

First Committee Meeting Summary, November 21, 2011 - Flucelvax

To: The File of STN 125408/0
Date: November 21, 2011

STN #: 125408/0
Supplement Type: Biologics License Application Original Submission
Sponsor: Novartis Vaccines and Diagnostics GmbH
Product: OPTAFLU®, Influenza vaccine (MDCK Cells)

Meeting Chair: Timothy Nelle, Ph.D.
Meeting Recorder: Timothy A. Fritz, Ph.D.
Signature:

CBER/FDA Attendees

Timothy Nelle, Ph.D., Senior Supervisory Regulator, DVRPA/OVRR
Melisse Baylor, M.D., Medical Officer, DVRPA/OVRR
Tammy Massie, Ph.D., Lead Mathematician, DB/VEB/OBE
Nabil Al-Humadi, Ph.D., Pharmacologist, DVRPA/OVRR
Damon Green, M.D., Medical Officer, DE/OBE
Lihan Yan, Ph.D., Mathematical Statistician, DB/VEB/OBE
Rajesh Gupta, Ph.D., Deputy Director, DPQ/OCBQ
Karen Campbell, Biologist, DPQ/OCBQ
Zhiping Ye, Ph.D., Microbiologist, DVP/OVRR
Anissa Cheung, MSc., Consumer Safety Officer, OVRR/DVP
Haruhiko Murata, Staff Fellow, DVP/OVRR
Xianghong Jing, Ph.D., DVP/OVRR
Anthony Hawkins, Consumer Safety Officer, DIS/BMB/OCBQ
Maryann Gallagher, Consumer Safety Officer, DCM/APLB/OCBQ
Mohammad Heidarani, Ph.D., Biologist, DMPQ/OCBQ
Pankaj Amin, Consumer Safety Officer, DMPQ/OCBQ
LT David Schwab, MSIS, DVRPA, OVRR
Brenda Baldwin, Ph.D., Microbiologist, DVRPA/OVRR
Timothy Fritz, Ph.D., Microbiologist, DVRPA/OVRR

CBER/FDA Invitees

Douglas Pratt, M.D., Supervisory Medical Officer, DVRPA/OVRR
Martin Green, Ph.D., Supervisory Toxicologist, DVRPA/OVRR
Rakesh Pandey, Ph.D., Branch Chief, DVRPA/OVRR
Elizabeth Sutkowski, Ph.D., Branch Chief, DVRPA/OVRR
Amelia Horne, Ph.D., Supervisory Mathematician, DB/VEB/OBE
Tsai-Lien Lin, Ph.D., Lead Mathematical Statistician, DB/VEB/OBE

William McCormick, Ph.D., Division Director, DPQ/OCBQ
Jerry Weir, Ph.D, Division Director, DVP/OVRR
Chiang Syin, Ph.D., Supervisory Chemist, DMPQ/OCBQ
Lori Austin-Hansbury, Senior Supervisory Regulator, DE/OBE
Lisa Stockbridge, Supervisory Consumer Safety Officer, DCM/APLB/OCBQ
Patricia Holobaugh, Supervisory Consumer Safety Officer, DIS/OCBQ

1.0 BACKGROUND AND PURPOSE

BLA STN #125408/0, Sequence #0 was submitted by Novartis Vaccines and Diagnostics GmbH on October 31, 2011 and received by CBER on November 1, 2011.

The proposed indication is for active immunization of persons 18 years of age and older for the prevention of influenza disease caused by influenza virus subtypes A and B contained in the vaccine. The purpose of this meeting is to discuss the milestones, roles and responsibilities of each member of the review team.

2.0 DISCUSSION TOPICS

2.1 Review Committee

The review committee is as follows:

Timothy Nelle, Ph.D.	Chair
Melisse Baylor, M.D.	Clinical Reviewer
Tammy Massie, Ph.D.	Statistical Reviewer, Clinical
Nabil Al-Humadi, Ph.D.	Toxicology Reviewer
Damon Green, M.D.	Epidemiology Reviewer
Lihan Yan, Ph.D.	Statistical Reviewer, Bioassay
Rajesh Gupta, Ph.D.	CMC Reviewer, Analytical Methods
Karen Campbell	Lot Release
Zhiping Ye, Ph.D.	Product Reviewer
Anissa Cheung, MSc.	Product Specialist
Haruhiko Murata	Product Reviewer
Xianghong Jing	Product Reviewer
Pankaj Amin	Facility Reviewer
Mohammad Heidarani, Ph.D.	Facility Reviewer
Anthony Hawkins	Bioresearch Monitoring Reviewer
Maryann Gallagher	Labeling Reviewer
LT David Schwab, MSIS	Electronic Integrity Reviewer
Brenda Baldwin, Ph.D.	Regulatory Project Manager
Timothy Fritz, Ph.D.	Regulatory Project Manager

2.2 Milestones

Submitted:	October 31, 2011
Received:	November 1, 2011
Committee Assignment:	November 15, 2011

First Committee Meeting:	November 21, 2011
Filing Meeting:	December 15, 2011
Filing Action:	December 30, 2011
Deficiencies Identified:	January 13, 2012
VRBPAC Determination:	December 30, 2011
PeRC Determination:	December 30, 2011
SWG Determination:	January 12, 2012
First Draft Reviews Due:	January 29, 2012 (February 28 for Stats and PhV)
Second Draft Reviews D	April 23, 2012 (May 8 for Stats and PhV)
Final Reviews Due:	June 22, 2012
Action Due:	August 31, 2012
Action Packing for Posting Due:	August 31, 2012

2.3 Meetings

First Committee Meeting:	November 16, 2011
Filing Meeting:	December 12, 2011
Monthly Team Meetings:	TBD
Mid-Cycle Review Meeting:	TBD
PeRC:	TBD
VRBPAC Planning:	TBD
Safety Working Group:	TBD
Labeling Meetings:	TBD

3.0 CONCLUSION

The primary review team members agreed to their assigned roles and with the timeline for the review of this supplement.

4.0 SUMMARY OF ACTION ITEMS

No action items were identified.