

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125592/0.0
Review Office	OVRR
Applicant	Merck Sharp & Dohme Corp. / Lic. # 0002
Product	House Dust Mites Allergenics Extract
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	06-FEB-2017 02:09 PM
Author	STEELE, MATTHEW
EDR	No
Post to Web	Yes
Outside Phone Number	3017967777
FDA Originated?	Yes
Communication Categories	AD - Advice
Related STNs	None
Related PMCs	None
Telecon Summary	Discussion with Applicant about revised PMC proposal.
FDA Participants	See List, Below
Applicant Participants	See List, Below

Telecon Body:

FDA Ateendees:

LCDR Matthew Steele, PhD, RPM
Taruna Khurana, PhD, RPM
CAPT Colleen Sweeney, MS, Chair
Patricia Rohan, MD, Pharmacovigilance Reviewer

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Meghna Alimchandani, MD, PV Team Leader
Scott Proestel, MD, Director, Division of Epidemiology
Karen Farizo, MD, Associate Director for Medical Policy, OVR
Roshan Ramanathan, MD, Clinical Team Leader
Jennifer Bridgewater, MPH, Associate Director for Regulatory Policy, DBPAP
Wellington Sun, MD, Director, DVRPA
Jay Slater, MD, Director, DBPAP
Tatiana Claro del Silva, PhD
CAPT Jon Daugherty, PhD, Regulatory Branch Chief
Kathleen Hise, MD, Clinical Reviewer

Applicant Attendees:

ALK:

- Anne Lützhøft Aarboeg, M.Sc., MBA, Senior VP Global Regulatory Affairs
- Mette Schou-Hanssen, M.Sc., Manager Global Regulatory Affairs
- Jens Strodl Andersen, PhD, Senior Statistician, Biometrics, Global Clinical Development
- William B. Gray BS, BSMT, MSA, Director Regulatory Affairs
- Asger Bering Kristensen, M.Sc., Head of Clinical Project Management
- Veronica Hulstrøm, MD, PhD, Head of Safety Surveillance
- Bodil Svanholm Fogh, M.Sc., Drug Safety Advisor

Merck:

- Daniel Mines, M.D., MSCE, Executive Director, Pharmacoepidemiology, Center for Observational and Real-World Evidence
- Vinay Mehta, Ph.D., Sr. Prin. Scientist, Pharmacoepidemiology
- Hendrik Nolte, M.D., Ph.D., Executive Director, Clinical Research
- Nadine Margaretten, Ph.D., Director, Regulatory Affairs
- Shenouda, Andro, Pharm.D., M.S, Post-Doctoral Fellow, Regulatory Affairs
- English Dupree Willis, M.D., Executive Director, Clinical Safety and Risk Management

Purpose of Tcon: To discuss revisions to the PMC safety study

The applicant described their proposed revisions to the PMC (see summary appended below).

CBER appreciated the revisions made, but expressed some concerns about the proposed sample size of 3000 subjects. CBER requested that the sample size be increased to 10000 subjects. The applicant agreed.

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Additionally, CBER expressed concerns about the proposed final study protocol submission date of October 31, 2018. We strongly recommended that the applicant submit the final study protocol within 6 months of approval.

The applicant noted that the proposed dates were based on the logistical difficulties inherent in their plan to (b) (4) Merck (b) (4). Additionally, the (b) (4) noted this date was provisional. CBER acknowledged this response.

The applicant committed to submitting a revised description that would incorporate the revision to 10,000 subjects.