



FILING MEETING AGENDA

Date and Time:	March 29, 2016
Location:	WO71 Rm 4244
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:	Katie Rivers, MS
Meeting Recorder:	LCDR Matt Steele, Ph.D./CAPT Colleen Sweeney, MSN

CBER/FDA Attendees

Katie Rivers, M.S., CBER/OVRR/DVRPA
LCDR Matthew Steele, Ph.D. CBER/OVRR/DVRPA
CAPT Colleen Sweeney, RN, M.S. CBER/OVRR/DVRPA
Jennifer Bridgewater, M.S., CBER/OVRR/DBPAP
Colonious King B.S., CBER/OCBQ/DIS
Zhong Gao, Ph.D., CBER/OBE/DB
Patricia Rohan, M.D., CBER/OBE/DE
Richard Heath Coats, M.S., CBER/OCBQ
Kathleen Hise, M.D., CBER/OVRR/DVRPA
Taruna Khurana, Ph.D., CBER/OVRR/DVRPA
David Schwab M.S., CBER/OVRR/DVRPA
Daphne Stewart, 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
Drusilla L. Burns Ph.D., CBER/OVRR/DBPAP
Dale Horne Ph.D., CBER/OBE/DB
Carolyn Renshaw, CBER/OCBQ/DMPQ
Ronald Rabin M.D., CBER/OVRR/DBPAP
Lisa L Stockbridge, Ph.D., CBER/OCBQ/DCM
Patricia Holobaugh, M.D., CBER/OCBQ/DIS

Meghna Alimchandani ,M.D., CBER/OBE/DE
 Lihan Yan, Ph.D., CBER/OBE/DB

Committee Member	Review Role	Module Assignment
Reviewer: LCDR Matthew Steele, Ph.D. BC: Jon Daugherty, Ph.D.	Regulatory Project Manager	All Modules
Reviewer: CAPT Colleen Sweeney, R.N., M.S. BC: CAPT Jon Daugherty, Ph.D.	Regulatory Project Manager	All Modules
Reviewer: Katie Rivers, M.S. BC: CAPT Jon Daugherty, Ph.D.	Chair	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: 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 milestones, roles and responsibilities of each member of the review team.

- To discuss the completeness of the BLA submission and ensure it is acceptable to file.

2.0 BACKGROUND

BLA STN#125592/0 (Sequence #0000) was submitted by Merck Sharp & Dohme on February 9, 2016 and received by CBER on February 9, 2016. 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

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 Reviews Due: 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: TBD (held no later than July 25, 2016)

Advisory Committee (APAC): N/A

PeRC Meeting: TBD (held no later than December 10, 2016)

Labeling Meetings: TBD post Mid-Cycle

3.2 Filing Review By Discipline

Each discipline reviewer discussed their filing checklist and noted any deficiencies that need to be communicated to the applicant.

3.2.1 Clinical/ K. Hise

The BLA is acceptable to file. The reviewer noted that table 6 required correction.

3.2.2 Biostatistics/ Z. Gao

The BLA is acceptable to file.

3.2.3 Labeling/ O. Elekwachi

The BLA is acceptable to file. The reviewer noted that the applicant has not provided the label in Microsoft Word format. CBER will request that the Microsoft Word version of the label be submitted.

3.2.4 Epidemiology/ P. Rohan

The BLA is acceptable to file.

3.2.5 Nonclinical/ J. Sun and N. Al-Humadi

The BLA is acceptable to file.

3.2.6 BIMO/C. King

The BLA is acceptable to file

3.2.7 CMC/ T. Khurana

The BLA is acceptable to file. The reviewer noted that a request for clarification regarding the identification of the product lots used in the supporting clinical trials will be sent to the applicant. . Additionally, the product review team needs to determine the acceptability of the proposed product unitage, SQ-HDM for carton and container labeling. An internal discussion will be scheduled. The applicant has requested feedback on this request no later than May 19, 2016.

3.2.8 CMC/Facility/ R. Coats and J. Rockwell

The BLA is acceptable to file. DMPQ plans to recommend a waiver for facility inspections.

3.2.9 CMC/Lot Release/ C. Hulme

The BLA is acceptable to file.

3.2.10 Regulatory/ M. Steele

The BLA is acceptable to file.

3.3 Information Requests/Deficiencies Identified

No deficiencies were identified. The following requests for information will be sent:

- 1) Request for correction to table 6.
- 2) Request for clarification regarding the identification of the product lots used in the supporting clinical trials. Request for Microsoft Word version of the package insert.

3.4 Notes of Importance

3.4.1 The review team was reminded that the first draft reviews are due July 21, 2016 and the final reviews are due January 9, 2017.

3.4.1 Monthly meetings – To be scheduled ASAP

3.4.2 Mid-cycle meeting – To be scheduled ASAP

3.4.3 The review team was reminded to notify C. Sweeney and M. Steel when memos are uploaded to the EDR

3.4.4 The review team was reminded to keep their outlook calendars up-to-date

3.4.5 The review team was reminded that their reviews must be 508 compliant.

4.0 CONCLUSION

During the Filing Meeting the committee agreed that the application could be filed.

5.0 ACTION ITEMS

- 5.1** The filing letter will be drafted by C. Sweeney for circulation and sign-off for issuance before or on April 9, 2016. At this point no deficiencies have been identified; therefore there are no plans for issuing a deficiencies identified (DI) letter.
- 5.2** Discipline reviewers that would like to request additional information should provide comments to C. Sweeney and M. Steele.
- 5.3** The monthly meetings and mid-cycle meeting will be scheduled as soon as possible.
- 5.4** Discuss the need to present the BLA to the Allergenic Product Advisory Committee (APAC) with management.