

# Record of Telephone Conversation, November 6, 2014 - GARDASIL 9

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125508/0 Office: OVRR

Product: Human Papillomavirus 9-valent Vaccine, Recombinant

Applicant: Merck Sharp & Dohme Corp.

Telecon Date/Time: 06-Nov-2014 11:00 AM

Initiated by FDA? Yes

Telephone Number: 888-664-9854 -----(b)(4)-----

Communication Category: Advice

Author: LAURA MONTAGUE

Telecon Summary: Clarifications related to facility issues

FDA Participants: Marion Michaelis

Laura Montague

Haru Murata

Jeremy Wally

Non-FDA Participants: Navdip Ghai

Alison Fisher

William M. Rankin

William H. Dodge

Paul Kolosick

Amit Bhatt

Andrew R. Wellen

Sean Fadden

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

### Background:

CBER requested this telecon with Merck to clarify some final issues related to the sterilization validations of autoclaves in ---(b)(4)---.

### Telecon Body:

CBER noted that Merck has provided sterilization validation data for autoclaves -----(b)(4)---, and not for autoclave -----(b)(4)----- . CBER asked Merck to clarify their plans for sterilization validation data autoclave (b)(4). Merck stated that they are only seeking approval for autoclaves -----(b)(4)----- under this BLA. CBER asked that Merck submit an amendment to the 125508 BLA stating directly Merck is not seeking approval of (b)(4), and that approval of the BLA would only include approval of autoclaves -----(b)(4)----- . Merck stated that they will do so. CBER followed by asking Merck their plans for submission of sterilization validation data for autoclave (b)(4), and Merck stated that they have no concrete plans at this time.

CBER stated that they will follow up regarding the missing validation data for cleaning of HPV Type 58 from the -----(b)(4)----- during the next inspection. Merck acknowledged CBER's statement. The telecon ended.