

§ 5.108 Authority relating to waivers or reductions of prescription drug user fees.

The Director, Center for Drug Evaluation and Research (CDER), and the Associate Director for Regulatory Policy, CDER, are authorized to perform all the functions of the Commissioner of Food and Drugs relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992, as originally enacted and as reauthorized by the Food and Drug Administration Modernization Act of 1997, except for the functions under section 736(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h(d)(1)(C)) that pertain to situations where “the fees will exceed the anticipated present and future costs,” on behalf of CDER, the Center for Biologics Evaluation and Research, and any other Food and Drug Administration Center. This authority pertains to waivers requested under the public health waiver provision (21 U.S.C. 379h(d)(1)(A)); the barrier to innovation waiver provision (21 U.S.C. 379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiver provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.) These officials may not further redelegate this authority.

§ 5.109 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e))

regarding the issuance of written notices.

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(6) The Associate Director for Medical Policy, and the Director and Deputy Director, Division of Scientific Investigations, Office of Medical Policy, CDER.

(7) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), the Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER, and the Directors, Division of Case Management, Division of Inspections and Surveillance, and Division of Manufacturing and Product Quality, OCBQ, CBER.

(8) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors of the Office of Device Evaluation, CDRH.

(9) Regional Food and Drug Directors.

(10) District Directors.

(b) These officials may not further redelegate this authority.

**Subpart D—Biologics;
Redelegations of Authority**

§ 5.200 Functions pertaining to safer vaccines.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) under part C, subtitle 2 of title XXI of the PHS Act (42 U.S.C. 300aa-25