Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

§5.10 Delegations from the Secretary of Health and Human Services to the Commissioner of Food and Drugs.

(a) The Secretary of Health and Human Services (the Secretary) has redelegated to the Commissioner of Food and Drugs (Commissioner), with authority to redelegate (except when specifically prohibited), all authority as follows:

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), as amended, the Filled Milk Act (21 U.S.C. 61–63), the Federal Import Milk Act (21 U.S.C. 141 *et seq.*), the Federal Caustic Poison Act (44 Stat. 1406; see also Public Law 86–613, section 19, formerly section 18) and The Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), under section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.

(2) Functions vested in the Secretary under section 301 (Research and Investigations); section 307 (International Cooperation); and section 311 (Federal-State Cooperation) of the Public Health Service Act (the PHS Act) (42 U.S.C. 241, 242l, 243), as amended, which relate to the functions of the Food and Drug Administration.

(3) Functions vested in the Secretary under section 361 of the PHS Act (42 U.S.C. 264), as amended, which relate to the law enforcement functions of the Food and Drug Administration concerning the following products and activities: Biologicals (including blood and blood products); interstate travel sanitation (except interstate transportation of etiologic agents under 42 CFR part 72); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration.

(4) Functions vested in the Secretary under sections 351 and 352 of part F, subpart 1 of the PHS Act (42 U.S.C. 262 and 263), as amended (Biological Products), insofar as they relate to the functions assigned to the Food and Drug Administration.

(5) Functions vested in the Secretary under section 302(a) of the PHS Act (42 U.S.C. 242(a)), as amended, which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.

(6) Functions vested in the Secretary under section 303 of the PHS Act (42 U.S.C. 242a), as amended, which relate to the authorization of persons engaged in research on the use and effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Public Law 91–513 for which an investigational new drug application is filed with the Food and Drug Administration and with respect to all drugs not scheduled under Public Law 91–513.

(7) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Public Law 91–513, 84 Stat. 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.

(8) Functions vested in the Secretary pertaining to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)), which relate to the merits of the research protocol and to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act.

(9) Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 *et seq.*), which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(10) Functions vested in the Secretary under section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)), which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(11) Functions vested in the Secretary under section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)), which relate to the detention

of any poultry carcass, part thereof, or poultry product.

(12) Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

(13) Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

(14) Function of issuing all regulations of the Food and Drug Administration, except as provided in § 5.11. The reservation of authority contained in Chapter 2–000 of the Department Organization Manual shall not apply.

(15) Functions vested in the Secretary under section 1103 of Executive Order 11490, as amended by Executive Order 11921, which relate to emergency health functions as they pertain to the operations and functional responsibilities assigned to the agency. This authority shall be exercised in accordance with section 102 and pertinent sections of part 30 of Executive Order 11490 and guidelines issued by the Federal Preparedness Agency of the General Services Administration and the Office of the Secretary.

(16) Function vested in the Secretary of authorizing and approving miscellaneous and emergency expenses of enforcement activities.

(17) Functions vested in the Secretary under the Federal Advisory Committee Act, Public Law 92–463, to:

(i) Renew, recharter, amend and terminate established Federal Advisory Committees;

(ii) Authority to approve waivers to appoint committee members to established Federal Advisory Committees;

(iii) Authority to close review meetings following approval by the Office of the General Counsel based on a determination that the Advisory Committee meeting or a portion thereof may be closed to the public under the provisions of 5 U.S.C. 552b(c) and section 10(d) of the Federal Advisory Committee Act. These authorities are to be exercised in accordance with the requirements of 5 U.S.C. 552b; the Federal Advisory Committee Act (Public Law 92–463); Departmental regulations (45 CFR part 11, superseded by 41 CFR part 101–6); and any other applicable statutes and regulations. These authorities may be redelegated.

(18) Functions vested in the Secretary under the second sentence of section 310(a) and under section 310(b) (Health Conferences and Health Education Information) of the PHS Act (42 U.S.C. 242o), as amended, to call for a conference and invite as many health authorities and officials of State or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of the Food and Drug Administration, and to issue information related to health for the use of the public and other pertinent health information for the use of persons and institutions concerned with health services when such information is related to the functions of the Food and Drug Administration.

(19) Functions vested in the Secretary under section 2701 of the PHS Act (42 U.S.C. 238), as amended, to accept offers of gifts, excluding the acceptance of gifts of real property. Only the authority to accept unconditional gifts of personal property valued at $5,000 or less may be redelegated.

(20) Functions vested in the Secretary under section 362 of the PHS Act (42 U.S.C. 265), as amended, which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of the Food and Drug Administration.

(21) Functions vested in the Secretary under section 401(a) of the Lead-Based Paint Poisoning Prevention Act, as amended by Public Law 94–317 (42 U.S.C. 4831(a)), relating to the prohibition of the application of lead-based paint to cooking, drinking, or eating utensils.

