

# Audit Report Request Email, August 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-Aug-2014 12:50 PM

Initiated by FDA? Yes

Telephone Number: N/A (email)

Communication Categories: Information Request

Author: Laura Montague

Telecon Summary: Follow-up to IR #10 – Request for audit report

FDA Participants: Laura Montague, Bharat Khurana

Non-FDA Participants: Alison Fisher

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

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From: Montague, Laura

Sent: Wednesday, August 20, 2014 12:50 PM

To: alison\_fisher@merck.com

Cc: Khurana, Bharat

Subject: Follow-up to IR #10

Dear Alison,

In amendment 18 of STN 125508, submitted June 12, 2014, Merck indicated an intention to conduct an internal audit of (b)(4)(b)(6) site for the V-503-001 study. Please submit a report of the audit's findings by August 31, 2014.

Thank you,

Laura Montague

Regulatory Project Manager

FDA/OMPT/CBER/OVRR

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