

Email Communication, November 5, 2014 - GARDASIL 9

From: Montague, Laura

To: alison_fisher@merck.com

Cc: Khurana, Bharat

Subject: Rationale behind decision regarding data from --(b)(3)(b)(4)(b)(7)--

Date: Wednesday, November 05, 2014 4:27:00 PM

Dear Alison,

CBER's decision to exclude data collected at V503-002 sites --(b)(3)(b)(4)(b)(7)-- was due to irregularities with the informed Consent process and documentation, as well as discrepancies and inconsistencies related to Vaccination Report Cards.

Thank you,

Laura

Laura Montague

Regulatory Project Manager

FDA/OMPT/CBER/OVRR

Division of Vaccines and Related Products Applications

WO71-3019

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