

Information Request Email, May 13, 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: 13-May-2014 11:21 AM **Initiated by FDA?** Yes

Telephone Number: Email

Communication Category(ies): 1. Information Request

Author: BHARAT KHURANA

Telecon Summary: Information Request #9: Non-clinical request RE: calculations used to derive the "rat doses equivalent to 160- 240 times the human dose."

FDA Participants: Bharat Khurana, Laura Montague

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: Tuesday, May 13, 2014 11:21 AM
To: alison_fisher@merck.com
Cc: Montague, Laura
Subject: STN 125508/0; Information Request #9

Dear Alison,

As review continues on STN 125508/0, we have the following question from our non-clinical reviewer:

Per your Draft Labeling Text (Module 1.14.1.3, draft Package Insert Section numbers 8.1 and 13.1), reproduction studies were performed in rats at doses up to 240 and 160 times the human dose on mg/kg basis and revealed no evidence of impaired fertility or harm to the fetus due to V503 study vaccine, Gardasil 9. Please provide details of the calculations used to derive the 'rat doses equivalent to 160-240 times the human dose.'

Please provide your response(s) to this information request as amendment(s) to the BLA as soon as possible. Please reference this information request by date and include comment/question numbers.

As always, Laura Montague and I are available if you have questions.

Thanks, Bharat

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