



MONTHLY COMMITTEE MEETING SUMMARY

Date and Time:	June 1, 2016
Location:	WO71 Rm 3244
Call-In Information:	301-796-7777
	Meeting ID: (b) (4)
STN #:	125592/0
Submission Type:	Biologics License Application (BLA)
Applicant:	Merck Sharp & Dohme
Product:	House Dust Mite (<i>Dermatophagoides pteronyssinus</i> and <i>Dermatophagoides farinae</i>) Allergen Extract
Meeting Chair:	CAPT Colleen Sweeney, MSN
Meeting Recorder:	LCDR Matt Steele, Ph.D./Taruna Khurana, Ph.D.

CBER/FDA Attendees

- LCDR Matthew Steele, Ph.D. CBER/OVRR/DVRPA
- Taruna Khurana, Ph.D., CBER/OVRR/DVRPA
- CAPT Colleen Sweeney, RN, M.S. CBER/OVRR/DVRPA
- Colonious King B.S., CBER/OCBQ/DIS
- Zhong Gao, Ph.D., CBER/OBE/DB
- Elizabeth Teeple, Ph.D., CBER/OBE/DB
- Patricia Rohan, M.D., CBER/OBE/DE
- Kathleen Hise, M.D., CBER/OVRR/DVRPA
- Roshan Ramanathan, M.D., CBER/OVRR/DVRPA
- Jeff Roberts, M.D., CBER/OVRR/DVRPA
- David Schwab M.S., CBER/OVRR/DVRPA
- Oluchi Elekwachi, Pharm.D., M.P.H., CBER/OCBQ/DCM
- Joe Sun, Ph.D., CBER/OVRR/DVRPA
- Nabil Al-Humadi Ph.D., CBER/OVRR/DVRPA
- Cheryl Hulme CSO, CBER/OCBQ/DMPQ
- Joyce Rockwell, CBER/OCBQ/DMPQ
- CAPT Jon Daugherty, Ph.D., CBER/OVRR/DVRPA
- Jay Slater M.D., Director, CBER/OVRR/DBPAP
- Ronald Rabin M.D., CBER/OVRR/DBPAP
- Lisa L Stockbridge, Ph.D., CBER/OCBQ/DCM

Review Committee

Committee Member	Review Role	Module Assignment
Reviewer: CAPT Colleen Sweeney, R.N., M.S.	Chair	All Modules

Committee Member	Review Role	Module Assignment
BC: CAPT Jon Daugherty, Ph.D.		
Reviewer: LCDR Matthew Steele, Ph.D. BC: Jon Daugherty, Ph.D.	Co-Regulatory Project Manager	All Modules
Reviewer: Taruna Khurana, Ph.D. BC: CAPT Jon Daugherty, Ph.D.	Co-Regulatory Project Manager	All Modules
Reviewer: Jennifer Bridgewater, M.S. DD: Jay Slater, M.D.	Regulatory Coordinator	All Modules
Reviewer: Kathleen Hise, M.D. TL: Roshan Ramanathan, M.D. BC: Jeff Roberts, M.D.	Clinical	Modules 1, 2, 5
Reviewer: Zhong Gao, Ph.D. TL: Lihan Yan, Ph.D. BC: Dale Horne, Ph.D.	Biostatistics	Modules 1, 2, 5
Reviewer: Elizabeth Teeple, Ph.D. TL: Lihan Yan, Ph.D. BC: Dale Horne, Ph.D.	Biostatistics	Module 1, 2, 5
Reviewer: David Schwab, M.S. BC: Laraine Henchal, M.S.	Electronic Integrity	All Modules
Reviewer: Oluchi Elekwachi, Pharm.D., M.P.H. BC: Lisa Stockbridge, Ph.D.	APLB/Promotional Labeling	Modules 1 & 2
Reviewer: Patricia Rohan, M.D. BC: Meghna Alimchandani, M.D.	Epidemiology	Modules 1, 2, 5
Reviewer: Joe Sun, Ph.D. BC: Dave Green, Ph.D.	Toxicology	Modules 1, 2, 4
Reviewer: Nabil Al-Humadi, Ph.D. BC: Dave Green, Ph.D.	Toxicology	Modules 1, 2, 4
Reviewer: Taruna Khurana, Ph.D. BC: CAPT Jon Daugherty, Ph.D.	CMC	Modules 1, 2, 3
Reviewer: Richard Heath Coats, M.S. BC: Carolyn Renshaw	Quality Control	Modules 1, 2, 3
Reviewer: Joyce Rockwell BC: Carolyn Renshaw	Quality Control	Modules 1, 2, 3
Reviewer: Cheryl Hulme, CSO BC: Joseph Quander III, CSO	Quality Control	Modules 1, 2, 3
Reviewer: Colonious King, B.S. BC: Patricia Holobaugh, M.D.	BIMO	Modules 1, 2, 5
Reviewer: Daphne Stewart BC: Laraine Henchal, M.S.	Carton/Container Labeling	Module 1