(22) Functions vested in the Secretary for the health information and health promotion program under title XVII of the PHS Act (42 U.S.C. 300u *et seq.*), as amended, insofar as the authorities pertain to functions assigned to the Food and Drug Administration. The delegation includes, but is not limited to, the authorities under: Section 1702(a)(1) and (3) and section 1704(1) and (2) (42 U.S.C. 300u–1(a) and (3) and 300u–

3(1) and (2)). The delegation excludes the authority to select all Senior Executive Service, supergrade and equivalent, and Schedule C (GS–12 and above) positions; issue regulations; and submit reports to the President.

(23) To administer a Small Business Innovation Research Program under section 9 of the Small Business Act (15 U.S.C. 638), as amended. The delegation excludes the authority to issue regulations, establish advisory councils and committees, appoint members to advisory councils and committees, and submit reports to Congress.

(24) Functions vested in the Secretary under sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981 (the Act) (42 U.S.C. 10007 and 10008), as amended. The delegation excludes the authority to issue regulations and submit reports to Congress. The authority delegated under section 983 of the Act may only be exercised as it relates to functions assigned to the Food and Drug Administration.

(25) Functions vested in the Secretary under section 156 of title 35 of the U.S. Code (35 U.S.C. 156), as amended, which allows for the extension of patent terms for human drug products, medical devices, food additives, and color additives subject to the Federal Food, Drug, and Cosmetic Act (the act). These authorities may be redelegated, except the authority to make due diligence determinations under section 156(d)(2)(B), which may not be redelegated to an Office below the Office of the Commissioner of Food and Drugs.

(26) Functions vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*) (the Act), as amended, and under Executive Order 12591 of April 10, 1987, as they pertain to the functions of the Food and Drug Administration. The delegation excludes the authority to issue regulations and submit reports to Congress; under section 11(a)(2) of the Act (15 U.S.C. 3710a(a)(2)) to approve agreements and contracts with invention management organizations; and under section 11(c)(3)(B) of the Act (15 U.S.C. 3710a(c)(3)(B)) to propose necessary statutory changes regarding conflict of interest.

(i) The authorities under section 11(c)(5)(A) and (B) of the act (15 U.S.C. 3710a(c)(5)(A) and (B)) to disapprove or require the modification of cooperative research and development agreements and licensing agreements after the agreement is presented to the Commissioner by the head of the laboratory concerned, and to transmit written explanation of such disapproval or modification to the head of the laboratory concerned, may be redelegated only to a senior official in the immediate Office of the Commissioner.

(ii) The following authorities may not be redelegated: The authority under section 11(b)(3)(D) of the Act (15 U.S.C. 3710a(b)(3)(D)) to waive a right of ownership which the Federal Government may have to an invention made under a cooperative research and development agreement; the authority under section 11(b)(3)(C) of the Act (15 U.S.C. 3710a(b)(3)(C)) to permit employees or former employees to participate in efforts to commercialize inventions they made while in the service of the United States; the authority under section 11(c)(3)(A) of the Act (15 U.S.C. 3710a(c)(3)(A)) to review employee standards of conduct for resolving potential conflicts of interest; the authority under section 13(a)(1) of the Act (15 U.S.C. 3710c(a)(1)) to retain any royalties or other income, except as provided in section 13(a)(2) of the Act (15 U.S.C. 3710c(a)(2)); and the authority under section 13(a)(1)(A)(i) of the Act (15 U.S.C. 3710c(a)(1)(A)(i)) to pay royalties or other income the agency receives on account of an invention to the inventor if the inventor was an employee of the agency at the time the invention was made.

(iii) Any authorities under paragraph (a)(26) of this section delegated by the Commissioner may not be further redelegated.

(27) Functions vested in the Secretary under sections 4702, 4703, and 4704 of the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401–1403) that relate to pesticide monitoring and enforcement information, foreign pesticide information, and pesticide analytical methods. The delegation excludes the authority to submit reports to Congress.

(28) Functions vested in the Secretary under sections 2312(a)(1) and (2)(B), (b), and (c) (Use of Investigational New Drugs with Respect to Acquired Immunodeficiency Syndrome); 2314(c) (Scientific and Ethical Guidelines for Certain Treatments); and 2317(d) and (e) (Information Services) of title XXIII of the PHS Act (42 U.S.C. 300cc–12(a)(1) and (2)(B), (b) and (c), 300cc–14(c) and 300cc–17(d) and (e)), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegation excludes the authority to issue regulations, submit reports to the Congress, establish advisory committees or national commissions, and appoint members to such committees or commissions.

