dated September 1, 1999, and effective September 16, 1999, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASO TN E5 Dayton, TN [Revised]

Dayton, Mark Anton Airport, TN
(Lat. 35°29′10″ N, long. 84°55′52″ W)
Hardwick Field Airport
(Lat. 35°13′12″ N, long 84°49′57″ W)
(Bledsoe County Hospital, Pikeville, TN
Point in Space Coordinates
(Lat. 35°37′34″ N, long. 85°10′38″ W)

That airspace extending upward from 700 feet or more above the surface within a 12.5-mile radius of Mark Anton Airport, and within a 6.5-mile radius of Hardwick Field Airport, and that airspace within a 6-mile radius of the point in space (lat. 35°37′34″ N, long. 85°10′38″ W) serving Bledsoe County Hospital, Pikeville, TN; excluding that airspace within the Athens, TN, Class E airspace area.

* * * * *

Issued in College Park, Georgia, on March 31, 2000.

Nancy B. Shelton,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 00–9218 Filed 4–12–00; 8:45 am]

BILLING CODE 4910–13–M

RAILROAD RETIREMENT BOARD

20 CFR Part 219

RIN 3220–AB43

Evidence Required for Payment

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (RRB) hereby amends its regulations to permit the use of noncertified copies and facsimile copies of records or documents needed to establish eligibility for benefits under the Railroad Retirement Act. These amendments will make it easier for individuals to apply for benefits under the Act.

DATES: Effective May 15, 2000.

FOR FURTHER INFORMATION CONTACT: Marguerite P. Dadabo, Senior Attorney, (312) 751–4945, TTD (312) 751–4701.

SUPPLEMENTARY INFORMATION: In order to receive benefits under the Railroad Retirement Act an individual may be required to provide proof of age, marriage, divorce, or death. Section 219.6 of the Board's regulations generally required that where a claimant must provide a record or document to establish an eligibility requirement, the original or a certified copy of such document or record must be provided. This requirement proved burdensome for claimants. Many claimants wish to transmit their documentary evidence electronically by use of telefax devices. Consequently, the Board amends its regulations to permit the use of uncertified copies and facsimiles of certain official records when the official custodian of such records transmits the facsimile directly to an office of the Board and the source of the transmittal is clearly identified on the facsimile. In addition, the Board amends it regulations to permit Board employees to certify translations of foreign documents.

On November 26, 1999, the Board published this rule as a proposed rule (64 FR 66433), inviting comments on or before January 25, 2000. No comments were received.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action under Executive Order 12866; therefore, no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR Part 219

Pensions, Railroad employees, Railroad retirement.

For the reasons set out in the preamble, the Railroad Retirement Board amends chapter II of title 20 of the Code of Federal Regulations as follows:

PART 219—EVIDENCE REQUIRED FOR PAYMENT

1. The authority citation for part 219 continues to read as follows:

Authority: 45 U.S.C. 231f.

2. In § 219.6 the section heading and paragraphs (a) and (b) are revised, and a new paragraph (d) is added to read as follows:

§ 219.6 Records as evidence.

(a) *General.* If a claimant or an annuitant provides an original document or record as evidence to prove eligibility or continued entitlement to payments, where possible, a Board employee will make a photocopy or transcript of these original documents or records and return the original documents to the person who furnished them. A claimant may also submit certified copies of original records as described in paragraph (c) of this section. The Board may also accept uncertified copies as described in paragraph (d) of this section.

(b) *Foreign-language documents.* If the evidence submitted is a foreign-language document, the Board may require that the record be translated. An acceptable translation includes, but is not limited to, a translation certified by a United States consular official or employee of the Department of State authorized to certify evidence, or by an employee of the Board or the Social Security Administration.

* * * * *

(d) *Uncertified copies and facsimiles.* In lieu of certified paper copies of records or extracts from such official sources as listed in paragraph (c) of this section, the Board will accept facsimile copies of such records or extracts when the official custodian of such records transmits the facsimile directly to an office of the Board and the source of the transmittal is clearly identified on the facsimile.

Dated: March 24, 2000.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 00–9024 Filed 4–12–00; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority and organization by updating the addresses for headquarters and the field offices. This action is necessary to ensure the accuracy of the regulations.

DATES: This rule is effective April 13, 2000.

FOR FURTHER INFORMATION CONTACT: Rodolfo Guillen, Jr., Division of Management Programs (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4815.

SUPPLEMENTARY INFORMATION: The regulations are being amended in subpart C of part 5 (21 CFR part 5) to reflect the central organization of the agency and to provide current addresses for headquarters and field offices.

Notice and comment about the amendments are not necessary under the Administrative Procedure Act because this is a rule of agency organization (5 U.S.C. 553(b)).

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 authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 15 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 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.

