SMG 1410.109

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – HUMAN DRUGS

PRESCRIPTION DRUG USER FEES, GENERIC DRUG USER FEES, BIOSIMILAR BIOLOGICAL PRODUCT USER FEES, AND FEES RELATED TO THE DRUG QUALITY AND SECURITY ACT

Effective Date: 4 May 2016

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs relating to human drug user fees and other fees on behalf of the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and any other Food and Drug Administration Center, including the authority to reconsider any user fee decisions:

1. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT).

2. Associate Director for Management, CDER, OMPT.

3. Director, Division of User Fee Management, Office of Management (OM), CDER, OMPT.

These authorities include functions under:

A. The Prescription Drug User Fee Act of 1992 (PDUFA I), 21 U.S.C. 379h) as reauthorized by:

1. Title I, Subtitle A of the Food and Drug Administration Modernization Act of 1997 (PDUFA II);

2. The Prescription Drug User Fee Amendments Act of 2002 (PDUFA III), as enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002;

3. The Food and Drug Administration Amendments of 2007 (PDUFA IV);

4. The Food and Drug Administration Safety and Innovation Act of 2012 (PDUFA V), (21 U.S.C. 379h).

These authorities do not include the functions under Section 736(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(d)(1)(C)) that pertain to situations where "the fees will exceed the anticipated present and future costs" and the functions under section 736(c)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379(h)(c)(4)) to establish application, product, and establishment fees under section 736(a), based on the revenue amounts established under section 363(b) and the adjustments under section 736(c). (See SMG 1410.21(K)(1) and (K)(3).

B. Functions under the Generic Drug User Fee Amendments Act of 2012 (21 U.S.C. Section 379j-42), as enacted in the Food and Drug Administration Safety and Innovation Act of 2012;

C. Functions under the Biosimilar User Fee Act of 2012 (21 U.S.C. Section 379j-52, 53) as enacted in the Food and Drug Administration Safety and Innovation Act of 2012;

D. Functions under the Drug Quality and Security Act of 2013 (21 U.S.C. Section 353; 379j-62.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on May 4, 2016.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	05/04/2016	N/a	CDER/OMIO	Robert M. Califf, M.D., Commissioner of Food and Drugs