DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Reorganization and Republication

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its regulation for its delegations of authority, to improve information retrieval, ensure consistency, clarify redelegation statements, update the legal citations and position and organizational titles, and, in some instances, redelegate authorities to additional agency officials and employees. This action is necessary to ensure the continued accuracy of the regulations.

DATES: This rule is effective April 2, 2001.

FOR FURTHER INFORMATION CONTACT: Donna Page or Robin Phipps, Division of Management Programs (HFA–340), Food and Drug Administration, 301–827–4816 or 301–827–4806, respectively.

SUPPLEMENTARY INFORMATION: FDA is revising its regulations for delegation of authority and organization in part 5 (21 CFR part 5) to improve information retrieval by agency officials and employees, the public, and affected industries; to ensure the accuracy of the regulation by removing or correcting obsolete references to legislation, organizational and position titles; and to improve consistency in the display of the information. This regulation includes revisions to § 5.10 to clarify that the authority of the Secretary of Health and Human Services (the Secretary) is delegated directly to the Commissioner of Food and Drugs (the Commissioner), as well as to correct or remove outdated statutory citations. In 21 CFR, subpart B has been substantially reorganized, made into additional subparts, and updated.

Prior to November 1995, the Commissioner had reported to the Assistant Secretary for Health (ASH), and the Commissioner exercised authority delegated from the Secretary through the ASH. In November 1995, the Secretary designated U.S. Public Health Service agencies, including FDA, as Operating Divisions within the Department of Health and Human Services that report directly to the Secretary, and deleted the Office of the ASH (60 FR 56605, November 9, 1995). In this revision, we have therefore modified the introductory language of § 5.10(a) to indicate that the delegations are from the Secretary directly to the Commissioner, and we have moved the delegations formerly listed in § 5.10(c), (d), and (f) into § 5.10(a).

In this revision, we have also removed or corrected obsolete citations to legislation in § 5.10 and in the agency delegations. Following are the legal citations that we removed or corrected, as appropriate:

(1) In § 5.10(a)(1) and in § 5.32 (formerly § 5.35), we removed references to the Tea Importation Act, which Congress repealed by Public Law 104–128, section 2.

(2) We removed § 5.10(a)(3), which pertained to electronic product radiation control under the PHS Act (PHS Act), because Congress transferred these provisions from the PHS Act to the Federal Food, Drug and Cosmetic Act (the act) by Public Law 101–629, section 19(a). Additionally in §§ 5.800, 5.601, 5.602, 5.603, 5.604, 5.605, and 5.606 (formerly §§ 5.45, 5.87, 5.88, 5.89, 5.90, 5.91, and 5.92), we revised citations for electronic product radiation control to the act instead of the PHS Act.

(3) In § 5.10(a)(19) (formerly § 5.10(a)(20)), we updated the reference to the acceptance of gifts, which was formerly codified under the PHS Act (at 42 U.S.C. 219) and is now codified at 42 U.S.C. 238 by Public Law 103–43, title XX, section 2010(a)(1)–(3).

(4) We removed § 5.10(a)(22), which pertained to waiving matching requirements on state and local governments under title X of the Public Works and Economic Development Act of 1965 (42 U.S.C. 3246b(b)(3)), because Congress repealed section 1003(b)(3), title X, of that act by Public Law 105–393, title I, section 102(c).

(5) In § 5.10(a)(22) (formerly § 5.10(a)(24)), we removed the reference to section 1704(6) of the PHS Act, because Congress repealed it by Public Law 98–551, section 2(b).

(6) We removed § 5.10(a)(28), which pertained to a registry for cardiac pacemaker devices and leads under section 1862(h)(1), (2)(A), and (3) of the Social Security Act (42 U.S.C. 1395y(h)(1), (2)(A), and (3)) because Congress repealed section 1862(h) (42 U.S.C. 1395y(h)) by Public Law 104–224, section 1. Additionally, we removed former § 5.28, regarding payments for cardiac pacemaker devices and pacemaker leads, because Congress repealed the statutory provision.

(7) In § 5.10(a)(26) (formerly § 5.10(a)(29)), we updated citations under the Stevenson-Wydler Technology Innovation Act of 1980, because Congress placed what had been section 11(b)(3) into 11(b)(3)(D) and what had been section 11(b)(4) into 11(b)(3)(C) by Public Law 104–113, section 4.

At the end of each section of the reorganized §§ 5.20 through 5.1000, we have added the appropriate redelegation statements. Although the officials under § 5.20(b) (the Deputy Commissioner; Senior Associate Commissioner; Deputy Commissioner for International and Constituent Relations; Senior Associate Commissioner for Management and Systems; Senior Associate Commissioner for Policy, Planning, and Legislation; and the Associate Commissioner for Regulatory Affairs) have all the authorities of the Commissioner, their titles appear in other sections of the reorganized §§ 5.21 through 5.1000, generally to indicate that they are the agency officials who would principally exercise the authority. Further, in some instances, the Commissioner has delegated authorities to additional agency officials to ensure more efficient operations.

For the convenience of the user, we have established additional subparts to categorize the information about delegations within FDA by functional areas. In this revision, the subparts are Subpart B, General Redelegations of Authority; Subpart C, Human Drugs, Redelegations of Authority; Subpart D, Biologics, Redelegations of Authority; Subpart E, Food and Cosmetics, Redelegations of Authority; Subpart F, Medical Devices, Redelegations of Authority; Subpart G, Animal Drugs, Redelegations of Authority; Subpart H, Radiation Control, Redelegations of Authority; Subpart I, Product Designation, Redelegations of Authority; Subpart J, Imports and Exports, Redelegations of Authority; Subpart K, Orphan Products, Redelegations of Authority; Subpart L, Mammography Facilities, Redelegations of Authority; and Subpart M, Organization. We have cross-referenced (in the attached Appendix) the former subparts and sections to the new subparts and sections; and we are displaying the entire text of the revised part 5.

The agency is issuing this rule as a final rule without publishing a general notice of proposed rulemaking because such notice is not required for this rule of agency organization, procedure, or practice under 5 U.S.C. 533(b)(A).

The agency has determined under 21 CFR 25.30 that this action is of a type that does not individually or

cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

FDA has examined the impacts of this final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or more, or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency finds that this final rule, which reorganizes, updates, and clarifies the agency's internal delegations, is not a significant rule as defined by Executive Order 12866. No analysis is required under the Regulatory Flexibility Act (5 U.S.C. 601–612) because the agency is issuing it without publishing a general notice of proposed rulemaking, as explained previously in this document.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

The agency plans to migrate to an Intra/Internet-based system for publishing the delegations of authority and eventually remove them from part 5. The agency will publish a notice to make that change effective and provide the Internet website address.

The Commissioner hereby ratifies and affirms any actions taken by the delegates and their subordinates, which in effect, involved the exercise of the authorities delegated herein prior to the effective date of this notice.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, title 21 CFR part 5 is revised to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. Part 5 is revised in its entirety to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

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

Sec.

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

5.11 Reservation of authority.

Subpart B—General Redelegations of Authority

Sec.

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

5.21 Emergency functions.

5.22 Certification of true copies and use of Department seal.

5.23 Disclosure of official records and authorization of testimony.

5.24 Authority relating to technology transfer.

5.25 Research, investigation, and testing programs and health information and promotion programs.

5.26 Service fellowships.

5.27 Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings.

5.28 Hearings.

5.29 Petitions under part 10.

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

5.31 Enforcement activities.

5.32 Certification following inspections.

5.33 Issuance of reports of minor violations.

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

5.35 Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.

Subpart C—Human Drugs; Redelegations of Authority

Sec.

5.100 Issuance of notices implementing the provisions of the Drug Amendments of 1962.

5.101 Termination of exemptions for new drugs for investigational use in human beings.

5.102 Authority to approve and to withdraw approval of a charge for investigational new drugs.

5.103 Approval of new drug applications and their supplements.

5.104 Responses to Drug Enforcement Administration temporary scheduling notices.

5.105 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

5.106 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

5.107 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

5.108 Authority relating to waivers or reductions of prescription drug user fees.

5.109 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.

Subpart D—Biologics; Redelegations of Authority

Sec.

5.200 Functions pertaining to safer vaccines.

5.201 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

5.202 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.

5.203 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

5.204 Notification of release for distribution of biological products.

Subpart E—Foods and Cosmetics; Redelegations of Authority

Sec.

5.300 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

5.301 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

5.302 Detention of meat, poultry, eggs, and related products.

5.303 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.

