**SMG 1410.109**

**FDA Staff Manual Guides, Volume II – Delegations of Authority**

**Regulatory – Human Drugs**

# Human Drug User Fees

Effective Date: 21 December 2021

## 1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized to perform all the functions of the Commissioner of Food and Drugs relating to human drug user fees administered by the Food and Drug Administration, including the authority to reconsider any user fee decisions:

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

(2) CBER Associate Director for Review Management.

(3) CBER/Office of Management (OM) Associate Director for Management.

(4) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.

(5) CDER/Office of Management (OM) Associate Director for Management.

(6) CDER/OM/Division of User Fee Management (DUFM) Director.

These authorities include functions under:

- Section 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379h), as added by the Prescription Drug User Fee Act;
- Section 744B of the FD&C Act (21 U.S.C. 379j-42), as added by the Generic Drug User Fee Amendments;
- Section 744H of the FD&C Act (21 U.S.C. 379j-52), as added by the Biosimilar User Fee Act;
- Section 744K of the FD&C Act (21 U.S.C. 379j-62), as added by the Drug Quality and Security Act;
- Section 744M of the FD&C Act (21 U.S.C. 379j-72), as added by the Coronavirus Aid, Relief, and Economic Security Act.

## 2. Redelegation.

These officials may not further redelegate this authority.

**3. Effective Date.**

The Acting Commissioner of Food and Drugs approved this delegation, via memorandum, on 21 December 2021.

| Status | Date Approved | Location of Change History | Contact | Approving Official |
|---|---|---|---|---|
| Initial | 04/27/2007 | N/A | CDER/ OMIO | Margaret A. Hamburg, M.D. Commissioner of Food and Drugs |
| Revision | 05/04/2016 | N/A | OMTP/ CDER/ OMIO | Robert M. Califf, M.D. Commissioner of Food and Drugs |
| Revision | 12/21/2021 | N/A | CDER/ OM | Janet Woodcock, M.D. Acting Commissioner of Food and Drugs |