(29) Functions vested in the Secretary under section 2672(a)(1) (A) and (B) (Provisions Relating to Blood Banks) and section 2672(a)(2) (Information and Training Programs) of the PHS Act (42 U.S.C. 300ff–72(a)(1)(A) and (B) and (a)(2) *et seq.*), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegations exclude the authority to issue regulations, submit reports to the Congress, establish advisory committees or national commissioners, and appoint members to such committees or commissions.

(30) Functions vested in the Secretary under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter, which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of this section. The delegation excludes the authority to submit reports to Congress.

(31) Functions vested in the Secretary under part C, subtitle 2 of title XXI of the PHS Act (42 U.S.C. 300aa–25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1 note), as amended hereafter, as follows:

(i) Section 2125 of the PHS Act (42 U.S.C. 300aa–25)—Recording and reporting of information.

(ii) Section 2127 of the PHS Act (42 U.S.C. 300aa–27)—-Mandate for safer childhood vaccines.

(iii) Section 2128 of the PHS Act (42 U.S.C. 300aa–28)—Manufacturer recordkeeping and reporting.

(iv) Section 312 of the National Childhood Vaccine Injury Act of 1986—Related studies (42 U.S.C. 300aa–1 note).

(v) Section 313 of the National Childhood Vaccine Injury Act of 1986—Study of other vaccine risks (42 U.S.C. 300aa–1 note).

(vi) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information (42 U.S.C. 300aa–1 note).

(vii) The delegation excludes the authority to issue regulations and submit reports to Congress.

(32) Functions vested in the Secretary under section 201(h)(4) of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended) (21 U.S.C. 811(h)(4)) to provide responses to the Drug Enforcement Administration's temporary scheduling notices. The delegation excludes the authority to submit reports to Congress.

(33) Functions vested in the Secretary under the Safe Medical Devices Act of 1990 (Pub. L. 101–629), as amended hereafter (e.g., 21 U.S.C. 360c note, 360i note, and 360j note). The delegation excludes the authority to submit reports to Congress.

(34) Functions vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Public Law 104–180), as amended hereafter. The delegation excludes the authority to issue reports to Congress.

(35) The Secretary has redelegated to the Commissioner of Food and Drugs, or his designee, the authority to take final action on matters pertaining to section 203 of the Equal Access to Justice Act (5 U.S.C. 504), and to develop

procedures and regulations where necessary to supplement the Department's regulations, 45 CFR part 13.

(36) The Secretary has delegated to the Commissioner, the authority to administer and make decisions regarding the invention and patent program as they pertain to the functions of the Food and Drug Administration and to make determinations of rights in inventions and patents in which the Department has an interest. This delegation excludes the authority to submit reports to Congress and further, it excludes those authorities under the Stevenson-Wydler Technology Innovation Act of 1980, as amended by the Federal Technology Transfer Act of 1986 and the National Technology Transfer and Advancement Act of 1995, which are governed by a separate delegation (under §5.10(a)(26)). All authorities other than the authority under 35 U.S.C. section 203 (March-In Rights) may be redelegated.

(37) Functions vested in the Secretary under title III, Section 354, of the PHS Act (42 U.S.C. 262 *et seq.*), as amended. The authority pertains to the Food and Drug Administration's oversight of mammography facilities.

(38) The Deputy Assistant Secretary for Health Management Operations, Public Health Service, has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration, or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the nonexistence of records on file within the Administration; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(39) The Secretary of Health and Human Services has redelegated to the Commissioner, of Food and Drugs, under 45 CFR 5b.8 regulations, appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act regulations (part 21 of this chapter and 45 CFR part 5b). The authority may not be redelegated.

(b) The Chief Counsel of the Food and Drug Administration has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, under section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335), section 4 of the Federal Import Milk Act (21 U.S.C. 144), and section 9(b) of the Federal Caustic Poison Act.

§5.11 Reservation of authority.

(a) Notwithstanding provisions of §5.10 or any previous delegations of authority to the contrary, the Secretary of Health and Human Services (Secretary) reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of title 5 U.S.C. apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of title 5 U.S.C. apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and it is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food and Drug Administration without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

Subpart B—General Redelegations of Authority

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs (Commissioner) is redelegated as set forth in these subparts. The Commissioner may continue to exercise all authority delegated in subparts B through L.

(b) The following officials are authorized to perform all of the functions of the Commissioner. These officials may not further redelegate this authority, or any part of this authority, except as elsewhere specified:

(1) Deputy Commissioner;

(2) Associate Commissioner for Regulatory Affairs;

(3) Senior Associate Commissioner;

(4) Senior Associate Commissioner for Management and Systems;

(5) Senior Associate Commissioner for Policy, Planning, and Legislation; and

(6) Deputy Commissioner for International and Constituent Relations.

