Information Request Email, May 20, 2014 - GARDASIL 9

RECORD OF EMAIL COMMUNICATION
Submission Type: BLA Submission ID: 125508/0 Office: OVRR
Product: Human Papillomavirus 9-valent Vaccine, Recombinant
Applicant: Merck Sharp & Dohme Corp.
Telecon Date/Time: 20-May-2014 05:54 PM
Initiated by FDA? Yes
Telephone Number: N/A (email)
Communication Category: Information Request
Author: Laura Montague
Telecon Summary: IR #10 - requested (1) information regarding clinical site V503-001-(b)(4)(b)(6) and (2) clarification regarding LRPs
FDA Participants: Laura Montague
Non-FDA Participants: Alison Fisher
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:
From: Montague, Laura
Sent: Tuesday, May 20, 2014 5:54 PM
To: alison_fisher@merck.com
Cc: Khurana, Bharat
Subject: STN 125508/0; Information Request #10
Dear Alison,
We have the following information requests regarding your supplement 125508.

1. It has come to CBER's attention that issues were identified regarding non-compliance with Good Clinical Practice for an investigational product (not 9vHPV) being studied at the clinical site of ---------(b)(4)(b)(6)--- (V503-001-(b)(4)(b)(6)). In review of study V503-001, we note that 495 subjects/14215 subjects in V503-001 were vaccinated with the mid-dose 9vHPV vaccine or qHPV at this site (3.48% of subjects).
   (a) Please indicate whether Merck has conducted an internal audit of site V503-001-(b)(4)(b)(6) for protocol V503-001 or whether an internal audit is planned.
   (b) If an internal audit has not been conducted, please provide an assessment of feasibility of conducting such an audit within the time frame of the review of STN 125508.
2. Please clarify how you intend to submit the lot release protocols for bulks of the original 4 HPV types in Gardasil. Will you be submitting to 125126 or 122508, or both?

Thank you,
Laura Montague
Regulatory Project Manager

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