

Employee/Officer List - BEXSERO

EMPLOYEE/OFFICER LIST MEMO

To: The File

Date: January 23, 2015

BLA: STN 125546/0

Sponsor: Novartis Vaccine and Diagnostics, Inc.

Product: BEXSERO®, Meningococcal Group B Vaccine

From: Edward Wolfgang, MSA. (RPM)

Through: Margaret Bash, M.D. (Chair)

Section 916 of the Food and Drug Administration Amendments Act (FDAAA) requires that the identity of each employee or officer who participated in the decision to approve an original application be listed and filed as part of the Action Package for that file.

The following employees and officers have consented to have their names published publicly as being a participant in the approval decision for this file.

Committee Members	Review Assignment
Margaret Bash, MD, MPH	Chair
Edward Wolfgang, MSA	Lead RPM
Kirk Prutzman, PhD	Co-RPM
Ramachandra S. Naik, PhD	Co-RPM
Anuja Rastogi, MD	Clinical
Douglas Pratt, MD	Clinical, Consult reviewer
Tina Roecklein, MS	DBPAP Regulatory Coordinator
Freyja Lynn, BS	Bioassay (Clinical and product)

Committee Members	Review Assignment
John Cipollo, PhD	Product test methodologies, CMC
Willie Vann, PhD	Product (CMC), Consult reviewer
Karen Campbell, MS	Coordination of lot release and Regulatory Coordinator – DBSQC
Anil Choudhary, PhD	Product test methodologies
Noel Baichoo, PhD	Product test methodologies
James Kenney, PhD	Product test methodologies
Hsiaoling Wang, PhD	Product test methodologies
Tao Pan, PhD	Product test methodologies
Cheryl Hulme, MLT	Coordination of lot release - DMPQ
Leigh Bernardino, RN, BSN	DMPQ RPM
Barbara Krasnicka, PhD	Statistical (Clinical-immunogenicity data)
Tammy Massie, PhD	Statistical (Clinical-safety data)
Zhong Gao, PhD	Statistical (Serology assays)
Tsai-Lien Lin, PhD	Statistical (CMC, potency assays)

Committee Members**Review Assignment**

Ching-Long (Joe) Sun, PhD

Non-Clinical Toxicology

Donald Ertel, MT

CMC, CCIT, Facilities reviewer and inspector

Jane Baumblatt, MD

Epidemiology/Pharmacovigilance

Carla Jordan, BS, MT

Bioresearch Monitoring

Michael Brony, PharmD

Advertising/Promotional Labeling

Daphne Stewart

Labeling

David Schwab, MSIS

Electronic Integrity