(c)(1) During the absence or disability of the Commissioner or in the event of a vacancy in that position, the first official who is available in the following positions, or who has been designated by the Commissioner to act in such position, shall act as Commissioner:

(i) Deputy Commissioner;

(ii) Associate Commissioner for Regulatory Affairs; or

(iii) Senior Associate Commissioner.

(2) These officials may not further redelegate this authority. However, for a planned period of absence, the Commissioner (or someone ''acting'' on his/her behalf) may specify a different order of succession.

(d) Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him/her as ''acting'' or unless not legally permissible.

(e)(1) The Senior Associate Commissioner is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public in accordance with § 5.10(a)(17).

(2) The Senior Associate Commissioner is authorized to perform other associated advisory committee functions (e.g., establishing technical and scientific review groups (advisory committees)); appointing and paying members; approving waivers to appoint members to established advisory committees; renewing and rechartering of established advisory committees; amending charters of established advisory committees; and terminating established advisory committees.

(3) The Senior Associate Commissioner is authorized to approve conflict of interest waivers for special Government employees serving on advisory committees in accordance with 18 U.S.C. 208(b)(3), as amended.

(4) The Senior Associate Commissioner is authorized to select temporary members to advisory committees if such voting members are serving on an advisory committee managed by another center.

(5) The Senior Associate Commissioner may not further redelegate these authorities.

(f)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation (SACPPL) and the Associate Commissioner for Policy (ACP) are authorized to perform any of the functions of the Commissioner with respect to the issuance of FEDERAL REGISTER notices and proposed and final regulations of the Food and Drug Administration. These officials may not further redelegate this authority.

(2) The SACPPL and the ACP are authorized to issue responses to the following matters under part 10 of this chapter as follows and these officials may not further redelegate this authority:

(i) Requests for waiver, suspension, or modification of procedural requirements under § 10.19 of this chapter;

(ii) Citizen petitions under § 10.30 of this chapter;

(iii) Petitions for reconsideration under § 10.33 of this chapter;

(iv) Petitions for stay under § 10.35 of this chapter; or

(v) Requests for advisory opinions under § 10.85 of this chapter.

(3) With respect to any matter delegated to the SACPPL and the ACP under this paragraph, the SACPPL and the ACP are authorized to perform the function of the Commissioner under §§ 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 of this chapter and of the Deputy Commissioner under § 10.206(g) and (h) of this chapter. These officials may not further redelegate this authority.

(4) The SACPPL and the ACP are authorized 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. The SACPPL and the ACP may further redelegate this authority.

(g) The following officials are authorized to perform all the functions of the officials under them in their respective offices and they may not further redelegate this authority:

(1) Senior Associate Commissioner;

(2) Deputy Commissioner for International and Constituent Relations;

(3) Senior Associate Commissioner for Management and Systems; or

(4) Senior Associate Commissioner for Policy, Planning, and Legislation.

(h)(1) The Chief Mediator and Ombudsman and the Deputy Chief Mediator and Ombudsman are authorized to act upon requests for reconsideration of any user fee decisions under section 735 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h) made by such officers and the former Deputy User Fee Waiver Officer prior to July 1, 1999. These officials may not further redelegate this authority. (See subpart C, § 5.108 for the user fee-related redelegation to officials within the Center for Drug Evaluation and Research.)

(2) The Senior Associate Commissioner for Management and Systems and the Director, Office of Financial Management, are authorized to perform the functions of the Commissioner under section 736(d)(1)(c) of the act (21 U.S.C. 379h(d)(1)(C)), as amended, to waive or reduce prescription drug user fees in situation where he or she finds that ''the fees will exceed the anticipated present and future costs.'' These officials may not further redelegate this authority.

(3) The Deputy Commissioner, or in the event of a vacancy in that position, the Senior Associate Commissioner, Office of the Commissioner, is designated as the User Fee Appeals Officer. The User Fee Appeals Officer is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters. The User Fee Appeals Officer may not further redelegate this authority.

(i) The Senior Associate Commissioner for Management and Systems is authorized to perform all of the administrative authorities (i.e., financial, personnel, facilities management, property management, etc.) of the Commissioner. These authorities may be further redelegated, except when specifically prohibited.

(j) Unless specifically noted, the persons to whom the Commissioner has delegated authority in subparts B through L of this part may not further redelegate that authority.

§ 5.21 Emergency functions.

(a) Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his or her region to:

(1) Fully represent the Food and Drug Administration within his or her region in cooperation with the Department of Health and Human Services regional emergency plans, and

(2) Exercise the authority of the Commissioner of Food and Drugs for supervision of and direction to all Food and Drug Administration activities and use of resources within his or her region for continuity and for Federal Emergency Health Service operations.

(b) These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters. These officials may not further redelegate this authority.

