

Information Request Email, March 21, 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: 21-Mar-2014 03:31 PM Initiated by FDA? Yes

Telephone Number: Email

Communication Category(ies): 1. Information Request

Author: BHARAT KHURANA

Telecon Summary: BIMO request regarding clinical site of Dr. Frank Civitarese.

FDA Participants: Bharat Khurana

Non-FDA Participants: Alison Fisher and David Gutsch (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: Friday, March 21, 2014 3:31 PM

To: 'Fisher, Alison L'; Gutsch, David

Cc: Montague, Laura

Subject: STN 125508/0; Information Request #3

Dear Alison and David:

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

1. The FDA Form 1572 for Dr. Frank Civitarese. Also, let us know the clinic location where Dr. Civitarese is storing the study records.
2. The SOP for transfer of subjects from one site to another.

Thanks and have a great weekend,

Bharat Khurana

Bharat Khurana, DVM, PhD, MBA

Microbiologist (Regulatory)

Food and Drug Administration

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