5.304 Approval of schools providing food-processing instruction.

Subpart F—Medical Devices and Radiological Health; Redelegations of Authority

Sec.

5.400 Issuance of **Federal Register** documents to recognize or to withdraw recognition of a standard to meet premarket submission requirements.

Subpart G—Animal Drugs; Redelegations of Authority.

Subpart H—Radiation Control; Redelegations of Authority

Subpart I—Product Designation; Redelegations of Authority

Subpart J—Imports and Exports; Redelegations of Authority

Subpart K—Orphan Products; Redelegations of Authority

Subpart L—Mammography Facilities; Redelegations of Authority

Subpart M—Organization

Authority: 5 U.S.C. 504, 552, App. 2 605; 7 U.S.C. 138a, 2217; 15 U.S.C. 638, 1261–1282, 1451–1461, 3701–3711a; 21 U.S.C., 61–63, 141–149, 301–394, 467f, 679(b), 801–886, 1031–1309, 1401–1403; 35 U.S.C. 156; 42 U.S.C. 238, 241, 242, 242a, 242l, 242n, 242o, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 300ar–25–28, 300cc, 300ff, 1395y, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

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 sections 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.

§ 5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of, or extracts from, any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) The Deputy Commissioner, the Senior Associate Commissioner, the Deputy Commissioner for International and Constituent Relations, the Senior Associate Commissioner for Management and Systems, and the Senior Associate Commissioner for Policy, Planning, and Legislation.

(2) The Associate and Deputy Associate Commissioners and the Chief Counsel and Deputy Chief Counsels.

(3) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, Office of the Commissioner (OC).

(4) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, OC.

(5)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).

(ii) The Director and Deputy Director, Office of Regional Operations, ORA.

(iii) The Director and Deputy Director, Office of Resource Management (ORM), ORA.

(iv) The Director, Division of Management Operations, ORM, ORA.

(v) Team Leader, FDA History Staff, ORM, ORA.

(6)(i) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC.

(ii) The Director, Division of Management Programs (DMP), OHRMS, OMS, OC.

(iii) The Chief, Dockets Management Branch, DMP, OHRMS, OMS, OC.

(7) The Associate Commissioner for Public Affairs, Office of Public Affairs (OPA), Office of the Senior Associate Commissioner (OSAC), OC.

(8)(i) The Chief Information Officer, Office of Information Resources Management (OIRM), Office of Management and Systems (OMS), OC.

(ii) The Director, Freedom of Information Staff, OIRM, OMS, OC.

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

(ii) The Director, Office of Management, CBER.

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

(iv) The Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance, CBER.

(v) The Director and Branch Chiefs, Division of Case Management, Office of

Compliance and Biologics Quality (OCBQ), CBER; and the Consumer Safety Officers, OCBQ, CBER.

(10)(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 Management Systems, CFSAN.

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

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

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

(vii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(viii) The Director, Office of Special Research Skills, CFSAN.

(ix) The Director, Office of Constituent Operations, CFSAN.

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

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

(xii) The Director, Office of Scientific Analysis and Support, CFSAN.

(11)(i) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(ii) The Associate Director and Deputy Associate Director for Management and Systems, CDRH.

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

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

(v) 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.

(vi) The Director, Office of Systems and Management, CDRH.

(vii) Freedom of Information Officers, CDRH.

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

(ii) The Director and Deputy Director, Office of Management and Communications, CVM.

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

(iv) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(13)(i) The Director and Deputy Director for Washington Operations, National Center for Toxicological Research (NCTR).

(ii) The Deputy Center Director, Office of Management (OM), NCTR, and the Associate Director, Office of Management Services, OM, NCTR.

(iii) The Deputy Center Director, Office of Research, NCTR.

(14)(i) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, the Associate Director for Regulatory Policy, and the Associate Director for Medical Policy, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Management, CDER.

(iii) The Director and Deputy Director, Office of Compliance, CDER.

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

(v) The Directors and Deputy Directors of the Offices of Testing and Research, Generic Drugs, New Drug Chemistry, and Clinical Pharmacology and Biopharmaceutics, Office of Pharmaceutical Science, CDER.

(vi) The Director, Office of Training and Communications (OTCOM), and the Director, Division of Information Disclosure Policy, Office of Regulatory Policy, CDER.

(vii) The Directors of the Divisions of Labeling and Non-prescription Drug Compliance, Prescription Drug Compliance and Surveillance, and Manufacturing and Product Quality, Office of Compliance, CDER.

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

(ii) District Directors.

(iii) The Director, St. Louis Branch.

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

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

(vi) The Director, National Forensic Chemistry Center.

(vii) The Director, Arkansas Regional Laboratory.

(viii) The Director, Winchester Engineering Analytical Center.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

(1) Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; and the Senior Associate Commissioner for Policy, Planning, and Legislation.

(2) The Associate and Deputy Associate Commissioners and the Chief Counsel and Deputies.

(3) The Director and Deputy Directors, CBER; the Director and Deputy Director, CFSAN; the Director and Deputy Directors, CDRH; the Director and Deputy Director, CVM; the Director and Deputy Directors, CDER; and the Director, NCTR, the Deputy Director for Washington Operations, NCTR, and the Deputy Center Directors, Offices of Management and Research, respectively, NCTR.

(4) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner (OSAC), OC; Director, Office of Management, CBER; Director, Office of Management, CDER; Director, Office of Management Systems, CFSAN; Director, Office of Systems and Management, CDRH; Director, Office of Management and Communications, CVM; Associate Director, Office of Management Services, NCTR; and the Director, Office of Resource Management, ORA.

(5) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC.

(c) The following officials may further redelegate the authorities under paragraphs (a) and (b) of this section the Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; the Senior Associate Commissioner for Policy, Planning, and Legislation; the Associate and Deputy Associate Commissioners; the Chief Counsel and Deputy Chief Counsels; the Directors and Deputy Directors for CBER, CFSAN, CDRH, CVM, CDER, and NCTR; the Director, Office of Executive Operations, OSAC, OC; the Directors of the Offices of Management, CBER and CDER; the Director, Office of Management Systems, CFSAN; the Director, Office of Systems and Management, CDRH; the Director, Office of Management and Communications, CVM; the Associate Director, Office of Management Services, NCTR; the Director, Office of Resource Management, ORA; and the Director, OHRMS, OMS, OC. The other officials delegated authority by this section may not further redelegate it.

(d) The Chief, Regulations Editorial Section (RES), Regulations Policy and Management Staff (RPMS), Office of Policy, Planning, and Legislation (OPPL), OC, and his or her alternates are authorized to certify true copies of **Federal Register** documents. The Chief, RES, RPMS, OPPL, OC may designate alternates as required.

§ 5.23 Disclosure of official records and authorization of testimony.

(a) The following officials are authorized to make determinations to disclose official records and information under part 20 of this chapter, except that only the officials, listed in paragraphs (a)(2) through (a)(8) of this section, have the authority under specific sections of part 20 of this chapter.

(1)(i) Deputy Commissioner, the Senior Associate Commissioner, the Deputy Commissioner for International and Constituent Relations, the Senior Associate Commissioner for Management and Systems, the Senior Associate Commissioner for Policy, Planning, and Legislation, and the Associate and Deputy Associate Commissioners.

(ii) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, Office of the Commissioner (OC).

(iii) The Director, Office of the Executive Secretariat, Office of the Senior Associate Commissioner, OC.

(iv) The Director, Office of Human Resources and Management Services (OHRMS), Office of Management and Systems (OMS), OC; the Director, Division of Management Programs (DMP), OHRMS, OMS, OC; and the Chief, Dockets Management Branch, DMP, OHRMS, OMS, OC.

(v) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(vi) Regional Food and Drug Directors and District Directors.

(vii) Director, Winchester Engineering and Analytical Center.

(viii) Chiefs of branches Field/District Offices and Centers.

(ix) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(x) The Director, Office of Enforcement (OE), Office of Regulatory Affairs (ORA); Deputy Director, OE, ORA; and Director, Division of Compliance Policy, OE, ORA.

(xi) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(xii) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, the Associate Director for Medical Policy, and the Associate Director for Regulatory Policy, Center for Drug Evaluation and Research (CDER).

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

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

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

(xvi) The Director, National Center for Toxicological Research (NCTR); the Deputy Center Directors, Offices of Research and Management, respectively, NCTR; and the Deputy Director for Washington Operations, NCTR.

