[Code of Federal Regulations]
[Title 21, Volume 1, Parts 1 to 99]
[Revised as of April 1, 1996]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR5.10]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 5--DELEGATIONS OF AUTHORITY AND ORGANIZATION--Table of Contents

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

Sec. 5.10 Delegations from the Secretary, the Assistant Secretary for Health, and Public Health Service Officials.

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

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Filled Milk Act (21 U.S.C. 61-63), the Federal Import Milk Act (21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406), and The Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), pursuant to 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 (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 sections 354 through 360F of the Public Health Service Act (42 U.S.C. 263b through 263n), as amended, which relate to electronic product radiation control.

(4) Functions vested in the Secretary under section 361 of the Public Health Service 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 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.

(5) Functions vested in the Secretary under sections 351 and 352 of part F, subpart 1 of the Public Health Service 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.

(6) Functions vested in the Secretary under section 302(a) of the Public Health Service 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.

(7) Functions vested in the Secretary under section 303 of the Public Health Service 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 Pub. L. 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 Pub. L. 91-513.

(8) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (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.

(9) 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 determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act, and the merits of the research protocol.

(10) 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.).

(11) 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.

(12) 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.

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

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

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

(16) 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 promulgated by the Federal Preparedness Agency of the General Services Administration; Office of the Secretary, HHS; and Office of the Assistant Secretary for Health.

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

(18) Functions vested in the Secretary under the Federal Advisory Committee Act, Public Law 92-463, 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 for those committees under the administrative jurisdiction of the Commissioner of Food and Drugs. This authority may be redelegated to a single official who reports directly to the Commissioner of Food and Drugs. This authority is to be exercised in accordance with the requirements of the Federal Advisory Committee Act and only with respect to the following:

(i) Meetings, to the extent that they directly involve review, discussion or consideration of records of the Department which are exempt from disclosure under 5 U.S.C. 552(b) (4), (6), and (7), namely, (a) records containing trade secrets and commercial or financial information obtained from a person and privileged or confidential; (b) personnel, medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (c) investigatory files compiled for law enforcement purposes;

(ii) Meetings to the extent that they involve the review, discussion, and evaluation of specific drugs and devices regulated by FDA which are intended to result in recommendations for regulatory decisions under the Federal Food, Drug, and Cosmetic Act and which are concerned with matters listed in 5 U.S.C. 552(b) (4), (5), and (7);

(iii) Meetings held for the sole purpose of considering and formulating advice which the committee will give or any final report it will render, Provided:

(a) The meetings will involve solely the internal expression of views and judgments of the members and it is essential to close the meeting or portions thereof to protect the free exchange of such views and avoid undue interference with agency or committee operations, and such views if reduced to writing would be protected from mandatory disclosure under 5 U.S.C. 552(b);

(b) The meeting is closed for the shortest time necessary, summarizing the work of the committee during the closed session, and a report, prepared by the executive secretary will be made available promptly to the public.

(c) When feasible, the public is given a timely opportunity to present relevant information and views to the committee; and

(d) Concurrence for closing the meetings for such purpose is obtained from the Office of the General Counsel and the Office of Public Affairs.

(19) 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 Public Health Service 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.

(20) Functions vested in the Secretary under section 2101 of the

Public Health Service Act (42 U.S.C. 219) 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.

(21) Functions vested in the Secretary under section 362 of the Public Health Service 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.

[[Page 30]]

(22) Functions vested in the Secretary under section 1003(b)(3), title X, of the Public Works and Economic Development Act of 1965 (42 U.S.C. 3246b(b)(3)) to waive any matching requirements for programs or projects of State and local governments funded under title X of that act where it is determined that State or local governments concerned cannot reasonably obtain any non-Federal contributions.

(23) Functions vested in the Secretary under section 401(a) of the Lead-Based Paint Poisoning Prevention Act, as amended by Pub. L. 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.

(24) Functions vested in the Secretary for the health information and health promotion program under title XVII of the Public Health Service 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), (2), and (6). The delegation excludes the authority to select all Senior Executive Service, supergrade and equivalent, and Schedule C (GS-12 and above) positions; promulgate regulations; and submit reports to the President.

(25) 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 promulgate regulations, establish advisory councils and committees, appoint members to advisory councils and committees, and submit reports to Congress.

(26) Functions vested in the Secretary under sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981 (42 U.S.C. 10007 and 10008), as amended. The delegation excludes the authority to promulgate 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.

(27) 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. 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.

(28) Functions vested in the Secretary 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)), as amended, which provides for a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under this title. The approval and issuance of regulations under that section are reserved to the Secretary, as provided in 21 CFR 5.11.

(29) 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 No. 12591 of April 10, 1987, as they pertain to the functions of the Food and Drug Administration. The delegation excludes the authority to promulgate 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 of Food and Drugs 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) of the Act (15 U.S.C. 3710a(b)(3)) to waive a right of

[[Page 31]]

ownership which the Federal Government may have to an invention made under a cooperative research and development agreement; the authority under section 11(b)(4) of the Act (15 U.S.C. 3710a(b)(4)) 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)(29) of this section delegated by the Commissioner of Food and Drugs may not be further redelegated.

