

Email Communication, October 31, 2014 - GARDASIL 9

From: Montague, Laura

To: alison_fisher@merck.com

Cc: Khurana, Bharat

Subject: Information regarding data from sites in -----(b)(3)(b)(4)(b)(7)-----

Date: Friday, October 31, 2014 2:38:53 PM

Dear Alison,

Thank you for the information Merck has provided regarding the collection of data at clinical sites V503-002----- (b)(3)(b)(4)(b)(7)-----, and site V503-001--(b)(4)(b)(6)--. The information you provided in response to our information requests regarding site V503-001----(b)(4)(b)(6)-- - has adequately addressed our concerns related to GCP at that site.

However, CBER has concluded that it is not appropriate to include data from V503-002 sites ----- (b)(3)(b)(4)(b)(7)-- to inform a regulatory decision. Therefore, CBER will be requesting that information presented in the proposed package insert be revised to exclude data collected at the two sites in (b)(3)(b)(4)(b)(7). CBER's specific requests regarding revisions that will need to be made to the package insert will be conveyed to Merck as soon as possible, but no later than November 10, 2014. For the purposes of our reviews, CBER may also request that specific tables submitted in the BLA be revised as well. We are discussing this internally, and if necessary, we will provide specific requests as soon as possible.

Please be assured that CBER continues to work toward an action date of December 10, 2014.

As always, if you have any questions, please feel free to call me or Dr. Bharat Khurana at (301)796-2640.

Thank you,

Laura

Laura Montague

Regulatory Project Manager

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WO71-3019

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