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

(2) The Deputy Associate Commissioner for Regulatory Affairs (Deputy ACRA), ORA; the Director and Deputy Director, Office of Enforcement OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are delegated the authority to grant requests for testimony or to authorize the giving of testimony under § 20.1 of this chapter. These officials may not further redelegate this authority.

(3) The Associate and Deputy Associate Commissioners are delegated the authority to disclose official records and information under § 20.82 of this chapter. These officials may not further redelegate this authority.

(4) The Associate and Deputy Associate Commissioners; the Director and Deputy Director, OE, ORA; and the Director, Division of Compliance Policy, OE, ORA are delegated the authority to disclose official records and information under § 20.85 of this chapter. These officials may not further redelegate this authority

(5) The following officials are delegated the authority to disclose confidential commercial information to State government officials under § 20.88(d) of this chapter and the ACRA and the Center Directors may further redelegate this authority.

(i) The ACRA, the Deputy ACRA, ORA and the Director, OE, ORA.

(ii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(iii) The Director and Deputy Director, CDER; the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Regulatory Policy, CDER.

(iv) The Director, CDRH, the Deputy Director for Regulations and Policy, the Deputy Director for Science, and the Director, Office of Health and Industry Programs, CDRH.

(v) The Director and Deputy Director, CFSAN.

(vi) The Director and Deputy Director, CVM.

(vii) The Director, the Deputy Center Directors, Offices of Research and Management, respectively, NCTR, and the Deputy Director for Washington Operations, NCTR.

(6) The following officials are delegated the authority to disclose nonpublic, predecisional documents to State and foreign government officials under §§ 20.88(e) and 20.89(d) of this chapter and they may not further redelegate this authority.

(i) The Associate Commissioner for Policy, Office of Policy, Planning and Legislation (OPPL); and the Director, Office of International Programs, Office of International and Constituent Relations (OICR).

(ii) For level 2 nonpublic, predecisional guidance documents, any Center Director or Deputy Director, and any Director for an OC office having program responsibilities.

(7) The Associate Commissioner for Policy, OPPL; and the Director, Office of International Programs, OICR are delegated the authority to receive nonpublic, predecisional documents from State and foreign government officials under §§ 20.88(e) and 20.89(d) of this chapter. These officials may not further redelegate this authority.

(8) The following officials are authorized to disclose confidential commercial information to foreign government officials under § 20.89(c) of this chapter; and they may not further redelegate it:

(i) The Deputy ACRA, ORA; and the Director, OE, ORA.

(ii) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER); and the Director and Deputy Director, Office of Communication, Training, and Manufacturer's Assistance (OCTMA), CBER.

(iii) The Director and Deputy Director, CDER; the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Medical Policy, CDER; the Associate Director for Regulatory Policy, CDER, and the Director, Division of Information Disclosure Policy, Office of Regulatory Policy, CDER.

(iv) The Director, CDRH, the Deputy Director for Regulations and Policy and the Deputy Director for Science, CDRH.

(v) The Director and Deputy Director, CFSAN.

(vi) The Director and Deputy Director, CVM.

(vii) The Director, the Deputy Center Directors, Offices of Research and Management, respectively, and the Deputy Director for Washington Operations, NCTR.

(b) The Chief, Information Management Team, Division of Data Management and Services, Office of Information Technology, CDER, is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments. This official may not further redelegate this authority.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records and these officials may not further redelegate this authority:

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

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

(3) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

(4) The Chief, Information Processing and Office Automation Branch, Division of Program Operations, Office of Compliance, CDRH.

(d) The Director, Office of Resource Management, Office of Regulatory Affairs is authorized to sign affidavits regarding the presence or absence of records in the files of that office and this official may not further redelegate this authority

(e) The Director and Deputy Directors, CBER, the Director and Deputy Director, Office of Blood Research and Review (OBRR), and the Director and Deputy Director, Division of Blood Applications, OBRR, CBER, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments. These officials may not further redelegate this authority.

§ 5.24 Authority relating to technology transfer.

(a) The Associate Commissioner for Regulatory Affairs is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under section 11(c)(5) (A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended.

(b) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) requested by the Commissioner under the Act (15 U.S.C. 3701 *et seq.*), as amended, and Executive Order 12591 of April 10, 1987 (except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(26)), as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with section 11(c)(5)(A) of the Act (15 U.S.C. 3710a(c)(5)(A):

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

(2) The Director, Center for Devices and Radiological Health.

(3) The Director, Center for Drug Evaluation and Research.

(4) The Director, Center for Food Safety and Applied Nutrition.

(5) The Director, Center for Veterinary Medicine.

(6) The Director, National Center for Toxicological Research.

(7) The Associate Commissioner for Regulatory Affairs.

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

§ 5.25 Research, investigation, and testing programs and health information and promotion programs.

(a) The following officials are authorized under sections 301, 307, 311, 1701, 1702, 1703, and 1704 of the Public Health Service Act (the PHS Act) (42 U.S.C. 241, 242l, 243, 300u, 300u–1, 300u–2, 300u–3) to establish research, investigation, and testing programs and health information and health promotion programs, which relate to their assigned functions, and to approve grants for conducting such programs:

(1) The Director, the Deputy Director for Washington Operations, and the Deputy Center Directors, Offices of Research and Management, respectively, National Center for Toxicological Research (NCTR).

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

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

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

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

(6) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(7) The Director, Office of Orphan Products Development (OPD), Office of the Senior Associate Commissioner (OSAC), Office of the Commissioner (OC).

(b) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, are authorized to establish an electronic product radiation control program and to approve grants for conducting the program under section 532 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ii).

(c) The Senior Associate Commissioner for Management and Systems, Office of Management and Systems (OMS), OC; the Director and Deputy Director, Office of Facilities, Acquisitions, and Central Services (OFACS), OMS, OC; the Director, Division of Contracts and Procurement Management (DCPM), OFACS, OMS, OC; and the Chief Grants Management Officer and the Grants Management Officer, DCPM, OFACS, OMS, OC are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof for grants approved under the authority delegated in paragraphs (a) and (b) of this section.

(d) The Director, NCTR, is authorized under section 301 of the PHS Act (42 U.S.C. 241), as amended by Public Law 95–622, to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of the Center that are not required to support Center research programs.

(e) The Senior Associate Commissioner for Management and Systems may further redelegate the authorities in paragraph (c) of this section. With the exception for paragraph (c) of this section, these officials may not further redelegate these authorities.

§ 5.26 Service fellowships.

(a) Under authority of sections 207(g) and 208(f) of the PHS Act (42 U.S.C. 209(g) and 210(f)), and within the limits of an approved service fellowship plan, the following officials are authorized to designate persons to receive service fellowships, appoint service fellows, and determine specific stipend rates for

individual actions within the ranges established under an approved service fellowship plan:

(1) The Deputy Commissioner; the Senior Associate Commissioner; the Deputy Commissioner for International and Constituent Relations; the Senior Associate Commissioner for Management and Systems; the Senior Associate Commissioner for Policy, Planning, and Legislation; the Chief Counsel and Deputy Chief Counsels; and the Associate Commissioners and their Deputies.

(2) The Director, the Deputy Director for Washington Operations, the Deputy Center Directors for Research and Management, respectively, and the Associate Director, Office of Management Services, National Center for Toxicological Research (NCTR).

(3) The Director, the Deputy Directors for Science and for Regulations and Policy, and the Director, Office of Systems and Management, Center for Devices and Radiological Health (CDRH).

(4) The Director, the Deputy Directors, the Associate Director for Research, the Office Directors, and the Director, Office of Management, Center for Biologics Evaluation and Research (CBER).

(5) The Director, the Deputy Director, and Director, Office of Management Systems, Center for Food Safety and Applied Nutrition (CFSAN).

(6) The Director, the Deputy Director, and the Director, Office of Management and Communications, Center for Veterinary Medicine (CVM).

(7) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, and the Director and Deputy Director, Office of Management, Center for Drug Evaluation and Research (CDER).

(8) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, Office of the Commissioner and the Director, Office of Resource Management, ORA.

(9) Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(b) These officials may further redelegate this authority, with the limitation that the Director, Office of Human Resources and Management Services, OMS, OC, is delegated the authority to approve service fellowship plans and exceptions to the approved plans, and this official may not further redelegate this authority.

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings.

(a) The Deputy Commissioner is authorized to perform the due diligence determinations and informal hearings functions under section 156(d)(2)(B)(ii) of title 35 U.S.C. (35 U.S.C. 156), as amended, relative to patent term extensions.

