

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FILING MEETING AND DECISION OF FILING ACTION FOR
STN 125428/0 HEPLISAV [Hepatitis B Vaccine (Recombinant)]

FILING MEETING DATE: June 5, 2012

FILING ACTION DUE DATE: June 25, 2012

COMMITTEE MEMBERS:

Marian Major, Ph.D.*	Committee Chair	OVRP/DVP/LHV
Richard Daemer, Ph.D.*	Regulatory Project Manager	OVRP/DVRPA/CMC2
Katherine Berkousen, CAPT*	Regulatory Project Manager	OVRP/DVRPA/CMC2
Lorie Smith, M.D.*	Clinical Review (Safety)	OVRP/DVRPA/CTB
Alexandra Worobec, M.D.*	Clinical Review (Efficacy)	OVRP/DVP/CTB
Stephen Kunder, Ph.D.	Preclinical Toxicology	OVRP/DVRPA/Tox
Claudia Wrzesinski, Ph.D.	Preclinical Toxicology	OVRP/DVRPA/Tox
Haiyan Qin Ph.D.*	Preclinical Immunology	OVRP/DVP/LHV
Iryna Zubkova, Ph.D.*	Product Review	OVRP/DVP/LHV
Brenda Baldwin, Ph.D.*	CMC Release Testing (Adjuvant)	OVRP/DVRPA/CMC1
Mridul Chowdhury, Ph.D.	Statistical Review	OBE/DB/VEB
Martha Lee, Ph.D.*	Bioassay Statistical Review	OBE/DB/VEB
Manette Niu M.D.*	Pharmacovigilance	OBE/DE/AEB
Bhanumahti Kannan*	Bioresearch Monitoring	OCBQ/DIS/BMB
Muhammad Shahabuddin, Ph.D.	Antigen & Potency Testing	OCBQ/DBSQC/LACBRP
Lokesh Bhattacharyya, Ph.D.*	Chemistry Testing	OCBQ/DBSQC/LACBRP
Karen Campbell*	Lot Release, LRP, Testing Plan	OCBQ/DBSQC/QAB
Cheryl Hulme*	Lot Release	OCBQ/DMPQ/PRB
Destry Sullivan*	Establishment/Facilities	OCBQ/DMPQ/BII
Priscilla Pastrana*	Establishment/Facilities	OCBQ/DMPQ/BII
Kristine Khuc*	Advertising/Promotional Labeling	OCBQ/DCM/APLB
David Schwab, LT	Electronic Integrity	OVRP/DVRPA/RMSB

* = review team members present at committee meeting

LEADERSHIP present at meeting:

Theresa Finn Ph.D.	Associate Director for Regulatory Policy	OVR
Maureen Hess	Health Science Advisor/Communications	OVR
Wellington Sun M.D.	Division Director	OVR/DVRPA
Loris McVittie Ph.D.	Deputy, Division Director	OVR/DVRPA
Liz Sukowski Ph.D.	CMC2 Branch Chief	OVR/DVRPA
Rakesh Pandey, Ph.D.	CMC3 Branch Chief	OVR/DVRPA
Andrea James M.D.	Clinical Team Lead	OVR/DVRPA
Tsai-Lien Lin Ph.D.	Team Leader	OBE/DB/VEB
William McCormick Ph.D.	Division Director	OCBQ/DBSQ/DPO
Chiang Syin Ph.D.	Branch II Chief	OCBQ/DMPQ
Quy	Quality Assurance	OCBQ/DMPQ
Nicole Trudel	Quality Assurance	OCBQ/DMPQ
Laurie Norwood		OCBQ/DMPQ

The committee has reviewed the application for completeness and recommends that the application be filed.