



MEMORANDUM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

RECORD OF TELEPHONE CONVERSATION

Submission Type: Submission ID: STN 125592/0

Product(s): House Dust Mite Allergen Extract

Applicant: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

Teleconference Date: July 25, 2016 Initiated by FDA? Yes

Telephone Number: 732-594-1021

Author: Joyce Rockwell

FDA Participants:

Joyce Rockwell, Consumer Safety Officer, OMPT/CBER/OCBQ/DMPQ/MRB1

Non-FDA Participants:

Nadine Margaretten, Ph.D., (Merck), Director Global Regulatory Affairs

Teleconference Purpose:

FDA contacted the Merck to request clarification and additional information pertaining to the first two paragraphs of the HDM BLA Module 2.4. Specifically,

1. Provide an update on the EU approval of Mitizax.
2. Provide more details about the product Alutard.

Teleconference Summary:

Dr. Margaretten understood the information request and agreed to submit an amendment with the requested information.

Call lasted less than 5 minutes.

Action Item:

Amendment 125592/0/22 was submitted on July 29, 2016 with the requested information.