

Information Request Email, March 12, 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: 12-Mar-2014 12:14 PM Initiated by FDA? Yes

Telephone Number: Email

Communication Category(ies): 1. Information Request

Author: BHARAT KHURANA

Telecon Summary: Clinical Information Request regarding graphical analysis, location of datasets and subjects whose temperatures were converted from axillary or rectal temperature.

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: Wednesday, March 12, 2014 12:14 PM

To: 'Fisher, Alison L'

Cc: Montague, Laura

Subject: STN 125508/0; Information Request #2

Dear Alison,

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

1. Per the protocols of Study V503-001 and -002, oral temperature was recorded on Day 1-5 after each vaccination. However, analyses were performed based on oral temperature or oral equivalent temperature (converted from axillary or rectal temperature). Please provide information regarding the number and percentage of subjects whose temperatures were converted from axillary or rectal temperature.
2. Please provide a graphical analysis of the following:
 - a. Time-to-event curves of HPV 31, 33, 45, 52 and 58 related CIN2, VIN2, VaIN2 or worse in 9vHPV and qHPV vaccinated 16-26 year old women in All-HN population
 - b. Time-to-event curves of HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58 related CIN2, VIN2, VaIN2 or worse in 9vHPV and qHPV vaccinated 16-26 year old women in a) PPE, b) All-HN, c) HN-TS and d) FAS population
 - c. Time-to-event curves of CIN2, VIN2, VaIN2 or worse irrespective of HPV types in 9vHPV and qHPV vaccinated 16-26 year old women in All-HN and FAS population
 - d. Time-to-event curves of HPV 6, 11, 16 and 18-related persistent infection (≥ 6 months) in 9vHPV and qHPV vaccinated 16-26 year old women in a) PPE, b) All-

HN and c) FAS population.

e. Time-to-event curves of HPV 31, 33, 45, 52 and 58-related persistent infection (\geq 6 months) in 9vHPV and qHPV vaccinated 16-26 year old women in All-HN and FAS population

For d. and e. above, please ensure that the duration of persistent infection is strictly \geq 6 months.

3. Please provide the locations of the datasets that contain the data collected on the Vaccination Report Cards for all protocols.

We request that you submit the requested information as an amendment to the BLA as soon as possible. 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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