(b) The Director, Center for Drug Evaluation and Research (CDER) and the Associate Director for Regulatory Policy, CDER, are authorized to perform the functions delegated to the Commissioner under title 35 U.S.C. 156, as amended, except for making due diligence determinations and holding of informal hearings under title 35 U.S.C. 156(d)(2)(B).

(c) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to perform the functions delegated to the Commissioner to make due diligence determinations under title 35 U.S.C. 156 (d)(2)(B), as amended, except for holding of informal hearings under title 35 U.S.C. 156(d)(2)(B)(ii).

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

§ 5.28 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335, 344(b), and 381(a)); section 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1455) (21 U.S.C. 145); section 9(b) of the Federal Caustic Poison Act (44 Stat. 1406; see also Public Law 86–613, section 19 formerly section 18); and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); and the Director of Regulations and Policy, CFSAN.

(2) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Associate Director for Regulatory Policy and the Associate Director for Medical Policy, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

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

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

(5) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Directors for Science and for Regulations Policy, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the PHS Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing under the provisions of part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of § 16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner of Food and Drugs (Commissioner).

(2) The Director and Deputy Director, CFSAN.

(3) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER); the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Regulatory Policy and the Associate Director for Medical Policy, CDER, the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management,

CDER; and the Director and Deputy Director, Office of Compliance, CDER.

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

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

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

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

§ 5.29 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 Directors, Center for Biologics Evaluation and Research (CBER).

(ii) 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.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

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

(ii) The Directors and Deputy 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.

(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, the Deputy Director, and the Directors, Office of Review Management and Office of 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, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); and the Director of Regulations and Policy, CFSAN.

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

(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, the Deputy Director, and the Directors, Office of Review Management and Office of 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 Director, CFSAN.

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

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

(iv) The Director, Office of Nutritional Products, Labeling and Dietary Supplements, 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 Field Programs, 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 Directors, 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, the Deputy Director, and the Associate Director for Regulatory Policy, 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 for Science and for Regulations and Policy, 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 Directors, 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 chapter:

(i) Section 5.203 *Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products*;

(ii) Section 5.204 *Notification of release for distribution of biological products*;

(iii) Section 5.101 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iv) Section 5.103 *Approval of new drug applications and their supplements*.

(v) Section 5.105 *Issuance of notices relating to proposals to refuse approval*

or to withdraw approval of new drug applications and their supplements.

(vi) Section 5.34 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of 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 chapter:

(i) Section 5.100 *Issuance of notices implementing the provisions of the Drug Amendments of 1962*;

(ii) Section 5.101 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iii) Section 5.103 *Approval of new drug applications and their supplements.*

(iv) Section 5.105 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.*

(v) Section 5.34 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(3) The Director and Deputy Director, 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 Directors and Deputy Directors of OBRR, OVRR, and OTRR, 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 Directors, CBER.

(ii) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of 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 § 5.34 *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.

(iii) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(5)(i) The Director, the Deputy Director, the Associate Director for Regulatory Policy, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

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

(iii) The Associate Director for Medical Policy, CDER.

(iv) The Director, Division of Drug Marketing, Advertising, and Communications, Office of Medical Policy, CDER.

(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.

(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).

(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.

(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, ODE, CDRH.

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

§ 5.102 Authority to approve and to withdraw approval of a charge for investigational new drugs.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under § 312.7(d)(1) of this chapter:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and the Office of Pharmaceutical Science, Center for Drug Evaluation and Research.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research.

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

§ 5.103 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355):

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and

Research, for drugs listed in § 314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the act.

(b) 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, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(c) The following officials are authorized to perform all the functions of the Commissioner with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or section 505(b)(2) of the act (21 U.S.C. 355 (b)(2)) applications under their jurisdiction. The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(1) For drugs submitted under §§ 314.50, 314.70, and 314.94 of this chapter, except for those drug products listed in § 314.440(b):

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), Office of Pharmaceutical Science, CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

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

(2) For drug products listed in § 314.440(b) of this chapter and submitted under §§ 314.50, 314.70, and 314.94 of this chapter: The Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(d) The following officials are authorized to perform all functions of the Commissioner with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or section 505(b)(2) applications for drugs for human use that are described in §§ 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. (Authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests are not included in this paragraph.)

(1) The Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(3) Associate Director for Chemistry, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER.

(e) The Director, Division of Labeling and Program Support, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, are authorized to perform all the functions of the Commissioner with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or section 505(b)(2) applications for drugs for human use that are described in §§ 314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver requests is not included in this paragraph.

(f) The supervisory and team leader chemists in the Divisions of New Drug Chemistry I, II, and III, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, are authorized to perform all functions of the Commissioner with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in §§ 314(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in § 5.10(a) and paragraphs (a) and (b) of this section.

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

§ 5.104 Responses to Drug Enforcement Administration temporary scheduling notices.

The Director, Center for Drug Evaluation and Research (CDER) and the Director, Executive Operations Staff, Office of the Center Director, CDER, are authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under section 201(h)(4) of the Controlled Substances Act, as amended (21 U.S.C. 811(h)(4)). The delegation excludes the authority to submit reports to Congress. These officials may not further redelegate this authority.

§ 5.105 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Directors, Center for Biologics Evaluation and Research, for those drugs listed in § 314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

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

§ 5.106 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

(a) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505 (c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) and section 505A of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 355(c)(3)(D), (j)(4)(B)(ii) and (j)(4)(D) and 355a) concerning the date of submission or the date of effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act (21 U.S.C. 355(j)) and of new drug applications including supplements thereto submitted under section 505(b)(1) (21 U.S.C. 355 (b)(1)) of the act and described under section 505(b)(2) of the act (21 U.S.C. 355(b)(2)):

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

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

§ 5.107 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

(a) The following officials are authorized to extend or stay an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1) For drugs assigned to their organizations:

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

(ii) 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.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(2) For drugs assigned to their organizations:

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy 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.

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

§ 5.108 Authority relating to waivers or reductions of prescription drug user fees.

The Director, Center for Drug Evaluation and Research (CDER), and the Associate Director for Regulatory Policy, CDER, are authorized to perform all the functions of the Commissioner of Food and Drugs relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992, as originally enacted and as reauthorized by the Food and Drug Administration Modernization Act of 1997, except for the functions under section 736(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h(d)(1)(C)) that pertain to situations where ''the fees will exceed the anticipated present and future costs,'' on behalf of CDER, the Center for Biologics Evaluation and Research, and any other Food and Drug Administration Center. This authority pertains to waivers requested under the public health waiver provision (21 U.S.C. 379h(d)(1)(A)); the barrier to innovation waiver provision (21 U.S.C. 379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiver provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.) These officials may not further redelegate this authority.

§ 5.109 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) regarding the issuance of written notices.

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

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

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(6) The Associate Director for Medical Policy, and the Director and Deputy Director, Division of Scientific Investigations, Office of Medical Policy, CDER.

(7) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), the Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER, and the Directors, Division of Case Management, Division of Inspections and Surveillance, and Division of Manufacturing and Product Quality, OCBQ, CBER.

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

(9) Regional Food and Drug Directors.

(10) District Directors.

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

Subpart D—Biologics; Redelegations of Authority

§ 5.200 Functions pertaining to safer vaccines.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) 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:

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

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

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

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

note), except that the authority to provide for notice and opportunity for public hearing on the review of vaccines and related illnesses and conditions under sections 312(a) and (d) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(5) Section 313 of the National Childhood Vaccine Injury Act of 1986–Study of other vaccine risks (42 U.S.C. 300aa–1 note), except that the authority to provide for notice and opportunity for public hearing on the establishment of guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(6) 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).

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

§ 5.201 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

(a) The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

(1) Deputy Directors, CBER.

(2) Associate Directors, CBER.

(3) Office Directors, CBER.

(4) Division Directors, CBER.

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

§ 5.202 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research are authorized to issue:

(1) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under § 601.4(b) of this chapter.

(2) Notices of opportunity for a hearing on proposals to revoke biologics licenses under § 601.5(b) of this chapter.

(3) Notices of revocation, at the manufacturer's request, of biologics licenses under §§ 601.5(a) and 601.8 of this chapter.

(4) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

(5) Notice of biologics license suspensions under § 601.6 of this chapter.

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

§ 5.203 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

(a) The following officials are authorized to issue licenses under section 351 of the PHS Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the PHS Act, and to revoke such licenses at the manufacturer's request:

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

(2) Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

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

§ 5.204 Notification of release for distribution of biological products.