2. Section 5.200 is revised to read as follows:

§ 5.200 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 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.
Team Biologics Liaison Staff.
Advertising and Promotional Labeling Staff.
Division of Case Management.
Division of Manufacturing and Product Quality.
Division of Inspections and Surveillance.
Office of Blood Research and Review.
Human Tissue Staff.
Policy and Publications Staff.
Division of Emerging and Transfusion Transmitted Diseases.
Division of Hematology.
Division of Blood Applications.
Office of Therapeutics Research and Review.
Division of Cellular and Gene Therapies.
Division of Therapeutic Proteins.
Division of Monoclonal Antibodies.
Division of Clinical Trial Design and Analysis.
Division of Application Review and Policy.
Office of Vaccines Research and Review.
Division of Bacterial, Parasitic, and Allergenic Products.
Division of Viral Products.
Division of Vaccines and Related Products Applications.
Office of Communication, Training, and Manufacturers Assistance.
Division of Disclosure and Oversight Management.
Division of Manufacturers Assistance and Training.
Division of Communication and Consumer Affairs.
Office of Biostatistics and Epidemiology.
Division of Biostatistics.
Division of Epidemiology.

Center for Food Safety and Applied Nutrition.[4]
Office of the Center Director.
Food Safety Initiatives Staff.
Senior Science Advisor's Staff.
Office of Regulations and Policy.
Regulations Coordination Staff.
Office of Constituent Operations.
Consumer Education Staff.
International Activities Staff.
Industry Activities Staff.
Office of Management Systems.
Safety Management Staff.
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.
Clinical Research and Review Staff.
Division of Compliance and Enforcement.
Division of Standards and Labeling Regulations.
Division of Nutrition Science Policy.
Division of Research and Applied Technology.
Office of Premarket Approval.
Division of Product Policy.
Division of Petition Control.
Division of Health Effects Evaluation.
Division of Molecular Biological Research and Evaluation.
Division of Product Manufacture and Use.
Office of Plant and Dairy Foods and Beverages.
Division of Virulence Assessment.
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.

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

[2] Mailing address: 5630 Fishers Lane, Rockville, MD 20852.

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

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

Division of Risk Assessment.
Office of Seafood.
Division of Special Programs.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.
Office of Special Research Skills.
Division of Toxicology Research.
Division of Microbiological Studies.
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.
Regulatory Policy Staff.
Office of Management.[1]
Strategic Planning Staff.[5]
Division of Management and Budget.[5]
Division of Management Services.[5]
Office of Training and Communication.[1]
Division of Communications Management.
Division of the Medical Library.
Division of Training and Development.
Division of Freedom of 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.[6]
Office of Review Management.[1]
Advisors and Consultants Staff.[2]
Office of Drug Evaluation I.[1]
Division of Cardio-Renal Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology Drug Products.
Office of Drug Evaluation II.[1]
Division of Metabolic and Endocrine Drug Products.
Division of Pulmonary and Allergy Drug Products.
Division of Anesthetic, Critical Care, and Addiction Drug Products.
Office of Drug Evaluation III.[1]
Division of Gastrointestinal and Coagulation Drug Products.
Division of Medical Imaging and Radiopharmaceutical Drug Products.
Division of Reproductive and Urologic Drug Products.
Office of Drug Evaluation IV.
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.*
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.
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.[5]
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]
Regulatory Research and Analysis Staff.
Laboratory of Clinical Pharmacology.[7]
Division of Applied Pharmacology Research.[8]
Division of Testing and Applied Analytical Development.[9]
Division of Product Quality Research.[1]
Office of Regulatory Affairs.[1]
Contaminants Policy Coordination Staff.
Equal Employment Opportunity Staff.
Strategic Initiatives Staff.
Office of Resource Management.
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.
Medical Products Quality Assurance Staff.
Division of Compliance Management and Operations.
Division of Compliance Policy.
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.[10]
Midwest Area Office.[11]
Northeast Area Office.[12]
Pacific Area Office.[13]
Southeast Area Office.[14]
Southwest Area Office.[15]

Center for Veterinary Medicine.[16]

Office of the Center Director.
Office of Management and Communications.
Administrative Staff.
Communications Staff.
Program Planning and Evaluation Staff.
Information Resources Management Staff.
Office of New Animal Drug Evaluation.
Division of Therapeutic Drugs for Food Animals.

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

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

[7] Mailing address: Four Research Ct., Rockville, MD 20850.

[8] Mailing address: 8308 Muirkirk Rd., Laurel, MD 20708.

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

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

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

[12] Mailing address: 850 Third Ave., Brooklyn, NY 11232.

