

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

premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Biological Product Review, CBER.

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

[56 FR 58759, Nov. 21, 1991, as amended at 62 FR 2555, Jan. 17, 1997; 62 FR 67271, Dec. 24, 1997]

**§ 5.34 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.**

(a) Each center director is authorized to select members of, and consultants to, scientific and technical FDA advisory committees under that center's management to serve temporarily as voting members on another advisory committee under that center's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees if such voting members are serving on an advisory committee managed by another center has not been redelegated. This authority will continue to be exercised by the Commissioner or his designee.

(b) Each center director is authorized, under 18 U.S.C. 208(b)(1), to sign conflict of interest waivers for special government employees without substantial interest to serve as consultants to advisory committees or in any other capacity within the centers except as advisory committee members.

[58 FR 39142, July 22, 1993]

**§ 5.35 Enforcement activities.**

(a) Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA-200A, Identification Record, and Form FDA-200B, Specification of General Authority, are authorized:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the act); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Import Milk Act, the Filled Milk Act, the Tea Importation Act, and sections 351 and 354 through 361 of the Public Health Service Act.

(2) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA-200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act:

(i) Carry firearms;

(ii) Serve and execute search warrants and arrest warrants;

(iii) Execute seizure by process issued pursuant to libel under section 304 of the act;

(iv) Make arrests without warrant for an offense under the act with respect to counterfeit drugs if the offense is committed in the presence of the criminal investigator or, in the case of a felony, if the investigator has probable cause to believe that the person so arrested has committed, or is committing, such offense; and