(a) The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 680.31) of this chapter:

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

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

(3) The Director and Deputy Director, Division of Manufacturing and Product Quality, OCBQ, CBER.

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

Subpart E—Food and Cosmetics; Redelegations of Authority

§ 5.300 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the assigned functions of the respective Center:

(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 Premarket Approval, CFSAN.

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

(2) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN are authorized to perform all the functions of the Commissioner under section 401 of the act (21 U.S.C. 341) regarding the issuance of proposed rulemaking (including notices of extension of, or reopening of, the comment period) pertaining to food standards.

(b)(1) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN are authorized to perform all of the functions of the Commissioner under section 409 and 721 of the act (21 U.S.C. 348 and 379e) regarding the approval of the use of food additives under section 409(e) of the act (21 U.S.C. 348(e)) and the listing of color additives under section 721(d)(1) of the act (21 U.S.C. 379e) where the listing does not involve novel or controversial issues and does not involve any questions about the applicability of the Delaney Anti-Cancer Clause.

(2) The following officials are authorized to perform all of the functions of the Commissioner under section 401 of the act (21 U.S.C. 341) regarding the issuance of notices of temporary permits for foods varying from standards of identity under § 130.17 of this chapter:

(i) The Director and Deputy Director, CFSAN.

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

(iii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner regarding approvals of the use of food additives under section 409(e) of the act (21 U.S.C. 348(e)), where these approvals do not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(c)(1) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act (21 U.S.C. 348(c)(2)) or to color additive petitions under section 721e(d)(1) (21 U.S.C. 379e(d)(1)) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CFSAN.

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

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

(iv) The Director, Division of Product Policy, Office of Premarket Approval, CFSAN.

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

(2) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act (21 U.S.C. 348(c)(2)) that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CVM.

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

(iii) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to certify batches of color additives under section 721 of the act (21 U.S.C. 379e):

(1) The Director and Deputy Director, CFSAN.

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

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

(e) The following officials are authorized to issue advance notices of proposed rulemaking pertaining to Codex Alimentarius food standards and notices terminating consideration of such standards when comments fail to support the desirability and need for proposing their adoption, under § 130.6 of this chapter:

(1) The Director and Deputy Director, CFSAN.

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

(3) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(f) The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming GRAS status of food substances under §§ 170.35 or 570.35 of this chapter where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

(1) The Director, Deputy Director, and Director of Regulations and Policy, CFSAN.

(2) The Director and Deputy Director, CVM.

(g)(1) The following officials are authorized to perform all of the functions of the Commissioner under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) regarding the issuance of decisions to grant or deny petitions for nutrient content claims and health claims that do not present controversial issues and regarding the issuance of any notices of proposed rulemaking that result from such action:

(i) The Director and Deputy Director, CFSAN.

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

(2) The following officials are authorized to perform all of the functions of the Commissioner under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) regarding the issuing of letters of filing in response to petitions for nutrient content claims and health claims:

(i) The Director and Deputy Director, CFSAN.

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

(iii) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

(h) The following officials are authorized to issue letters concerning substances determined to be below the ''threshold of regulation'' under § 170.39 of this chapter:

(1) The Director and Deputy Director, CFSAN.

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

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

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

(i) The following officials are authorized to perform all of the functions of the Commissioner under section 409(h) of the act (21 U.S.C. 348(h)), excluding the duties to set out in section 409(h)(5) of the act (21 U.S.C. 348(h)(5)), regarding premarket notification of food-contact substances:

(1) The Director and Deputy Director, CFSAN.

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

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

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

§ 5.301 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

(a) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN), the Director, Office of Field Programs, CFSAN, and the Director, Division of Enforcement and Programs, Office of Field Programs, CFSAN, are authorized to issue initial emergency permit orders under § 108.5 of this chapter.

(b) The following officials are authorized to issue notices of confirmation of effective date of final regulations on food matters issued under section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)):

(1) The Director and Deputy Director, CFSAN.

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

(3) The Director, Office of Nutritional Products, Labeling, and Dietary Supplements, CFSAN.

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

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

6) The Director, Office of Field Programs, CFSAN.

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

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

§ 5.302 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)), that relates to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f (b)) that relates to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 5.303 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.

The Director, Deputy Director, and Director of Regulations and Policy, Center for Food Safety and Applied Nutrition, are authorized to perform all the functions of the Commissioner of Food and Drugs 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 these sections. The delegation excludes the authority to submit reports to the Congress. These officials may not further redelegate this authority.

§ 5.304 Approval of schools providing food-processing instruction.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections:

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

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

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

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

Subpart F—Medical Devices and Radiological Health; Redelegations of Authority

§ 5.400 Issuance of Federal Register documents to recognize or to withdraw recognition of a standard to meet premarket submission requirements.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health; and the Director and Deputy Directors, Center for Biologics Evaluation and Research, are authorized to issue **Federal Register** documents under section 514(c) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360d(c)) recognizing or withdrawing recognition of a standard for which a person may submit a declaration of conformity in order to meet a premarket submission requirement.

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

§ 5.401 Issuance of Federal Register documents pertaining to exemptions from premarket notification.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health; and the Directors and Deputy Directors, Center for Biologics Evaluation and Research, are authorized to make determinations and issue **Federal Register** notices and rules under § 510(m) of the act (21 U.S.C. 360(m)) concerning exemptions from premarket notification.

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

§ 5.402 Detention of adulterated or misbranded medical devices.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)) and in accordance with § 800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(1) For medical devices assigned to their respective organizations:

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

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

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

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

§ 5.403 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(a)(3)(B)) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act (21 U.S.C. 360c, 360d, and 360e):

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

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Director, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

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

§ 5.404 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f) and 360 j(1)) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the act (21 U.S.C. 360c(e)) (except for petitions submitted in response to **Federal Register** notices initiating standard-setting under § 514(b) of the act (21 U.S.C. 360d(b)) or premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)):

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

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

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

§ 5.405 Determination of classification of devices.

(a) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device in commercial distribution prior to May 28, 1976, under section 513(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(d)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors of the Office of Blood Research and Review (OBRR), the Office of Vaccines Research and Review (OVRR), and the Office of Therapeutics Research and Review (OTRR), CBER.

(b) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, under section 513 (f)(1)(A) of the act (21 U.S.C. 360c(f)(1)(A)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director, Deputy Directors, Division and Deputy Division Directors, Associate Division Directors, Branch Chiefs, and Chief, Premarket Notification Section, ODE, CDRH.

(2) The Director and Deputy Directors, CBER, and the Directors and Deputy

Directors of the OBRR, OVRR, and OTRR, CBER.

(c) The following officials are authorized to make determinations and issue orders classifying devices under section 513(f)(2)(b):

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

(2) The Director and Deputy Directors, ODE, CDRH.

(3) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVRR, and OTRR, CBER.

(d) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, and the Director and Deputy Directors, CBER, and the Directors and Deputy Directors of the OBRR, OVRR, and OTRR, CBER, are authorized to issue **Federal Register** notices under section 513(f)(2)(C) of the act (21 U.S.C. 360c(f)(2)(C)) announcing classification of devices under section 513(f)(2)(B) of the act (21 U.S.C. 360c(f)(2)(B)).

(e) These officials may not further redelegate those authorities.

§ 5.406 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f) and 360j(l)):

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

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

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

§ 5.407 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(f)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, and the Division Directors, ODE, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director 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.

(b)(1) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the act (21 U.S.C. 360e and 360j(l)):

(i) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Directors, ODE, CDRH, and the Division Directors, ODE, CDRH.

(ii) The Director and Deputy Directors, CBER, and the Directors and Deputy Directors, OBRR, OVRR, and OTRR, CBER.

(2) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications.

(c) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515(d), (e), and (g) and 520(h)(1) of the act (21 U.S.C. (d), (e), and (g) and 360j(h)(1)).

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

§ 5.408 Determinations concerning the type of valid scientific evidence submitted in a premarket approval application.

(a) The following officials are authorized to make determinations under section 513(a)(3)(D) of the act (21 U.S.C. 360c(a)(3)(D)) concerning the type of valid scientific evidence to be submitted in a premarket approval application that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person:

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

(ii) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(iii) The Director, Program Operations Staff, ODE, CDRH.

(iv) For devices assigned to their respective Divisions: the Division Directors and Deputy Division Directors, ODE, CDRH.

