

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Officer/Employee List
Application NDA 208065

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

Adams, Mike
Ayalew, Kassa
Blumenthal, Gideon
Bijwaard, Karen CDRH
Cheng, Joyce
Eradiri, Okpo
Fan, Ingrid
Ford, Latonia
Fuller, Barbara
Gieser, Gerlie
He, Kun
Hughes, Monica
Jewell, Charles
Keegan, Patricia
Leighton, John K
Maguire, Jennifer
Pierce, Melanie
Redd, Naomi
Stephens, Olen
Summers, Jeff
Thompson, Susan
Townsend, Otto
Weinstock, Chana
Weis, Shawn
Yancey, Carolyn L
Yang, Jun
Zhang, Ying
Zhao, Hong