

## RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA

Submission ID: 125592

Office: OVR

Product: House Dust Mite Allergen extract

Applicant: Merck Sharp & Dohme Corp.

Telecon Date/Time: June 23, 2016 10:00 AM

Initiated by FDA? No

Telephone Number: +1 (443) 961-0100 US Toll

Communication Category(ies): Other (Assay Transfer)

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### **Telecon Summary:**

Discussion and information exchange to initiate transfer of lot release potency assay (b) (4) for lot testing.

### **FDA Participants:**

Jennifer Bridgewater DBPAP, OVR

Taruna Khurana DVRPA, OVR

Aaron Chen DBPAP, OVR

Ekaterina Dobrovolskaia DBPAP, OVR

### **Non-FDA Participants:**

Merck

Colleen Godshall, Associate Director, GRA Biologics CMC

Mirko Bollen, Associate Principal Scientist, Analytical Development and Validations

(b) (4)

### **Telecon Body:**

Prior to the scheduled telecon the Applicant shared multiple documents related to (b) (4) [redacted]. This assay is used to measure potency of the finished product. The Applicant indicated the equipment, general reagents, and critical reagents needed to run the assay. The Applicant will provide all the critical reagents except (b) (4) [redacted] that Laboratory of Immunobiochemistry (LIB) can purchase from (b) (4). The Agency inquired about HDM DP control and the Applicant clarified that this is 12 DU tablet that is used at high and low concentrations during each run as system suitability test for the assay.

Applicant also shared contact information (emails and phone) of the personnel (b) (4) whom Lot testing lab (Laboratory of Immunobiochemistry) can directly approach for general questions related to the assay. There will be no need of a mediator from Merck for this purpose. The Agency indicated that email confidentiality is not guaranteed if the contact emails are not secure. (b) (4) will confirm the security of its emails.

The Applicant also stated that currently (b) (4) PPQ batches of the tablet are available, (b) (4) launch batches will be ready in November 2016, and (b) (4) commercial batches will be manufactured in 2017. The Applicant asked the Agency for the calculated amount of critical reagents needed for the lot release tests. The Agency clarified the general testing plan that is currently in place for other lot release tests and stated that the amount of reagents required by the Laboratory of Immunobiochemistry for the (b) (4) assay transfer will be discussed internally. The Agency inquired about the time frame needed for shipment of reagents. The Applicant explained that will take approximately 5 weeks to ship reagents to Agency's lot testing lab (LIB).

The Agency asked for any other recommendations about the assay transfer. The Applicant mentioned initial lab set up, number of analysts running the assay, number of runs per batch and comparing data for similarity between the Applicant and testing lab are but a few areas of concern. The Applicant offered to provide training to LIB in performing the (b) (4) assay. The Agency affirmed that there is no need for training at this time pending internal discussion regarding what type of assay transfer is expected.

The Applicant asked about the ideal time for launch batch testing as the launch samples can be provided between December 1 and December 15. The Agency indicated that we will talk about this as we get closer to shipping of reagents. The Applicant also asked about the location of reagents shipment. The Agency mentioned that the general process for shipment of lots and reagents for release and surveillance is through the Product Release Branch (PRB) in order to maintain the chain of custody and ensure proper shipping and storage conditions. It takes approximately 1-2 weeks for LIB to complete Lot Release Protocol review, and sample testing. The Agency will confer with PRB and inform the Applicant once confirmed.

The Applicant also mentioned that the reagents can be shipped sooner so that the lot testing lab can initiate the assay set up and prepare the lab for launch testing. The Agency agreed and stated this will be discussed internally.

Call ended at 11:00 AM