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

§ 5.409 Determinations that medical devices present unreasonable risk of substantial harm.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(a)):

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

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

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

§ 5.410 Orders to repair or replace, or make refunds for, medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to order repair or replacement of, or refund for, medical devices under section 518(b) and (c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(b) and (c)):

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

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and

Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

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

§ 5.411 Medical device recall authority.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)), which have been delegated to the Commissioner of Food and Drugs:

(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) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

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

§ 5.412 Temporary suspension of a medical device application.

(a) The following officials for medical devices assigned to their respective organizations are authorized under section 515(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(e)), to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

(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) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(4) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(5) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

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

§ 5.413 Approval, disapproval, or withdrawal of approval of applications and entering into agreements for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation, CDRH, and the Director and Deputy Director, Office of Compliance, CDRH.

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

(b) For medical devices assigned to their respective divisions, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the act (21 U.S.C. 360j(y)).

(c) The following officials are authorized to enter into written agreements concerning investigational device exemption protocols under section 520(g)(7) of the act (21 U.S.C. 360j(g)(7)):

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

(2) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(3) The Director, Program Operations Staff, ODE, CDRH.

(4) The Chief, Investigational Device Exemption Section, ODE, CDRH.

(5) For medical devices assigned to their respective Divisions: The Division Directors and Deputy Division Directors, ODE, CDRH.

(6) The Director and Deputy Directors, CBER, and the Director and Deputy Directors of the OBRR, OVRR, and OTRR, CBER.

(d) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH and the Director and Deputy Directors, ODE, CDRH, the Director and Deputy Directors, CBER, and the Director and Deputy Directors of the OBRR, OVRR, and OTRR, CBER, are authorized to make decisions under section 520(g)(7) of the act (21 U.S.C. 360j(g)(7)) with respect to an agreement on an investigational plan, that a substantial scientific issue essential to determining the safety and effectiveness of the device involved has been identified.

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

§ 5.414 Postmarket surveillance.

(a) For any class II or class III device (including any device that is or contains a drug or biologic), the failure of which would be reasonably likely to have serious adverse health consequences, or which is intended to be implanted in the human body for more than 1 year, or a life supporting or life sustaining device used outside a user facility, any of the following officials is authorized to require a manufacturer of such device to conduct postmarket surveillance:

(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 Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics (OSB), and the Director, Issues Management Staff, OSB, CDRH.

(4) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(5) The Director and Deputy Director, Office of Science and Technology, CDRH.

(6) The Director and Deputy Director, Office of Health and Industry Programs, CDRH.

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

(8) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

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

(10) The Director and Deputy Director, Office of Compliance, CDER.

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

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

(13) The Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, and Office of Therapeutics Research and Review, CBER.

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

§ 5.415 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), 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, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH are authorized to request the submission of additional information under § 803.15 of this chapter.

(c) The Director and Deputy Directors for Science and for Regulations and Policy, CDRH, the Director and Deputy Director, OSB, CDRH, and the Director and Deputy Director, DSS, OSB, CDRH are authorized to grant or revoke exemptions and variances from reporting requirements under § 803.19 of this chapter.

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

§ 5.416 Medical device tracking.

(a) The following officials are authorized to issue orders under section 519(e) of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360i(e)) requiring manufacturers to adopt methods of tracking devices:

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

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

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

§ 5.417 Authority pertaining to accreditation functions for medical devices.

(a) The following officials are authorized under section 523(a)(1) and (b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m(a)(1) and (b)(2)(A)) to respond to a request for accreditation and to accredit persons for the purpose of reviewing reports submitted under section 510(k) of the act (21 U.S.C. 360(k)) and making recommendations regarding the initial classification of devices:

(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 Health and Industry Programs (OHIP), CDRH.

(3) The Director and Deputy Director, Division of Small Manufacturers Assistance (DSMA), OHIP, CDRH.

(b) The following officials are authorized under section 523(a)(2)(B) and (C) of the act (21 U.S.C. 360m(a)(2)(B) and (C)) to make a determination with respect to the recommendation of an initial classification of a device; and to change the initial classification under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)) that is recommended by an accredited person to provide to such person, and the person who submitted the report under section 510(k) of the act (21 U.S.C. 360(k)) for the device, a statement explaining in detail the reasons for the change:

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

(2) The Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH.

(3) The Division Directors and Deputy Division Directors, ODE, CDRH.

(c) The following officials are authorized under section 523(b)(2)(B) of the act (21 U.S.C. 360m(b)(2)(B)) to suspend or withdraw accreditation of any person accredited to review reports and to make recommendations under section 523 of the act (21 U.S.C. 360m):

(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, DSMA, OHIP, CDRH.

(d) The following officials are authorized under section 523(b)(2)(C) of the act (21 U.S.C. 360m(b)(2)(c)) to implement the measures described in that section to ensure that persons accredited under section 523 of the act (21 U.S.C. 360m) will continue to meet the standards of accreditation:

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

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

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

Subpart G—Animal Drugs; Redelegations of Authority

§ 5.500 Issuance of FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.

The Director and Deputy Director, Center for Veterinary Medicine (CVM) are authorized to issue **Federal Register** documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use related to implementation of section 512(a)(4) and (5) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360b(a)(4) and (5)). These officials may further redelegate this authority.

§ 5.501 Approval of new animal drug applications, medicated feed mill license applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted under section 512 of the act (21 U.S.C. 360b):

(1) The Director, the Deputy Director for Human Food Safety and Consultative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

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

(c) The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of supplemental applications to new animal drug applications that are

described by section 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Manufacturing Technologies, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Epidemiology and Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner with regard to the approval of medicated feed mill license applications for the manufacture of animal feeds containing new animal drugs under section 512(m) of the act (21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250):

(1) The Director and Deputy Director, CVM.

(2) The Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

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

§ 5.502 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted under section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250);

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

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

§ 5.503 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal, Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(D)(iv) and (c)(2)(F) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act (21 U.S.C. 360b(b)(2)), and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)):

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

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

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

§ 5.504 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new animal drugs and feeds bearing or containing new animal drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under sections 512(e) and 512 (m)(4)(B)(ii) and (m)(4)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e), (m)(4)(B)(ii), and (m)(4)(B)(iii)) regarding the issuance of written notices:

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

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

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

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

§ 5.505 Termination of exemptions for new drugs for investigational use in animals.

(a) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under § 511.1 of this chapter:

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

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

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

Subpart H—Radiation Control; Redelegations of Authority

§ 5.600 Variances from performance standards for electronic products.

(a) The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in subchapter J of this chapter:

(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.

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

§ 5.601 Exemption of electronic products from performance standards and prohibited acts.

(a) The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 534 (a)(5) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360kk(a)(5)) and to exempt an electronic product or class of products from all or part of the provisions of section 538(a) of the act (21 U.S.C. 360oo(a)) under section 538(b) of the act (21 U.S.C. 360oo(b)):

(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.

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

§ 5.602 Testing programs and methods of certification and identification for electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to review and evaluate industry testing programs under section 534(g) of the Federal Food, Drug and Cosmetic Act the act (21 U.S.C. 360kk(g)) and to approve or disapprove alternate

methods of certification and identification and to disapprove testing programs upon which certification is based under section 534(h) of the act (21 U.S.C. 360kk(h)).

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

§ 5.603 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to perform all functions of the Commissioner of Food and Drugs (Commissioner), relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 534 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360kk) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

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

(b) The Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 535(e) of the act (21 U.S.C. 360ll(e)) and under § 1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

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

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

§ 5.604 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 537(c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360nn(c)).

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

§ 5.605 Dealer and distributor direction to provide data to manufacturers of electronic products.

(a) The Director and Deputy Director for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 537(f) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360nn(f)).

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

§ 5.606 Acceptance of assistance from State and Local authorities for enforcement of radiation control legislation and regulations.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to accept assistance from State and Local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 541 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360rr).

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

Subpart I—Product Designation; Redelegations of Authority

§ 5.700 Authority relating to determination of product primary jurisdiction.

The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, as product jurisdiction officer is authorized to make a determination under section 563 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–2) respecting the classification of a product as a drug, biological product, device, or a combination product subject to section 503(g) of the act (21 U.S.C. 353(g)), and to assign primary responsibility respecting the organizational component of the Food and Drug Administration that will regulate the product. This official may not further redelegate this authority.

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

(a) 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:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) and the Directors of the Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

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

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

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

Subpart J—Imports and Exports; Redelegations of Authority

§ 5.800 Imports and exports.

(a) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized, under section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of food, drugs (including biological products), devices, or cosmetics imported or offered for import.

