



**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

<b>Committee Member</b>	<b>Review Role</b>	<b>Module Assignment</b>
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 1<sup>st</sup> 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.