1.0 PURPOSE

The purpose of this meeting was:

- To discuss the proposed blister pack labeling
- To discuss the proposed pediatric study plan

- To discuss upcoming milestones
- To discuss review issues, action items and other necessary items

2.0 BACKGROUND

BLA STN#125592 (Sequence #0000) was submitted by Merck Sharp & Dohme Corp. on February 9, 2016 and received by CBER on February 9, 2016. The product is house dust mites (Der p and Der f) (b) (4) extract. The proposed indication is “immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, in adults 18 through 65 years of age”.

3.0 DISCUSSION TOPICS

1. Blister package (container) label
 - Merck’s proposed mockup’s for use of abbreviated proper name
 - The mockup’s proposed by Merck do not comply with 21CFR§201 subpart A and 21CFR§610 Subpart G. The font sizes in both the mockups are small and difficult to read. It was decided that an increase in blister size will be suggested to the applicant in order to have a legible font size and to capture all required label information on blister cell and carton-container.
 - It was concurred during the meeting that genus *Dermatophagoides* can be abbreviated.
2. Revised Proposed Pediatric Study Plan (PSP)
 - Proposed Bayesian model to augment efficacy data from HDM studies in adults to the efficacy evaluation of pediatric population
 - Based on preliminary review of the revised proposed PSP it appears that the applicant is relying too much on assumptions based on adult efficacy data. Statistical reviewer(s) will need input from clinical reviewer for adult efficacy data and a separate meeting to discuss the PSP.
 - PeRC Scheduled for November 16, 2016
No issues were raised regarding PeRC meeting date

3.1 Milestones

Submitted: February 9, 2016

Received: February 9, 2016

Committee Assignment: February 23, 2016

First Committee Meeting: March 29, 2016

Filing Meeting: March 29, 2016

Filing Action: April 09, 2016

Deficiencies Identified: April 23, 2016

Proprietary Name Review: May 19, 2016

First Draft Reviews Due: No Later Than July 21, 2016

Final Draft Reviews w/supervisory concurrence: November 10, 2016

Final Reviews Due: January 9, 2017

Draft SBRA: January 9, 2017

Action Due: February 8, 2017

Meetings

First Committee Meeting: March 29, 2016

Filing Meeting: March 29, 2016

Monthly Team Meetings: Recurring 1st Wednesday of each month starting May 4, 2016

Mid-Cycle Review Meeting: July 20, 2016 at 1:30PM (held no later than July 25, 2016)

Advisory Committee (APAC): N/A

PeRC Meeting: November 16, 2016

Labeling Meetings: TBD post Mid-Cycle

3.2 Review Status By Discipline

Discipline reviews were not discussed in detail during this meeting.

3.2.1 Quality Control (OCBQ/DMPQ)-Joyce Rockwell

The classification of the (b) (4) biennial inspection is still under review by the Division of Case Management (DCM).

A determination of the classification should be finalized within the next month or so. If DCM agrees with the inspector's recommendation of Official Action

Indicated (OAI), this will negatively impact if the pre-approval inspection can be waived or performed, which will impact the review timeline and approval of the BLA.

4.0 CONCLUSION

A revised proposed Pediatric Study Plan will be reviewed by clinical and statistical review teams before the PeRC meeting. The blister and carton label issues will be communicated to the applicant.

5.0 ACTION ITEMS

5.1. Schedule meeting to discuss PSP before PeRC meeting on November 16, 2016

5.2. Send information request to the applicant suggesting increasing blister size