Record of Telephone Conversation, May 14, 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: 14-May-2014 04:00 PM Initiated by FDA? Yes

Telephone Number: 215-652-8102

Communication Categorie(s): 1. Other - Discussion of Emailed Strategy

Author: Jeremy Wally

Telecon Summary: Discussion of Strategy to Validate New Autoclave Load Patterns

FDA Participants: Marion Michaelis

Non-FDA Participants: Cathy Hoath

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body: The following email was received from the firm on May 9, 2014:

From: Hoath, Cathy [mailto:cathy_hoath@merck.com]
Sent: Friday, May 09, 2014 2:59 PM
To: Michaelis, Marion; Huang, Ellen (CBER); Schmidt, Jennifer
Subject: Merck STN 125508/0

Good afternoon!

Thank you for discussing the strategy for generating additional data to support our BLA for 9-Valent Human Papillomavirus (STN 125508/0) in light of 2 Complete Response Letters received for autoclave sterilization in March for the same autoclaves used for the new product. When we spoke last Thursday, I mentioned that we were planning to consolidate some of the many loads we validated over the past year, to operate more efficiently. Our plan was to use --(b)(4)-- loads, discussed during our February 2013

Type C Meeting, rather than (b)(4) loads in our --(b)(4)-- autoclaves. Since then, it has been determined that we will use ----------(b)(4)----------. Testing will be performed to determine whether there is a worst case configuration prior to qualification.

Although our autoclave qualification approach is now more standard since we are using ----------(b)(4)----------, on time approval of this BLA is important to us, so we would still like to submit an amendment to confirm that our study designs meet expectations prior to execution. Developmental data and the protocols for both the ----------(b)(4)---------- will be available on June 9th. If we submit this information on approximately June 9th, would it be possible for it to be reviewed in about a week? Our goal is to submit final reports from the Performance Qualification testing to you as soon as possible prior to the December 10th PDUFA date.

Cathy Hoath
Director, Vaccines and Biologics CMC
Merck Sharp & Dohme Corp.
215-652-8102

The firm was telephoned on May 14, 2014, in response to this email and CBER indicated that their approach is acceptable. CBER further noted that we would try to review what they submit for their development work within one week, but could not guarantee that the one week time frame could be met. CBER acknowledged that Merck would like feedback within a short time so that they could execute their studies.