

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208612Orig1s000

OFFICER/EMPLOYEE LIST

Officer/Employee List (alphabetical order)

The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list.

1. Mammah Borbor, M.S., M.B.A. –Regulatory Health Project Manager, OSE
2. Hong Cai, Ph.D. – Chemist, Branch V, Division II, OPQ
3. Miriam Chehab, Pharm.D, BCPPs – Office of Surveillance and Epidemiology, Office of Pharmacovigilance and Epidemiology, Division of Pharmacovigilance II
4. Jennifer Dao – Regulatory Health Project Manager, DBRUP
5. Audrey Gassman, M.D. – Deputy Director, Office of New Drugs III, Division of Bone, Reproductive and Urologic Products
6. Sarah Harris – Team Leader, Safety Regulatory Project Manager, OSE
7. Richard Ishihara– Regulatory Scientist, ODEIII
8. Li, Li – Ph.D. – Clinical Pharmacology Reviewer, OCP
9. Jeffrey Medwid, PhD – Senior CMC Chemistry Reviewer, Office of Pharmaceutical Quality
10. Jennifer Mercier – Chief, Project Management Staff
11. Lynn Panholzer – Reviewer, OPDP
12. Catherine Sewell– Acting Clinical Team Leader, Division of Bone, Reproductive and Urologic Products
13. Xiaohui, Shen, M.S. – Division of Inspection Assessment, Office of Process and Facilities, Office of Pharmaceutical Quality
14. Lisa Soule – Clinical Team Leader, Division of Bone, Reproductive and Urologic Products
15. Mukesh Summan, PhD –Pharmacology/Toxicology Supervisor, DBRUP
16. Doanh Tran Pharm.D. – Clinical Pharmacology Team Leader, Division of Clinical Pharmacology III (DCPIII), Office of Clinical Pharmacology (OCP)
17. Thao, Vu – Regulatory Business Project Manager, Office of Program and Regulatory Operations, Office of Pharmaceutical Quality
18. Chris Wheeler, Pharm.D – Patient Labeling, Team Lead Project Manager
19. Marcia B. Williams, PhD – DMPP, Patient Labeling Reviewer
20. Sharon Williams, MSN, BSN, RN – DMPP, Senior Patient Labeling Reviewer