

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

(a) 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:

- (1) The Associate Commissioner for Regulatory Affairs.
  - (2) The Director, Center for Biologics Evaluation and Research.
  - (3) The Director, Center for Drug Evaluation and Research.
  - (4) The Director, Center for Devices and Radiological Health.
  - (5) The Director, Center for Food Safety and Applied Nutrition.
  - (6) The Director, Center for Veterinary Medicine.
  - (7) Other Food and Drug Administration Officials authorized to issue FEDERAL REGISTER documents.
- (b) These officials may not further redelegate this authority.

**Subpart C—Human Drugs; Redelegations of Authority**

**§ 5.100 Issuance of notices implementing the provisions of the Drug Amendments of 1962.**

The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research; and the Director, the Deputy Directors for Regulations and Policy and for Science, and the Director and Deputy Directors, Office of Device Evaluation, Center for Devices and Radiological Health, are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the provisions of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). These officials may not further redelegate this authority.

**§ 5.101 Termination of exemptions for new drugs for investigational use in human beings.**

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under § 312.44 of this chapter and in animals under § 312.160 of this chapter:

- (1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).
- (2) The Director, the Deputy Director, and the Directors, Office of Review Management and Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).
- (3) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under § 312.44(b)(1)(viii) of this chapter:

- (1) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
- (2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.
- (3) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), OVRP, and Office of Therapeutics Research and Review (OTRR), CBER.
- (4) The Directors and Deputy Directors of the Division of Blood Applications, OBRR, the Division of Vaccines and Related Products Applications, OVRP, and the Division of Application Review and Policy, OTRP, CBER.
- (5) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in

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§ 312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVR), and Office of Therapeutics Research and Review (OTRR), CBER.

(4) The Directors and Deputy Directors of the Division of Blood Applications, OBRR, the Division of Vaccines and Related Products Applications, OVR, and the Division of Application Review and Policy, OTRR, CBER.

(5) The Director and Deputy Directors, ODE, CDRH.

(d) These officials may not further redelegate these authorities.

### **§ 5.102 Authority to approve and to withdraw approval of a charge for investigational new drugs.**

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under § 312.7(d)(1) of this chapter:

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

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research.

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

### **§ 5.103 Approval of new drug applications and their supplements.**

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to approval of new drug applications and

supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355):

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

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research, for drugs listed in § 314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the act.

(b) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(c) The following officials are authorized to perform all the functions of the Commissioner with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or section 505(b)(2) of the act (21 U.S.C. 355(b)(2)) applications under their jurisdiction.