

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209376Orig1s000**

**OFFICER/EMPLOYEE LIST**

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

DATE: July 2, 2020

TO: Administrative file for NDA 209376

FROM: Thao Vu, Regulatory Project Manager  
Division of Regulatory Operations for Hepatology and Nutrition (DHN), Office of  
Regulatory Operations

SUBJECT: Officer/Employee list for NDA 209376

APPLICATION/DRUG: NDA 209376, Tralement (trace elements injection 4\*)

\*zinc 3 mg, copper 0.3 mg, manganese 55 mcg, selenium 60 mcg

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

Sandhu, Sukhminder	Yes: 6/30/2020 4:27 PM
Khurana, Mona	Yes: 6/29/2020 12:51 PM
Toerner, Joseph	Yes: 6/29/2020 12:09 PM
Racoosin, Judith A	Yes: 6/29/2020 11:58 AM
Radden, Erica	Yes: 6/29/2020 11:08 AM
Puigbo, Jacqueline	Yes: 6/29/2020 11:03 AM
Lee, Bethanie	Yes: 6/29/2020 11:03 AM
Joseph, David B	Yes: 6/29/2020 10:56 AM
Dinatale, Miriam	Yes: 6/29/2020 10:46 AM
Barry, Oumou	Yes: 6/29/2020 10:34 AM
Cheng, Kejun	Yes: 6/29/2020 10:32 AM
Weissfeld, Joel	Yes: 6/29/2020 10:26 AM
Kim, Insook	Yes: 6/29/2020 10:26 AM
Baer, Gerri	Yes: 6/29/2020 10:25 AM
Vee, Sarah	Yes: 6/29/2020 10:23 AM
Tobenkin, Anne	Yes: 6/29/2020 10:23 AM
Meyer, Joette M	Yes: 6/29/2020 10:20 AM
Chang, Jane (CDER)	Yes: 6/29/2020 10:18 AM
Shang, Elizabeth	Yes: 6/29/2020 10:17 AM

Burnett, Friedrich	Yes: 6/29/2020 10:16 AM
Alexander, John J	Yes: 6/29/2020 1:01 PM
Zhu, Yao-Yao	Yes: 6/29/2020 1:01 PM
Zhang, Ke	Yes: 6/29/2020 10:20 AM

-----  
**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/  
-----

THAO M VU  
07/02/2020 10:42:35 AM