

Record of Email Communication, Late Cycle Memo, August 28, 2014 - GARDASIL 9

RECORD OF EMAIL COMMUNICATION

Submission Type: BLA Submission ID: 125508/0 Office: OVRP
Product: Human Papillomavirus 9-valent Vaccine, Recombinant
Applicant: Merck Sharp & Dohme Corp.
Telecon Date/Time: 28-Aug-2014 4:32 PM
Initiated by FDA? Yes
Telephone Number: N/A (email)
Communication Categories: Other (Late Cycle Memo)
Author: Laura Montague
Telecon Summary: Late cycle memo sent to sponsor
FDA Participants: Laura Montague, Bharat Khurana
Non-FDA Participants: Alison Fisher
Trans-BLA Group: No
Related STNs: None
Related PMCs: None
Telecon Body:

From: Montague, Laura
Sent: Thursday, August 28, 2014 4:32 PM
To: alison_fisher@merck.com
Cc: Khurana, Bharat
Subject: Late Cycle Memo

Dear Alison,
Our Late Cycle Memo is attached. Note that we would like your input regarding agenda items by September 4. However, if topics arise closer to the Late Cycle meeting, they can be included in the discussion at the meeting.

Thanks, and we look forward to hearing from you,
Laura - and Bharat

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(Attachment included in email follows)