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,

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 (21 U.S.C. 372(e)(1)–(e)(5)):

(i) Carry firearms;

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

(iii) Execute seizure by process issued under libel under section 304 of the act (21 U.S.C. 334);

(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

(v) Make, prior to the institution of libel proceedings under section 304(a)(2) of the act (21 U.S.C. 334(a)(2)), seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or the criminal investigator has reasonable grounds to believe that they are, subject to seizure and condemnation under section 304(a)(2) of the act.

(2) Perform such other functions under the act, or any other law, as the Commissioner may prescribe.

(3) 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.

(c) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to provide specialized law enforcement support involving criminal investigations under the act, and other duties as assigned by the Commissioner, and issued the Food and Drug Administration Official Credential consisting of Form FDA–200E, Special Authority for Criminal Investigative Specialists, is authorized to receive information as to all matters relating to such act and regulations issued under the act.

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

§ 5.32 Certification following inspections.

Regional Food and Drug Directors and District Directors are authorized to issue certificates of sanitation under § 1240.20 of this chapter. These officials may not further redelegate this authority.

§ 5.33 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under section 309 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 336) (the act) regarding the issuance of written notices or warnings:

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

(ii) The Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

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

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

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

(iv) 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.

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

(ii) The Director of Regulations and Policy, CFSAN.

(iii) The Director, Office of Field Programs, CFSAN.

(iv) The Director, Division of Enforcement and Programs, Office of Field Programs, CFSAN.

(4)(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(m) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH are authorized to impose sanctions under section 354(h)(2) of the PHS Act (42 U.S.C. 263b(h)(2)).

(n) The following officials are authorized to develop and implement the procedures for determining when and how to impose sanctions as provided by section 354(h)(3) of the PHS Act (42 U.S.C. 263b(h)(3)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(o) The following officials are authorized to suspend or revoke individual facility certificates under section 354(i)(1) and (i)(2) of the PHS Act (42 U.S.C. 263b(i)(1) and (i)(2)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(p) The following officials are authorized under section 354(i)(3) of the PHS Act (42 U.S.C. 263b(i)(3)) to ensure that no person who owned or operated a facility at the time the cause of revocation occurred may, within 2 years of the revocation of the certificate, own or operate a mammography facility:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(q) The following officials are authorized to compile and make available to physicians and the general public information determined to be useful in evaluating the performance of mammography facilities as provided by section 354(l) of the PHS Act (42 U.S.C. 263b(l):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(r) The following officials are authorized to ensure that appropriate Federal agencies are consulted in the development of standards, regulations, evaluations, procedures for compliance and oversight as provided by section 354(o) of the PHS Act (42 U.S.C. 263b(o)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(3) The Director and Deputy Director, DMQRP, OHIP, CDRH.

(s) The following officials may authorize a State to carry out certification program requirements and implement quality standards under section 354(q)(1) and (q)(2) of the PHS Act (42 U.S.C. 263b(g)(1) and (g)(2)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH.

(2) The Director and Deputy Director, OHIP, CDRH.

(t) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH are authorized, after providing notice and opportunity for corrective action, to withdraw the approval of a State's authority to carry out certification requirements and implement quality standards under section 354(q)(4) of the PHS Act (42 U.S.C. 263b(g)(4)).

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

Subpart M—Organization

§ 5.1100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.[1]

Office of the Chief Counsel.

Office of Equal Opportunity.

Office of the Administrative Law Judge.

Office of the Senior Associate Commissioner.

[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

Office of Executive Secretariat.

Office of Public Affairs.

Office of the Ombudsman.

Office of Orphan Products Development.

Office of Internal Affairs.

Office of Executive Operations.

Office of Science Coordination and Communication.

Office of Human Research Trials.

Office of International and Constituent Relations.

Office of International Programs.

Office of Consumer Affairs.

Office of Women's Health.

Office of Special Health Issues.

Office of Policy, Planning, and Legislation.

Office of Policy.

Office of Planning.

Office of Legislation.

Office of Management and Systems.

Office of Human Resources and Management Services.

Office of Information Resources Management.

Office of Financial Management.

Office of Facilities, Acquisitions, and Central Services.[2]

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.[3]

Office of the Center Director.

Scientific Advisors and Consultants Staff.

Equal Employment Opportunity and Workforce Diversity Staff.

Quality Assurance Staff.

Regulations and Policy Staff.

Veterinary Services Staff.

Office of Management.

Regulatory Information Management Staff.

Division of Planning, Evaluation, and Budget.

Division of Management Services.

Office of Information Technology Management.

Division of Information Technology Operations.

Division of Information Technology Development.

Division of Information Technology Infrastructure.

Office of Compliance and Biologics Quality.

Division of Case Management.

Division of Manufacturing and Product Quality.

Division of Inspections and Surveillance.

Office of Blood Research and Review.