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

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

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

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

Division of Biometrics and Production Drugs.
Division of Therapeutic Drugs for Non-Food Animals.
Division of Human Food Safety.
Division of Manufacturing Technologies.
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.[17]
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, Respiratory, and Neurological Devices.
Division of Reproductive, Abdominal, Ear, Nose, Throat, and Radiological Devices.
Division of General and Restorative Devices.
Division of Clinical Laboratory Devices.
Division of Ophthalmic Devices.
Division of Dental, Infection Control, and General Hospital Devices.
Office of Science and Technology.
Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.
Division of Electronics and Computer Sciences.
Division of Management Information and Support Services.
Office of Health and Industry Programs.
Program Operations Staff.
Regulations Staff.
Staff College.
Division of Device User Programs and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.
Office of Surveillance and Biometrics.
Issues Management Staff.
Division of Biostatistics.
Division of Postmarket Surveillance.
Division of Surveillance Systems.
National Center for Toxicological Research.[18]
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.
Contracts and Procurement Staff.
Division of Facilities, Engineering, and Maintenance.
Division of Administrative Services.
Office of Planning, Finance and Information Technology.
Division of Planning.
Division of Financial Management.
Division of Information Technology.

3. Section 5.210 is revised to read as follows:

§ 5.210 FDA 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).* The Press Offices are located in rm. 15–05, Parklawn Bldg., 5600 Fisher 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.

4. Section 5.215 is revised to read as follows:

§ 5.215 Field structure.

NORTHEAST REGION

Regional Field Office: 850 Third Ave., Brooklyn, NY 11232.
Northeast Regional Laboratory: 850 Third Ave., Brooklyn, NY 11232–1593.
New York District Office: 850 Third Ave., Brooklyn, NY 11232–1593.
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: 1141 Central Pkwy., Cincinnati, OH 45202–1097.
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.
Nashville District Office: 297 Plus Park Blvd., Nashville, TN 37217.
New Orleans District Office: 4298 Elysian Fields Ave., New Orleans, LA 70122.
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.

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

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

*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 MacArthur 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 23d Dr. SE., Bothell, WA 98021–4421.

Dated: April 5, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–9126 Filed 4–12–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868, 884, and 890

[Docket No. 98N–0564]

Medical Devices; Effective Date of Requirement for Premarket Approval for Three Preamendment Class III Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to retain three class III preamendment devices in class III and to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following devices: The lung water monitor, the powered vaginal muscle stimulator, and the stair-climbing wheelchair. The agency has summarized its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices.

DATES: This rule is effective April 13, 2000.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 18, 1998 (63 FR 44177), FDA published a proposed rule to require the filing under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)), of a PMA or a notice of completion of a PDP for three preamendment class III devices. In accordance with section 515(b)(A)(2) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the premarket approval requirements of the act, and the benefits to the public from use of the devices. The proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings. Under section 515(b)(2)(B) of the act, FDA provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. If anyone wanted to submit a petition requesting a change in the classification of the three devices, they were required to submit it by September 2, 1998. The comment period closed November 16, 1998.

FDA received no comments on the proposed rule. FDA received one citizen petition requesting a change in the classification of the stair-climbing wheelchair from class III to class II. FDA reviewed the petition and determined that there was not sufficient information to establish special controls to reasonably assure the safety and effectiveness of the device. FDA informed the petitioner in a letter dated May 10, 1999, that if additional information was submitted under section 513(e) of the act (21 U.S.C. 360c(e)) within 30 days to support the reclassification of the device, FDA would review the information. FDA also stated that if the petitioner did not submit additional information within 30 days to show that sufficient information is available to establish special controls to reasonably assure the safety and effectiveness of the device, FDA would deem the reclassification petition withdrawn. FDA has not received any new information from the petitioner and has deemed the reclassification petition withdrawn.

II. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings it published in the proposed rule. As required by section 515(b) of the act, FDA published its findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP; and (2) the benefits to the public from the use of the devices.

These findings are based on the reports and recommendations of the advisory committees (the panels) for these devices, the Anesthesiology and Respiratory Devices Panel, the Obstetrical and Gynecological Devices Panel, and the Orthopedic and Rehabilitation Devices Panel for the classification of the devices along with any additional information that FDA discovered. Additional information can be found in the proposed and final rules classifying these devices published in the **Federal Register** of November 2, 1979 (44 FR 63292), and July 16, 1982 (47 FR 31130), for the lung water monitor; April 3, 1979 (44 FR 19894), and February 26, 1980 (45 FR 12682), for the powered vaginal muscle stimulator; and August 28, 1979 (44 FR 50458), and November 23, 1983 (48 FR 53032), for the stair-climbing wheelchair.

III. The Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and issuing this final rule to require premarket approval of these generic types of devices for class III preamendment devices by revising parts 868, 884, and 890 (21 CFR parts 868, 884, and 890).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before July 12, 2000, for any of these class III preamendment devices that were in commercial distribution before May 28, 1976, or that have been found by FDA to be substantially equivalent to such a device on or before July 12, 2000. An approved PMA or a declared completed PDP is required to be in effect for any such devices on or before 180 days after FDA files the application. Any other class III preamendment device subject to this rule that was not in commercial distribution before May 28, 1976, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.