

## § 5.30

## 21 CFR Ch. I (4-1-03 Edition)

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

(g) The Director and Deputy Directors for Science and for Regulations and Policy, 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) These officials may not further redelegate this authority.

### **§ 5.30 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 of Food and Drugs (Commissioner) or the Senior Associate Commissioner, Office of the Commissioner.

(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.

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

### **§ 5.31 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) (21 U.S.C. 372 (e) (5)); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461), the Federal Caustic Poison Act (44 Stat. 140b; see also Public Law 86-613, section 19, formerly section 18), the Import Milk Act (21 U.S.C. 141-149), the Filled Milk Act (21 U.S.C. 61-64), and sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264).

(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 of Food and Drugs (Commissioner) to conduct examinations, investigations,