Human Tissue Staff.

Policy and Publications Staff.

Division of Emerging and Transfusion Transmitted Diseases.

Division of Hematology.

Division of Blood Applications.

Office of Therapeutics Research and Review.

Division of Cellular and Gene Therapies.

Division of Therapeutic Proteins.

Division of Monoclonal Antibodies.

Division of Clinical Trial Design and Analysis.

Division of Application Review and Policy.

Office of Vaccines Research and Review.

Division of Bacterial, Parasitic, and Allergenic Products.

Division of Viral Products.

Division of Vaccines and Related Products Applications.

Office of Communication, Training, and Manufacturers Assistance.

Division of Disclosure and Oversight Management.

Division of Manufacturers Assistance and Training.

Division of Communication and Consumer Affairs.

Office of Biostatistics and Epidemiology.

Division of Biostatistics.

Division of Epidemiology.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.[4]

[2] Mailing address: 5630 Fishers Lane, Rockville, MD 20857.

[3] Mailing address: 1401 Rockville Pike, Rockville, MD 20852–1448.

[4] Mailing address: 5100 Paint Branch Pkwy., College Park, MD 20740.

Office of the Center Director.
Food Safety Initiatives Staff.
Office of Science
Quality Assurance Staff.
CFSAN Staff College.
Microbial Research and Risk Assessment Staff.
JIFSAN Liaison Staff.
CFSAN Food Advisory Committee Staff.
Office of Applied Research and Safety Assessment.
Muirkirk Technical Operations Staff.
Division of Molecular Biology.
Division of Virulence Assessment.
Division of Toxicology and Nutritional Product Studies.
Division of In Vitro and Biochemical Toxicology.
Office of Regulations and Policy.
Regulations Coordination Staff.
Office of Constituent Operations.
Consumer Education Staff.
Industry Activities Staff.
International Activities Staff.
Office of Management Systems.
Safety Management Systems.
Division of Information Resources Management.
Division of Planning and Financial Resources Management.
Division of Management Operations.
Division of Administrative Services Management.
Office of Operations.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Office of Cosmetics and Colors.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Nutritional Products, Labeling and Dietary Supplements.
Division of Compliance and Enforcement.
Division of Standards and Labeling Regulations.
Division of Nutrition Science Policy.
Office of Premarket Approval.
Division of Product Policy.
Division of Petition Control.
Division of Health Effects Evaluation.
Division of Product Manufacture and Use.
Office of Plant and Dairy Foods and Beverages.
Division of Pesticides and Industrial Chemicals.
Division of Natural Products.
Division of Food Processing and Packaging.
Division of Plant Product Safety.
Division of Dairy and Egg Safety.
Division of Risk Assessment.
Division of Microbiological Studies.
Office of Seafood.
Division of Special Programs.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Field Programs.
Division of Enforcement and Programs.
Division of HACCP Programs.
Division of Cooperative Programs.
Office of Scientific Analysis and Support.
Division of General Scientific Support.
Division of Mathematics.
Division of Market Studies.
CENTER FOR DRUG EVALUATION AND RESEARCH.[1]
Office of the Center Director.
Equal Employment Opportunity Staff.
Executive Operations Staff.
Office of Regulatory Policy.
Division of Regulatory Policy I.
Division of Regulatory Policy II.
Division of Information Disclosure Policy.
Office of Management.[1]
Strategic Planning Staff.[1]
Division of Management and Budget.[5]
Division of Management Services.[1]
Office of Training and Communication.[1]
Medwatch Staff.
Division of Library and Information Services.
Division of Training and Development.

[5] Mailing address: 7500 Standish Pl., Rockville, MD 20855.

Division of Public Affairs.

Division of Drug Information.

Office of Compliance.[6]

Division of Manufacturing and Product Quality.

Division of Prescription Drug Compliance and Surveillance.

Division of Labeling and Non-Prescription Drug Compliance.

Office of Information Technology.[1]

Quality Assurance Staff.

Technology Support Services Staff.

Division of Data Management and Services.

Division of Applications Development and Services.

Division of Infrastructure Management and Services.

Office of Medical Policy.[1]

Division of Drug Marketing, Advertising and Communication.[1]

Division of Scientific Investigations.[5]

Office of Review Management.[1]

Advisors and Consultants Staff.[2]

Office of Drug Evaluation I.[1]

Division of Cardio-Renal Drug Products.

Division of Neuropharmacological Drug Products.

Division of Oncology Drug Products.

Office of Drug Evaluation II.[1]

Division of Metabolic and Endocrine Drug Products.

Division of Pulmonary and Allergy Drug Products.

Division of Anesthetic, Critical Care and Addiction Drug Products.

Office of Drug Evaluation III.[1]

Division of Gastrointestinal and Coagulation Drug Products.