(30) 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) which relate to pesticide monitoring and enforcement information, foreign pesticide information, and pesticide analytical methods. The delegation excludes the authority to submit reports to Congress.

(31) Functions vested in the Secretary under the Government Patent Policy Act of 1980 as amended by the Federal Court Reorganization Act of 1984, as they pertain to the functions of the Food and Drug Administration (FDA). The delegated authorities, to be exercised in

compliance with all existing rules and regulations regarding patent and invention rights and responsibilities, are restricted to the extent that 35 U.S.C. 203, as amended, may not be redelegated and that under 35 U.S.C. 207(a), the Assistant Secretary for Health is to be notified of any significant invention, patent, or license, so that the Assistant Secretary for Health may decide whether or not documentation concerning any such invention, patent, or license should be submitted to the Assistant Secretary for Health for signature. All other authorities may be redelegated to officials at the level equivalent to bureau and institute directors.

(i) Disposition of rights, 35 U.S.C. 202(c)(7), as amended: The authority to permit a nonprofit organization to assign the rights to a subject invention in the United States to organizations which do not have as one of their primary functions the management of inventions.

(ii) Disposition of rights, 35 U.S.C. 202(d), as amended: The authority to permit a contractor to grant requests for retention of rights by the inventor.

(iii) Disposition of rights, 35 U.S.C. 202(e), as amended: The authority to transfer or assign whatever rights FDA may acquire in the subject invention in any case when an agency employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm. Such rights may be transferred or assigned from the FDA employee to the contractor subject to the conditions set forth in this chapter.

(iv) March-in-rights, 35 U.S.C. 203, as amended: The authority to require the contractor to grant nonexclusive, partially exclusive, or exclusive licenses to responsible applicant(s), or the authority for FDA to grant such licenses, provided such action would be in the best interest of FDA, in accordance with all provisions of this section.

(v) Preference for United States industry, 35 U.S.C. 204, as amended: The authority to waive the preference for U.S. industry requirement.

(vi) Domestic and foreign protection of federally owned inventions, 35 U.S.C. 207(a) as amended, the authority to:

(A) Apply for, obtain, and maintain patents or other forms of protection in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(B) Grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to

[[Page 32]]

the licensee of the right of enforcement pursuant to the provisions of chapter 29 of title 35 as determined appropriate in the public interest;

(C) Undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract; and

(D) Transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(vii) Determination as to domestic rights and notice to employee of determination, 45 CFR 7.3 and 7.7, as amended, authority to:

(A) Leave title to invention in the FDA employee inventor where the Government has insufficient interest in an invention to obtain the

entire domestic right, title, and interest therein; and

(B) Notify the FDA employee inventor of the determination in writing.

(32) 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 Public Health Service 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 promulgate regulations, submit reports to the Congress, establish advisory committees or national commissions, and appoint members to such committees or commissions.

(33) 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 Public Health Service Act (42 U.S.C. 300ff 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 promulgate regulations, submit reports to the Congress, establish advisory committees or national commissioners, and appoint members to such committees or commissions.

(34) 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.

(35) Functions vested in the Secretary under part C, subtitle 2 of title XXI of the Public Health Service 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 Public Health Service Act (42 U.S.C. 300aa-25)--Recording and reporting of information.

(ii) Section 2127 of the Public Health Service Act (42 U.S.C. 300aa-27)--Mandate for safer childhood vaccines.

(iii) Section 2128 of the Public Health Service 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.

(v) Section 313 of the National Childhood Vaccine Injury Act of 1986--Study of other vaccine risks.

(vi) Section 314 of the National Childhood Vaccine Injury Act of 1986--Review of warnings, use instructions, and precautionary information.

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

(36) Functions vested in the Secretary under section 354(b) through (l) and (n), (o), (q), and (r) of the Public Health Service Act (section 2 of the Mammography Quality Standards Act of 1992 (Pub. L. 102-539)), as amended, which deal with the certification of mammography facilities. The delegation excludes the authority to submit reports to Congress.

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

(b) The Chief Counsel of the Food and Drug Administration, i.e., the Associate General Counsel in charge of the Food and Drug Division, has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act, section 4 of the Federal Import Milk Act, and section 9(b) of the Federal Caustic Poison Act.

(c) The Director, Office of Management, 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 of be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(d) The Executive Officer, Public Health Service, has redelegated to the Commissioner of Food and Drugs 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.

(e) [Reserved]

(f) The Secretary of Health and Human Services 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.

[42 FR 15560, Mar. 22, 1977]

Editorial Note: For Federal Register citations affecting Sec. 5.10, see the List of CFR Sections Affected in the Finding Aids section of this volume.