

Subpart C—Organization

§ 5.100 Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under the Regulatory Flexibility Act (5 U.S.C. 605(b)), to certify that a proposed or final rule, if issued, will not have a significant economic impact on a substantial number of small entities:

- (a) The Associate Commissioner for Regulatory Affairs (ACRA).
- (b) The Director, Center for Biologics Evaluation and Research (CBER).
- (c) The Director, Center for Drug Evaluation and Research (CDER).
- (d) The Director, Center for Devices and Radiological Health (CDRH).
- (e) The Director, Center for Food Safety and Applied Nutrition (CFSAN).
- (f) The Director, Center for Veterinary Medicine (CVM).
- (g) Other FDA Officials authorized to issue FEDERAL REGISTER documents.

[62 FR 48757, Sept. 17, 1997]

§ 5.101 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 Policy, CDER, are authorized to perform all 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relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992, as originally enacted and as reauthorized by the FDA Modernization Act of 1997, except for the functions under 21 U.S.C. 379h(d)(1)(C) that pertain to situations where “the fees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 FDA 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 waiv-

er provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. These authorities may not be further redelegated. (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.)

[64 FR 59618, Nov. 3, 1999]

§ 5.200 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

- OFFICE OF THE COMMISSIONER.¹
- Office of the Chief Counsel.
- Office of Equal Opportunity.
- Office of the Administrative Law Judge.
- Office of the Senior Associate Commissioner.
- Office of Executive Secretariat.
- Office of Public Affairs.
- Office of the Ombudsman.
- Office of Orphan Products Development.
- Office of Internal Affairs.
- Office of Executive Operations.
- Office of International and Constituent Relations.*
- Office of International Programs.
- Office of Consumer Affairs.
- Office of Women’s Health.
- Office of Special Health Issues.
- Office of Policy, Planning, and Legislation.*
- Office of Policy.
- Office of Planning.
- Office of Legislation.
- Office of Management and Systems.*
- Office of Human Resources and Management Services.
- Office of Information Resources Management.
- Office of Financial Management.
- Office of Facilities, Acquisitions, and Central Services.²

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²Mailing address: 5630 Fishers Lane, Rockville, MD 20852.