Division of Medical Imaging and Radiopharmaceutical Drug Products.

Division of Reproductive and Urologic Drug Products.

Office of Drug Evaluation IV.[1]

Division of Anti-Infective Drug Products.

Division of Anti-Viral Drug Products.

Division of Special Pathogen and Immunologic Drug Products.

Office of Drug Evaluation V.[1]

Division of Anti-Inflammatory, Analgesic and Opthalmologic Drug Products.

Division of Dermatologic and Dental Drug Products.

Division of Over-The-Counter Drug Products.

Office of Biostatistics.[1]

Quantitative Methods Research Staff.

Division of Biometrics I.

Division of Biometrics II.

Division of Biometrics III.

Office of Post-Marketing Drug Risk Assessment.[1]

Extramural Programs Staff.

Information Technology Staff.

Division of Drug Risk Evaluation I.

Division of Drug Risk Evaluation II.

Office of Pharmaceutical Science.[1]

Quality Implementation Staff.[1]

Operations Staff.[1]

Office of Clinical Pharmacology and Biopharmaceutics.

Pharmacometrics Staff.

Division of Pharmaceutical Evaluation I.[1]

Division of Pharmaceutical Evaluation II.[1]

Division of Pharmaceutical Evaluation III.[1]

Office of Generic Drugs.[6]

Division of Bioequivalence.

Division of Chemistry I.

Division of Chemistry II.

Division of Labeling and Program Support.

Office of New Drug Chemistry.[1]

Division of New Drug Chemistry I.[1]

Division of New Drug Chemistry II.[1]

Division of New Drug Chemistry III.[1]

Office of Testing and Research.[1]

Informatics and Computational Safety Analysis Staff.

Laboratory of Clinical Pharmacology.[1]

[6] Mailing address: 7520 Standish Pl., Rockville, MD 20855.

Division of Applied Pharmacology Research.[7]

Division of Pharmaceutical Analysis.[8]

Division of Product Quality Research.[1]

OFFICE OF REGULATORY AFFAIRS.[1]

Equal Employment Opportunity Staff.

Office of Resource Management.

Strategic Initiatives Staff.

Division of Planning, Evaluation, and Management.

Division of Information Systems.

Division of Human Resource Development.

Division of Management Operations.

Division of Personnel Operations.

Office of Enforcement.

Division of Compliance Management and Operations.

Division of Compliance Policy.

Division of Compliance Information and Quality Assurance.

Office of Regional Operations.

Division of Federal-State Relations.

Division of Field Science.

Division of Emergency and Investigational Operations.

Division of Import Operations and Policy.

Office of Criminal Investigations.

Mid-Atlantic Area Office.[9]

Midwest Area Office. [10]

Northeast Area Office.[11]

Pacific Area Office.[12]

Southeast Area Office.[13]

Southwest Area Office.[14]

CENTER FOR VETERINARY MEDICINE.[15]

Office of the Center Director.

Office of Management and Communications.

Administrative Staff.

Communications Staff.

Information Resources Management Staff.

Office of New Animal Drug Evaluation.

Division of Therapeutic Drugs for Food Animals.

Division of Biometics and Production Drugs

Division of Therapeutic Drugs for Nonfood Animals.

Division of Manufacturing Technologies.

Division of Human Food Safety.

Office of Surveillance and Compliance.

Division of Surveillance.

Division of Animal Feeds.

Division of Compliance.

Division of Epidemiology.

Office of Research.

Administrative Staff.

Division of Residue Chemistry.

Division of Animal Research.

Division of Animal and Food Microbiology.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.[16]

Office of the Center Director.

Equal Employment Opportunity Staff.

Office of Systems and Management.

Integrity Committee and Conference Management Staff.

Division of Management Operations.

Division of Information Dissemination.

Division of Information Technology Management.

Division of Planning, Analysis and Finance.

Office of Compliance.

Promotion and Advertising Policy Staff.

Division of Bioresearch Monitoring.

Division of Program Operations.

Division of Enforcement I.

Division of Enforcement II.

Division of Enforcement III.

[7] Mailing address: 8301 Muirkirk Rd., Laurel, MD 20708.

[8] Mailing address: 1114 Market St., St. Louis, MO 63101.

[9] Mailing address: 900 U.S. Customhouse, Second Chestnut St., Philadelphia, PA 19106.

[10] Mailing address: 901 Warrenville Rd., suite 360, Lisle, IL 60532.

[11] Mailing address: 158–15 Liberty Ave., Jamaica, NY 11433.

[12] Mailing address: 13301 Clay St., Oakland CA 94512.

[13] Mailing address: 60 Eighth St. NE, Atlanta, GA 30309.

[14] Mailing address: 7920 Elmbrook Rd., Dallas, TX 75247.

