

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

[48 FR 8440, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8316, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997; 62 FR 67270, Dec. 24, 1997]

§ 5.31 Petitions under part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors of the Offices of Biological Product Review and Biologics Research, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Biological Product Review and Biologics Research, CBER.

(2)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

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

(iii) 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.

(iv) The Director and supervisory consumer safety officers, Pilot Drug Evaluation Staff, Office of the Center Director, CDER.

(b) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting in vitro test modifications under § 331.29 of this chapter:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(c) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in § 211.132, § 700.25, or § 800.12 of this chapter for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director and Deputy Directors, Center for Devices and Radiological Health.

(d) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting exemption from the general pregnancy-nursing warning for over-the-counter (OTC) drugs required under § 201.63 of this chapter, requesting exemption from a general overdose warning required under § 330.1(g) of this chapter, and requesting exemption from OTC drug administrative procedures under § 330.10 of this chapter:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(e)(1) The following officials are authorized to issue 180-day tentative responses to citizen petitions on food and cosmetic matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center:

(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Cosmetics and Colors, CFSAN.

(iv) The Director, Office of Food Labeling, CFSAN.

(v) The Director, Office of Premarket Approval, CFSAN.

(vi) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(vii) The Director, Office of Seafood, CFSAN.

(viii) The Director, Office of Special Nutritionals, CFSAN.

(2) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(3) The Director and Deputy Director, CBER, are authorized to issue 180-day tentative responses to citizen petitions on biological product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(4) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER, are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(5) The Director and Deputy Directors, CDRH, are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(f)(1) The Director and Deputy Director, CBER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug and biological product matters in program areas where they have been delegated final approval authority in the following sections of this part:

(i) Section 5.68 *Issuance and revocation of licenses for the propagation or*

manufacture and preparation of biological products;

(ii) Section 5.69 *Notification of release for distribution of biological products;*

(iii) Section 5.71 *Termination of exemptions for new drugs for investigational use in human beings or in animals;*

(iv) Section 5.80 *Approval of new drug applications and their supplements;* and

(v) Section 5.82 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.*

(vi) Section 5.99 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug product matters in program areas where they have been delegated final approval authority in the following sections of this part:

(i) Section 5.70 *Issuance of notices implementing the provisions of the Drug Amendments of 1962 (DESI);*

(ii) Section 5.71 *Termination of exemptions for new drugs for investigational use in human beings or in animals;*

(iii) Section 5.73 *Certification of insulin;*

(iv) Section 5.74 *Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin;*

(v) Section 5.75 *Designation of official master and working standards for antibiotic drugs;*

(vi) Section 5.76 *Certification of antibiotic drugs;*

(vii) Section 5.78 *Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs;*

(viii) Section 5.80 *Approval of new drug applications and their supplements;* and

(ix) Section 5.82 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.*

(x) Section 5.99 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(3) The Director and Deputy Director, Division of Bioequivalence, Office of

Generic Drugs, Office of Pharmaceutical Science, CDER, except for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(4) The Director and Deputy Director, Office of Biological Product Review, CBER, for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(5) For drugs assigned to their organization, the following officials are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter from sponsors of an investigational new drug application who request approval to ship in interstate commerce, in accordance with § 2.125(j) of this chapter, an investigational new drug for human use containing a chlorofluorocarbon.

(i) The Director and Deputy Director, CBER.

(ii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(6) The Director and Deputy Director, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter from sponsors of an investigational new animal drug application who request approval to ship in interstate commerce, in accordance with § 21.125(j) of this chapter, an investigational new animal drug for animal use containing a chlorofluorocarbon.

(7) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter, seeking a determination of the suitability of an abbreviated new animal drug application for an animal drug product.

(8) The Director and Deputy Director, CVM, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter concerning actions they are authorized to take under § 5.99 *Issuance of notices relating to proposals*

and orders for debarment and denial of an application to terminate debarment.

(g) The Director and Deputy Directors, CDRH, and the Director, Office of Compliance, CDRH, are authorized to grant or deny citizen petitions submitted under §§ 10.30 and 821.2(b) of this chapter, requesting an exemption or variance from medical device tracking requirements in part 821 of this chapter.

(h) The Director and the Director of the Office of Compliance, CDER, are each authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting an exception or alternative to any requirement in part 211 of this chapter pertaining to current good manufacturing practice for positron emission tomography radiopharmaceutical drug products.

[47 FR 38480, Aug. 31, 1982]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 5.31, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 5.32 Authority relating to determination of product primary jurisdiction.

The FDA ombudsman as product jurisdiction officer is authorized to determine whether the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), or the Center for Drug Evaluation and Research (CDER) has primary responsibility for premarket review and regulation of a product that constitutes a combination of a drug, device, or biological product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act or that is a drug, device or biologic product where the center with primary jurisdiction is unclear or in dispute.

[56 FR 58758, Nov. 21, 1991]

§ 5.33 Premarket approval of a product that is or contains a biologic, a device, or a drug.

For a product that is or contains a biologic, a device, or a drug, the following officials in the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, or Center for Drug Evaluation and Research who currently hold delegated