

Food and Drug Administration, HHS

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(6)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) Chiefs of District Compliance Branches.

(iv) The Director, St. Louis Branch.

(v) The Director, Northeast Regional Laboratory, Northeast Region.

(vi) The Director, Southeast Regional Laboratory, Southeast Region.

(vii) The Director, Winchester Engineering and Analytical Center.

(viii) The Director, National Forensic Chemistry Center.

(ix) The Director, Arkansas Regional Laboratory.

(b) The following officials are authorized to perform all the functions of the Commissioner under section 539(d) of the act (21 U.S.C. 360pp(d)) regarding the issuance of written notices or warnings:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

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

(3) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(4) The Director and Deputy Director, Office of Surveillance and Biometrics (OSB), CDRH, and the Director and Deputy Director, Division of Surveillance Systems (DSS), OSB, CDRH.

(5) Regional Food and Drug Directors; District Directors; the Director, St. Louis Branch; the Director, Northeast Regional Laboratory, Northeast Region; the Director, Southeast Regional Laboratory, Southeast Region; the Director, Winchester Engineering and Analytical Center; the Director, National Forensic Chemistry Center, and the Director, Arkansas Regional Laboratory when such functions relate to:

(i) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter; and

(ii) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product as defined in § 1040.20(b) of this chapter.

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

§ 5.34 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

(a) The Director, the Deputy Director, and the Associate Director for Regulatory Policy, Center for Drug Evaluation and Research, the Director and Deputy Director, Center for Veterinary Medicine, and the Director and Deputy Directors, Center for Biologics Evaluation and Research are authorized to issue the following notices and make all findings required in relation to these notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 335a) which relate to the assigned functions of their organizations:

(1) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(2) Notices ordering debarment when opportunity for a hearing has been waived.

(3) Notices ordering debarment where the person notifies the agency that the person consents to debarment under section 306(c)(2)(B) of the act (21 U.S.C. 335a(c)(2)(B)).

(4) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act (21 U.S.C. 335u(d)(3)).

(5) Orders denying an application to terminate debarment under section 306(d)(3) of the act (21 U.S.C. 335u(d)(3)) when opportunity for a hearing has been waived.

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

§ 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.

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(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).

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(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), OVRR, 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, OVRR, and the Division of Application Review and Policy, OTRR, 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 § 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 (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.