

Date January 29, 2019

From Jean Dehdashti, MSc, RAC, DRPM, OTAT
 DIVISION OF REGULATORY PROJECT MANAGEMENT (DRPM)
 Office of Tissues and Advanced Therapies (OTAT)
 Center for Biologics Evaluation and Research (CBER)
 Food and Drug Administration (FDA)

To Biologics License Application Submission Tracking Number # 125671/0

Subject Officer/Employee List

Background Section 916 of the Food and Drug Administration Amendments Act (FDAAA) includes a requirement to identify by name each officer or employee who participated in the decision to approve an application for which an “Action Package” is prepared (i.e., NDA/BLA/MDUFA BLA original application). This provision also requires that the employee’s consent must be obtained to list his/her name. To implement this provision, an Officer/Employee List memo will be prepared and included as part of the Action Package for Posting.

The Officers or employees of FDA that participated in the decision to approve this application and consented to be identified on this list are identified below in Table 1.

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

Table 1. Officer/Employee List for BLA 125671/0

Name	Organization
Jean Dehdashti, MS, RAC	CBER/OTAT/DRPM
Erica Giordano, BS	CBER/OTAT/DRPM
Ramani Sista, PhD	CBER/OTAT/DRPM
Najat Bouchkouj, MD	CBER/OTAT/DCEPT
Gaya Hettiarachi, PhD	CBER/OTAT/DCEPT
Iftekhar Mahmood, PhD	CBER/OTAT/DCEPT
Tejashri Purohit-Sheth, MD	CBER/OTAT/DCEPT
Andrey Sarafanov, PhD	CBER/OTAT/DPPT
Haarin Chun, PhD	CBER/OTAT/DPPT
Mikhail Ovanesov, PhD	CBER/OTAT/DPPT
Ze Peng, PhD	CBER/OTAT/DPPT

Name	Organization
Yideng Liang, PhD	CBER/OTAT/DPPT
Mark Verdecia, PhD	CBER/OTAT/DPPT
Basil Golding, MD, PhD	CBER/OTAT/DPPT
Mahmood Farshid, PhD	CBER/OTAT/DPPT
Ekaterina Allen, PhD	CBER/OCBQ/DMPQ
Anthony Hawkins, M.S.	CBER/OCBQ/DIS
Dennis Cato	CBER/OCBQ/DIS
Parmesh Dutt, PhD	CBER/OCBQ/DBSQC
Jing Lin, PhD	CBER/OCBQ/DBSQC
Lokesh Bhattacharyya, PhD	CBER/OCBQ/DBSQC
Maryna Eichelberger, PhD	CBER/OCBQ/DBSQC
James Kenney, PhD	CBER/OCBQ/DBSQC
Kim Benton, PhD	CBER/OTAT/IOD
Wislon W. Bryan, MD	CBER/OTAT/IOD
Ohenewa Ahima, MD	CBER/OBE/DE
Arya Deepa, MD	CBER/OBE/DE
Adamma Mba-Jonas, MD	CBER/OBE/DE
Lin Huo, PhD	CBER/OBE/DB
John Scott, PhD	CBER/OBE/DB
Hina Mehta, PhD	CDER/OSE/OMEPRM/DMEPA
Idalia Rychlik, PhD	CDER/OSE/OMEPRM/DMEPA