, tetanus, pertussis and meningococcal antigens.
2. Please provide data that support the continued assay performance since validation and through the testing of the samples from Protocol 005.

We request that you submit the requested information as an amendment to the BLA as soon as possible but not later than April 21, 2014. In your responses, please identify this information request by date and include comment numbers.

If you have any questions, please feel free to contact Ms. Laura Montague or myself at (301) 796-2640.

Thank you, Bharat

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