SMG 1410.419

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Medical Device User Fees

Effective Date: 20 May 2025

1. Authority Delegated and To Whom Delegated.

A. The officials listed below, for medical devices assigned to their respective organizations, are authorized to take actions necessary to implement and administer section 738 of the Federal Food, Drug, and Cosmetic Act, as added by the Medical Device User Fee and Modernization Act (MDUFMA). This includes the authority to:

- determine the kind of fee appropriate for a specific application;
- waive, adjust or refund medical device user fees for a specific application; and
- decide appeals of medical device user fee waiver decisions.

(1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director.

(2) CBER/Office of Regulatory Operations (ORO) Director.

(3) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

2. Redelegation.

A. These officials may redelegate this authority in whole or in part.

B. Delegates must be certified as knowledgeable about the legal, regulatory, and policy requirements regarding the subject authorities and they are subject to compliance audits.

C. Any redelegation must be in writing and specify the nature and extent of the authority redelegated.

D. A copy of the redelegation must be furnished to the Principal Delegation Control Officer.

3. Effective Date.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 20 May 2025.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/23/2009	N/A	OC/ OA/ OM/ OMP	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	11/22/2013	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	05/20/2025	N/A	CDRH/ OP	Martin A. Makary, M.D., M.P.H. Commissioner of Food and Drugs