

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**211996Orig1s000**

**212161Orig1s000**

**OFFICER/EMPLOYEE LIST**

MEMORANDUM

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

**DATE:** April 30, 2019

**TO:** Administrative file for NDA 211996

**FROM:** Maryam Changi, Regulatory Health Project Manager  
Division of Cardiovascular and Renal Products, Office of Drug Evaluation I

**SUBJECT:** Officer/Employee List for NDA 211996

**APPLICATION/DRUG:** NDA 211996, Vyndaquel, tafamidis meglumine 20 mg Capsules.  
The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list:

Adams, Grafton  
Baisden, Kristie  
Blank, Melanie  
Changi, Maryam  
Chelliah, Mariappan  
Dunnmon, Preston  
Eworuke, Efe  
Fanti, Paolo  
Fromm, Edward J  
Gentles, Carlisha  
Goulding, Margie R.  
Hariharan, Sudharshan  
Li, Ruoqing  
Link, William T Y  
Liu, Chao  
McDowell, Tzu-Yun  
Monteleone, Michael V.  
Patel, Zarna  
Redwood, Susan  
Rose, Martin  
Samant, Snehal  
Shah, Sapna  
Southworth, Mary Ross  
Stockbridge, Norman L.  
Thompson, Aliza  
Unger, Ellis  
Wilson, Wendy

-----  
**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
-----

/s/  
-----

MARYAM K CHANGI  
04/30/2019 08:33:45 AM

MEMORANDUM

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

**DATE:** April 30, 2019

**TO:** Administrative file for NDA 212161

**FROM:** Maryam Changi, Regulatory Health Project Manager  
Division of Cardiovascular and Renal Products, Office of Drug Evaluation I

**SUBJECT:** Officer/Employee List for NDA 212161

**APPLICATION/DRUG:** NDA 212161, Vyndamax, tafamidis, 61 mg Capsules  
The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list:

Adams, Grafton  
Baisden, Kristie  
Blank, Melanie  
Changi, Maryam  
Chelliah, Mariappan  
Dunnmon, Preston  
Eworuke, Efe  
Fanti, Paolo  
Fromm, Edward J  
Gentles, Carlisha  
Goulding, Margie R.  
Hariharan, Sudharshan  
Li, Ruoqing  
Link, William T Y  
Liu, Chao  
McDowell, Tzu-Yun  
Monteleone, Michael V.  
Patel, Zarna  
Redwood, Susan  
Rose, Martin  
Samant, Snehal  
Shah, Sapna  
Southworth, Mary Ross  
Stockbridge, Norman L.  
Thompson, Aliza  
Unger, Ellis  
Wilson, Wendy

-----  
**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
-----

/s/  
-----

MARYAM K CHANGI  
04/30/2019 08:38:12 AM

Ṛ