[15] Mailing address: 7500 Standish Pl., MPN–2, Rockville, MD 20855.

[16] Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

Office of Device Evaluation.

Program Management Staff.

Program Operations Staff.

Division of Cardiovascular and Respiratory Devices.

Division of Reproductive, Abdominal and Radiological Devices.

Division of General, Restorative and Neurological Devices.

Division of Clinical Laboratory Devices.

Division of Ophthalmic, Ear, Nose, and Throat Devices.

Division of Dental, Infection Control, and General Hospital Devices.

Office of Science and Technology.

Division of Mechanics and Materials Science.

Division of Life Sciences.

Division of Physical Sciences.

Division of Electronics and Computer Sciences.

Division of Management Information and Support Services.

Office of Health and Industry Programs.

Program Operations Staff.

Regulations Staff.

Staff College.

Division of Device User Programs and Systems Analysis.

Division of Small Manufacturers Assistance.

Division of Mammography Quality and Radiation Programs.

Division of Communication Media.

Office of Surveillance and Biometrics.

Issues Management Staff.

Division of Biostatistics.

Division of Postmarket Surveillance.

Division of Surveillance Systems.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.[17]

Office of the Center Director.

Environmental Health and Program Assurance Staff.

Office of Research.

Technology Advancement Staff.

Division of Biochemical Toxicology.

Division of Genetic and Reproductive Toxicology.

Division of Biometry and Risk Assessment.

Division of Microbiology.

Division of Chemistry.

Division of Neurotoxicology.

Division of Veterinary Services.

Division of Molecular Epidemiology.

Office of Management.

Office of Management Services.

Division of Facilities, Engineering and Maintenance.

Division of Administrative Services.

Division of Contracts and Acquisitions.

Office of Planning, Finance and Information Technology.

Division of Planning.

Division of Financial Management.

Division of Information Technology.

[66 FR 30993, June 8, 2001, as amended at 66 FR 56035, Nov. 6, 2001]

§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is 5600 Fishers Lane, rm. 6–57, Rockville, MD 20857.

§ 5.1110 Food and Drug Administration Public Information Offices.

(a) *Dockets Management Branch (HFA–305).* The Dockets Management Branch Public Room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Telephone: 301–827–6860.

(b) *Freedom of Information Staff (HFI–35).* The Freedom of Information Public Room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6567.

(c) *Press Relations Staff (HFI–40).* Press Offices are located in rm. 15–05, Parklawn Bldg, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6242; and in rm. 3807, FB–8, 5100 Paint Branch Pkwy., College Park, MD 20740. Telephone 202–205–4144.

[66 FR 30993, June 8, 2001, as amended at 66 FR 56035, Nov. 6, 2001]

[17] Mailing address: 3900 NCTR Dr., Jefferson, AR 72079.

§ 5.1115 Field structure.

NORTHEAST REGION

Regional Field Office: 158–15 Liberty Ave., Jamaica, NY 11433.

Northeast Regional Laboratory: 158–15 Liberty Ave., Jamaica, NY 11433.

New York District Office: 158–15 Liberty Ave., Jamaica, NY 11433.

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Winchester Engineering and Analytical Center: 109 Holton St., Winchester, MA 01890.

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201–2199.

Cincinnati District Office: 6751 Steger Dr., Cincinnati, OH 45237–3097.

Forensic Chemistry Center: 6751 Steger Dr., Cincinnati, OH 45237–3097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d Floor, Parsippany, NJ 07054.

Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.

Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207–3179.

Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401–1912.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

New Orleans District Office: Textron Bldg., 6600 Plaza Dr., suite 400, New Orleans, LA 70127.

Nashville Branch of NOL-DO: 297 Plus Park Blvd., Nashville, TN 37217.

Florida District Office: 555 Winderley, suite 200, Maitland, FL 32751.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901–3223.

SOUTHWEST REGION

Regional Field Office: 7920 Elmwood Rd., suite 102, Dallas, TX 75247–4982.

Dallas District Office: 3310 Live Oak St., Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225–0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214–3338.

St. Louis Branch: 12 Sunnen Dr., suite 122, St. Louis, MO 63143–3800.

Arkansas Regional Laboratory: 3900 NCTR Rd., Bldg. 14–T, rm. 104, Jefferson, AR 72079–9502.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180–N, Oakland, CA 94612–5217.

San Francisco District Office: 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070.

Los Angeles District Office: 19900 Mac Arthur Blvd., suite 300, Irvine, CA 92715.

Seattle District Office: P.O. Box 3012, Bothell, WA 98021–3012.

Pacific Regional Laboratory, SW: 1521 West Pico Blvd., Los Angeles, CA 90015–2488.

Pacific Regional Laboratory, NW: 22201 23rd Dr. SE., Bothell, WA 98021–4421.

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities