

Employee/Officer List - GARDASIL 9

125508 EMPLOYEE/OFFICER LIST MEMO

To: The File of 125508/0

Date: December 8, 2014

BLA: STN 125508/0

Applicant: Merck Sharp & Dohme Corp.

Product: GARDASIL®9, Human Papillomavirus 9-valent Vaccine, Recombinant

From: Laura Montague (RPM)

Through: Haruhiko Murata, M.D., Ph.D. (Committee 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.

Nabil Al-Humadi, Ph.D. - Toxicology Reviewer

Karen Campbell, M.S. - Lot Release Protocol and Testing Plan Reviewer

Anil Choudhary, Ph.D., M.B.A. - Analytical Methods Reviewer

Cheryl Hulme, A.S.C.P. - Consult Lot Release Reviewer

James Kenney, Ph.D. - Analytical Methods Reviewer

Bharat Khurana, D.V.M., Ph.D., M.B.A. - Regulatory Project Manager

Tsai-Lien Lin, Ph.D. - Consult CMC/Assay Reviewer

Freyja Lynn, B.S. - Assay Reviewer

Dana Martin - Labeling Reviewer

LCDR Adamma Mba-Jonas, M.D., M.P.H. - Epidemiology Reviewer

Erin McDowell, B.S., B.A. - Bioresearch Monitoring Reviewer

Nancy Miller, M.D. - Consult Clinical Reviewer

Laura Montague, B.S. - Regulatory Project Manager

Haruhiko Murata, M.D., Ph.D. - Committee Chair and Product Reviewer

Leslie Wagner, Ph.D. - Assay Reviewer

CDR Jeremy L. Wally, Ph.D. - CMC/Facilities Reviewer

Lihan Yan, Ph.D. - Clinical Statistical Reviewer

Sixun Yang, M.D., Ph.D. - Clinical Reviewer