

Date March 23, 2020

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 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 # 125641/0

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 125641/0

Name	Organization
Jean Dehdashti, MS, RAC	CBER/OTAT/DRPM
Ramani Sista, PhD	CBER/OTAT/DRPM
Ilan Irony, MD	CBER/OTAT/DCEPT
Mercedes Serabian, PhD	CBER/OTAT/DCEPT
Iftekhar Mahmood, PhD	CBER/OTAT/DCEPT
Tejashri Purohit-Sheth, MD	CBER/OTAT/DCEPT
Andrey Sarafanov, PhD	CBER/OTAT/DPPT
Alexey Khrenov, PhD	CBER/OTAT/DPPT
Mikhail Ovanesov, PhD	CBER/OTAT/DPPT
Yideng Liang, PhD	CBER/OTAT/DPPT
Basil Golding, MD, PhD	CBER/OTAT/DPPT

Name	Organization
Mahmood Farshid, PhD	CBER/OTAT/DPPT
Yideng Liang, PhD	CBER/OTAT/DPPT
Wojciech Jankowski, PhD	CBER/OTAT/DPPT
Dennis Cato	CBER/OCBQ/DIS
Colonious Kink, PhD	CBER/OCBQ/DIS
Kim Benton, PhD	CBER/OTAT/IOD
Wilson W. Bryan, MD	CBER/OTAT/IOD
Rachael Anatol, PhD	CBER/OTAT/IOD
Firoozeh Alvandi, MD	CBER/OBE/DE
Renee Rees, PhD	CBER/OBE/DB
Boris Zaslavsky, PhD	CBER/OBE/DB
Lisa Stockbridge, PhD	CBER/OCBQ/DCM
Amanda Trayer, PhD	CBER/OCBQ/DMPQ
Maryna Eichelberger, PhD	CBER/OCBQ/DBSQC
Claire Wernly, PhD	CBER/OCBQ/DBSQC
Hsiaoling Wang, PhD	CBER/OCBQ/DBSQC
Grainne Tobin, PhD	CBER/OCBQ/DBSQC