

Information Request Email, November 24, 2014 - GARDASIL 9

From: Montague, Laura

To: alison_fisher@merck.com

Cc: Khurana, Bharat; Rankin, _William M. (RAS-B) (william_rankin@merck.com)

Subject: IR #20 - STN 125508/0 (re LRP templates)

Date: Monday, November 24, 2014 4:57:11 PM

Dear Alison and Bill,

Please submit the final lot release protocol template for the new (b)(4) to the BLA by December 1, 2014. The template you used for the completed LRPs was fine, and we have no requests to revise it.

Thank you,

Laura Montague

Regulatory Project Manager

FDA/OMPT/CBER/OVRR

Division of Vaccines and Related Products Applications

WO71-3019

10903 New Hampshire Ave Silver Spring, MD 20993-0002 phone: (301)796 -2640

fax: (301)595 -1244

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