(2) Determine whether such articles are in compliance with the act.

(3) Authorize relabeling or other compliance actions to bring articles into compliance under the Act.

(4) Supervise such compliance actions.

(b) The Director and Deputy Directors for Science and for Regulations and

Policy, Center for Devices and Radiological Health (CDRH); the Director and Deputy Director, Office of Compliance, CDRH; Regional Food and Drug Directors; District Directors; and the Director, St. Louis Branch, are authorized, under section 536 of the act (21 U.S.C. 360mm), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of electronic products imported or offered for import to determine whether such products are in compliance with section 534 of the act (21 U.S.C. 360kk).

(2) Refuse admission of noncomplying products and notify the Secretary of the Treasury of such refusal.

(3) Supervise operations to bring noncomplying products into compliance under section 534 of the act (21 U.S.C. 360kk).

(4) Refuse or grant permission and time extensions to bring noncomplying products into compliance with section 534 of the act (21 U.S.C. 360kk) in accordance with a corrective action plan approved by the Directors, Offices of Compliance Surveillance and Biometrics, CDRH.

(c) The following officials are authorized, under section 538(b) of the act (21 U.S.C. 360oo(b)), to exempt persons from issuing a certification, as required by section 534(h) of the act (21 U.S.C. 360kk(h)) for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function will be destroyed or exported in accord with U.S. Customs Service's regulations:

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

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

(3) Regional Food and Drug Directors.

(4) District Directors.

(5) The Director, St. Louis Branch.

(d) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to exercise all of the functions of the Commissioner of Food and Drugs (Commissioner) under section 362 of the Public Health Service Act (42 U.S.C. 265) that relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, and 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, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) The following officials are authorized to perform all the functions of the Commissioner pertaining to exportation of medical devices under section 801(e) of the act (21 U.S.C. 381(e)):

(1) For medical devices assigned to their respective organization:

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

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

(iii) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

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

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

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the act (21 U.S.C. 381(d)(2)) for emergency medical care:

(1) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Compliance and Biologics Quality, CBER.

(2) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

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

§ 5.801 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b)(2) and (b)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382(b)(2) and (b)(3)), to grant or deny petitions to export unapproved new drugs and biological products and to issue notices of receipt of such petitions for human drugs assigned to their respective organizations:

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

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

(3) The Director, the Deputy Director, and the Directors, Office Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(4) The Director and Deputy Director, Office of Compliance, CDER.

(b) The following officials are authorized, under section 802(e) of the act (21 U.S.C. 382(e)), to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease or another disease as described in section 802(e) for human drugs assigned to their respective organizations:

(1) The Director and Deputy Directors, CBER.

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

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.

(4) The Director and Deputy Director, Office of Compliance, CDER.

(c) The following officials are authorized, under section 351(h) of the Public Health Service Act (42 U.S.C. 262(h)), to approve or disapprove an application to export a partially processed biological product:

(1) The Director and Deputy Directors, CBER.

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

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

§ 5.802 Manufacturer's resident import agents.

The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under § 1005.25(b) of this chapter. These officials may not further redelegate this authority.

Subpart K—Orphan Products; Redelegations of Authority

§ 5.900 Orphan products.

(a) The Director, Office of Orphan Products Development (OPD), Office of the Senior Associate Commissioner (OSAC), Office of the Commissioner (OC), is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for biologics licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, OPD, OSAC, OC, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa(a)) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act (21 U.S.C. 360bb(a)).

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act (921 U.S.C. 360cc(b)(1)).

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act (21 U.S.C. 360dd).

(c) The following officials are authorized to provide sponsors, under section 525(a) of the act (21 U.S.C. 360aa(a)), with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy 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.

(2) For biological products under their jurisdiction:

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

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

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

Subpart L—Mammography Facilities; Redelegations of Authority

§ 5.1000 Authority to ensure that mammography facilities meet quality standards.

(a) The following officials are authorized to ensure mammography facilities obtain certificates under section 354(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b(b)):

(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 Health and Industry Programs (OHIP), CDRH.

(3) The Director and Deputy Director, Division of Mammography Quality and Radiation Programs (DMQRP), OHIP, CDRH.

(b) The following officials are authorized to issue, renew and extend certificates to mammography facilities under section 354(c) of the PHS Act (42 U.S.C. 263b(c)):

(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.

(c) The following officials are authorized to accept an application for a certificate under section 354(d)(1) of the PHS Act (42 U.S.C. 263b(d)(1)):

(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.

(d) The following officials are authorized to approve accreditation bodies to accredit mammography facilities under section 354(e)(1)(A) of the PHS Act (42 U.S.C. 263b(e)(1)(A)):

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

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

(e) The following officials are authorized to ensure accreditation bodies provide satisfactory assurances of compliance under section 354(e)(1)(C) of the PHS Act (42 U.S.C. 263b(e)(1)(c)):

(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.

(f) The Director, CDRH is authorized to issue regulations under which the Director may withdraw approval of accreditation bodies under section 354(e)(2)(A) of the PHS Act (42 U.S.C. 263b(e)(2)(A)).

(g) The following officials are authorized to determine the expiration date of a certificate of a facility accredited by an accreditation body after the body's approval is withdrawn, or a State's certification authority has been withdrawn, or a facility's accreditation has been revoked by an accreditation body under sections 354(e)(2)(B) and 354(e)(5) of the PHS Act (42 U.S.C. 263b(e)(2)(B) and (e)(5)):

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

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

(h) The following officials are authorized to determine the applicable standards for a facility for accreditation under section 354(e)(3) of the PHS Act (42 U.S.C. 263b(e)(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.

(i) The following officials are authorized to ensure accreditation bodies make on site visits and to determine whether other measures are appropriate under section 354(e)(4) of the PHS Act (42 U.S.C. 263b(e)(4)):

(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.

(j) The following officials are authorized to evaluate annually the performance of each approved accreditation body as provided by section 354(e)(6)(A) of the PHS Act (41 U.S.C. 263b(e)(6)(A)):

(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.

(k) The following officials are authorized to determine the compliance of certified facilities with established standards through annual facility inspections as provided by section 354(g) of the PHS Act (42 U.S.C. 263b(g)):

(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.

(l) The following officials are authorized to promote voluntary compliance with established standards instead of taking actions under section 354(i) of the PHS Act (42 U.S.C. 263b(i)) by imposing directed plans of correction and/or payment of the cost of onsite monitoring under section 354(h)(1) of the PHS Act (42 U.S.C. 263b(h)(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.

(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 sections 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.

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.

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

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

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

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]

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.
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.

[4] Mailing address: 200 C St. SW., Washington, DC 20204.

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

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

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]

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.

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.

[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.

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.

§ 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, 200 C St. SW., Washington, DC 20204. Telephone 202–205–4144.

§ 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.

Dated: May 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

Note: This appendix will not appear in the Code of Federal Regulations.

