

Record of Email Communication, September 8, 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: 8-Sep-2014 1:50 PM
Initiated by FDA? Yes
Telephone Number: N/A (email)
Communication Categories: Other (Late Cycle Agenda)
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: Monday, September 08, 2014 1:50 PM
To: alison_fisher@merck.com
Cc: Khurana, Bharat
Subject: Late Cycle Meeting agenda

Dear Alison,
Attached is the meeting agenda for tomorrow's Late Cycle Meeting for STN 125508.

Thanks,
Laura

Laura Montague
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FDA/OMPT/CBER/OVRR
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(Attachment included in email follows)