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

APPENDIX A—PART 5; CORRESPONDING FORMER AND NEW SUBPARTS, SECTION NUMBERS, AND SUBJECTS

Former CFR Subpart, Section No., and Subject	New CFR Subpart, Section No., and Subject
Subpart A, § 5.10–Delegations from the Secretary, the Assistant Secretary for Health, and Public Health Service Officials.	Subpart A, § 5.10–Delegations from the Secretary for Health and Human Services to the Commissioner of Food and Drugs
Subpart A, § 5.11–Reservation of Authority	Subpart A, § 5.11–(same subject)
Subpart B, § 5.20–General Redelegations of Authority from the Commissioner to other officers of FDA..	Subpart B, § 5.20–(same subject)
Subpart B, § 5.21–Emergency functions	Subpart B, § 5.21–(same subject)
Subpart B, § 5.22–Certification of true copies and use of Department seal.	Subpart B, § 5.22–(same subject)
Subpart B, § 5.23–Disclosure of official records	Subpart B, § 5.23–Disclosure of official records and authorization of testimony
Subpart B, § 5.24–Authority relating to technology transfer	Subpart B, § 5.24–(same subject)
Subpart B, § 5.25–Research, investigation, and testing programs and health information and health promotion programs.	Subpart B, § 5.25–Research, investigation, and testing programs and health information and promotion programs
Subpart B, § 5.26–Service fellowships	Subpart B, § 5.26–(same subject)
Subpart B, § 5.27–Patent term extensions for human drug products, medical devices, and food and color additives.	Subpart B, § 5.27–Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings
Subpart B, § 5.28–Cardiac pacemaker devices and pacemaker leads	Deleted because the Social Security Act was repealed.
Subpart B, § 5.29–Functions pertaining to safer vaccines	Subpart D, § 5.200–(same subject)
Subpart B, § 5.30–Hearings	Subpart B, § 5.28–(same subject)
Subpart B, § 5.31–Petitions under part 10	Subpart B, § 5.29–(same subject)
Subpart B, § 5.32–Authority relating to determination of product primary jurisdiction.	Subpart I, § 5.700–(same subject)
Subpart B, § 5.33–Premarket approval of a product that is or contains a biologic, a device, or a drug.	Subpart I, § 5.701–(same subject)
Subpart B, § 5.34–Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.	Subpart B, § 5.30–(same subject)
Subpart B, § 5.35–Enforcement activities	Subpart B, § 5.31–(same subject)
Subpart B, § 5.36–Certification following inspections	Subpart B, § 5.32–(same subject)
Subpart B, § 5.37–Issuance of reports of minor violations	Subpart B, § 5.33–(same subject)
Subpart B, § 5.38–Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs.	Subpart C, § 5.109–Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.
	Subpart G, § 5.504–Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new animal drugs and feeds bearing or containing new animal drugs.
Subpart B, § 5.39–Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.	Subpart D, § 5.201–(same subject)
Subpart B, § 5.40–Issuance of FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.	Subpart G, § 5.500–(same subject)
Subpart B, § 5.44–Export of unapproved drugs	Subpart J, § 5.801–(same subject)
Subpart B, § 5.45–Imports and exports	Subpart J, § 5.800–(same subject)
Subpart B, § 5.46–Manufacturer's resident import agents	Subpart J, § 5.802–(same subject)
Subpart B, § 5.47–Detention of adulterated or misbranded medical devices.	Subpart F, § 5.402–(same subject)
Subpart B, § 5.49–Authorization to use alternative evidence for determination of the effectiveness of medical devices.	Subpart F, § 5.403–(same subject)
Subpart B, § 5.50–Notification to petitioners of determinations made on petitions for reclassification of medical devices.	Subpart F, § 5.404–(same subject)
Subpart B, § 5.51–Determination of classification of devices	Subpart F, § 5.405–(same subject)
Subpart B, § 5.52–Notification to sponsors of deficiencies in petitions for reclassification of medical devices.	Subpart F, § 5.406–(same subject)
Subpart B, § 5.53–Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.	Subpart F, § 5.407–(same subject)
Subpart B, § 5.54–Determinations that medical devices present unreasonable risk of substantial harm.	Subpart F, § 5.409–(same subject)
Subpart B, § 5.55–Orders to repair or replace, or make refunds for, medical devices.	Subpart F, § 5.410–(same subject)
Subpart B, § 5.56–Recall authority	Subpart F, § 5.411–Medical device recall authority
Subpart B, § 5.57–Temporary suspension of a medical device application.	Subpart F, § 5.412–(same subject)
Subpart B, § 5.58–Orphan products	Subpart K, § 5.900–(same subject)
Subpart B, § 5.59–Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.	Subpart F, § 5.413–Approval, disapproval, or withdrawal of approval of applications and entering into agreements for investigational device exemptions
Subpart B, § 5.60–Required and discretionary postmarket surveillance	Subpart F, § 5.414–Postmarket surveillance (proposed subject)

APPENDIX A—PART 5; CORRESPONDING FORMER AND NEW SUBPARTS, SECTION NUMBERS, AND SUBJECTS—Continued

Former CFR Subpart, Section No., and Subject	New CFR Subpart, Section No., and Subject
Subpart B, § 5.61–Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.	Subpart E, § 5.300–(same subject)
Subpart B, § 5.62–Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.	Subpart E, § 5.301–(same subject)
Subpart B, § 5.63–Detention of meat, poultry, eggs, and related products.	Subpart E, § 5.302–(same subject)
Subpart B, § 5.64–Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.	Subpart E, § 5.303–(same subject)
Subpart B, § 5.66–Approval of schools providing food-processing instruction.	Subpart E, § 5.304–(same subject)
Subpart B, § 5.67–Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses, suspension of licenses, or revocation of licenses and certain notices of revocation of licenses.	Subpart D, § 5.202–(same subject)
Subpart B, § 5.68–Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.	Subpart D, § 5.203–(same subject)
Subpart B, § 5.69–Notification of release for distribution of biological products.	Subpart D, § 5.204–(same subject)
Subpart B, § 5.70–Issuance of notices implementing the provisions of the Drug Amendments of 1962.	Subpart C, § 5.100–(same subject)
Subpart B, § 5.71–Termination of exemptions for new drugs for investigational use in human beings and in animals (Note: § 5.71(d) is under animal drugs).	Subpart C, § 5.101–(same subject)
.....	Subpart G, § 5.505–(same subject)
Subpart B, § 5.72–Authority to approve and to withdraw approval of a charge for investigational new drugs.	Subpart C, § 5.102–(same subject)
Subpart B, § 5.75–Removed, effective 5/20/99	None
Subpart B, 5.76–Removed, effective 5/20/99	None
Subpart B, § 5.78–Removed, effective 5/20/99	None
Subpart B, § 5.80–Approval of new drug applications and their supplements.	Subpart C, § 5.103–(same subject)
Subpart B, § 5.81–Responses to Drug Enforcement Administration temporary scheduling notices.	Subpart C, § 5.104–(same subject)
Subpart B, § 5.82–Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.	Subpart C, § 5.105–(same subject)
Subpart B, § 5.83–Approval of new animal drug applications, medicated feed mill license applications and their supplements.	Subpart G, § 5.501–(same subject)
Subpart B, § 5.84–Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.	Subpart G, § 5.502–(same subject)
Subpart B, § 5.85–Authority to ensure that mammography facilities meet quality standards.	Subpart L, § 5.1000–(same subject)
Subpart B, § 5.86–Variances from performance standards for electronic products.	Subpart H, § 5.600–(same subject)
Subpart B, § 5.87–Exemption of electronic products from performance standards and prohibited acts.	Subpart H, § 5.601–(same subject)
Subpart B, § 5.88–Testing programs and methods of certification and identification for electronic products.	Subpart H, § 5.602–(same subject)
Subpart B, § 5.89–Notification of defects in, and repair or replacement of, electronic products.	Subpart H, § 5.603–(same subject)
Subpart B, § 5.90–Manufacturers requirement to provide data to ultimate purchasers of electronic products.	Subpart H, § 5.604–(same subject)
Subpart B, § 5.91–Dealer and distributor direction to provide data to manufacturers of electronic products.	Subpart H, § 5.605–(same subject)
Subpart B, § 5.92–Acceptance of assistance from State and Local authorities for enforcement of radiation control legislation and regulations.	Subpart H, § 5.606–(same subject)
Subpart B, § 5.93–Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.	Subpart C, § 5.106–(same subject)
Subpart B, § 5.94–Extensions or stays of effective dates for compliance wit certain labeling requirements for human prescription drugs.	Subpart C, § 5.107–(same subject)
Subpart B, § 5.95–Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.	Subpart G, § 5.503–(same subject)
Subpart B, § 5.98–Authority relating to medical device reporting procedures.	Subpart F, § 5.415–(same subject)
Subpart B, § 5.99–Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.	Subpart B, § 5.34–(same subject)
Subpart B, § 5.100–Officials authorized to make certification under 5 U.S.C. 605(b) for any proposed and final rules.	Subpart B, § 5.35–(same subject)

APPENDIX A—PART 5; CORRESPONDING FORMER AND NEW SUBPARTS, SECTION NUMBERS, AND SUBJECTS—Continued

Former CFR Subpart, Section No., and Subject	New CFR Subpart, Section No., and Subject
Subpart B, § 5.101–Authority relating to waivers or reductions of prescription drug user fees.	Subpart C, § 5.108–(same subject)
Subpart C, § 5.200 through § 5.215–Organization	Subpart M, § 5.1100–(same subject)
New–Not previously codified	Subpart F, § 5.416–Medical device tracking
New–Not previously codified	Subpart F, § 5.400–Issuance of FEDERAL REGISTER documents to recognize or to withdraw recognition of a standard to meet premarket submission requirements
New–Not previously codified	Subpart F, § 5.401–Issuance of FEDERAL REGISTER documents pertaining to exemptions from premarket notification.
New–Not previously codified	Subpart F, § 5.408–Determinations concerning the type of valid scientific evidence submitted in a premarket approval application.
New–Not previously codified	Subpart F, § 5.417–Authority pertaining to accreditation functions for medical devices.

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