

(1) Directors, officers, employees, and others authorized by the air carrier operating the aircraft;

(2) Directors, officers, employees, and others authorized by the air carrier or another carrier traveling pursuant to a pass interchange agreement;

(3) Travel agents being transported for the purpose of familiarizing themselves with the carrier's services;

(4) Witnesses and attorneys attending any legal investigation in which such carrier is involved;

(5) Persons injured in aircraft accidents, and physicians, nurses, and others attending such persons;

(6) Any persons transported with the object of providing relief in cases of general epidemic, natural disaster, or other catastrophe;

(7) Any law enforcement official, including any person who has the duty of guarding government officials who are traveling on official business;

(8) Guests of an air carrier on an inaugural flight or delivery flights of newly-acquired or renovated aircraft;

(9) Security guards who have been assigned the duty to guard such aircraft against unlawful seizure, sabotage, or other unlawful interference;

(10) Safety inspectors of the National Transportation Safety Board or the FAA in their official duties;

(11) Postal employees on duty in charge of the mails or traveling to or from such duty;

(12) Technical representatives of companies that have been engaged in the manufacture, development or testing of a particular type of aircraft or aircraft equipment, when the transportation is provided for the purpose of in-flight observation and subject to applicable FAA regulations;

(13) Persons engaged in promoting transportation; and

(14) Other authorized persons, when such transportation is undertaken for promotional purpose.

* * * * *

Revenue passenger means a passenger for whose transportation an air carrier receives commercial remuneration. This includes for example:

(1) Passengers traveling under publicly available tickets including promotional offers (for example two-for-one) or loyalty programs (for example, redemption of frequent flyer points);

(2) Passengers traveling on vouchers or tickets issued as compensation for denied boarding or in response to consumer complaints or claims;

(3) Passengers traveling at corporate discounts;

(4) Passengers traveling on preferential fares (Government, seamen, military, youth student, etc.);

(5) Passengers traveling on barter tickets; and

(6) Infants traveling on confirmed-space tickets.

PART 298—[AMENDED]

5. The authority citation for part 298 continues to read as follows:

Authority: 49 U.S.C. chapters 401, 411, 417.

6. The paragraph designations are removed and definitions for *Nonrevenue passenger* and *Revenue passenger* are added in alphabetical order to § 298.2 to read as follows:

§ 298.2 Definitions.

* * * * *

Nonrevenue passenger means a person traveling free or under token charges, except those expressly named in the definition of *revenue passenger*; a person traveling at a fare or discount available only to employees or authorized persons of air carriers or their agents or only for travel on the business of the carriers; and an infant who does not occupy a seat. The following passengers are examples of nonrevenue passengers when traveling free or pursuant to token charges:

(1) Directors, officers, employees, and others authorized by the air carrier operating the aircraft;

(2) Directors, officers, employees, and others authorized by the air carrier or another carrier traveling pursuant to a pass interchange agreement;

(3) Travel agents being transported for the purpose of familiarizing themselves with the carrier's services;

(4) Witnesses and attorneys attending any legal investigation in which such carrier is involved;

(5) Persons injured in aircraft accidents, and physicians, nurses, and others attending such persons;

(6) Any persons transported with the object of providing relief in cases of general epidemic, natural disaster, or other catastrophe;

(7) Any law enforcement official, including any person who has the duty of guarding government officials who are traveling on official business;

(8) Guests of an air carrier on an inaugural flight or delivery flights of newly-acquired or renovated aircraft;

(9) Security guards who have been assigned the duty to guard such aircraft against unlawful seizure, sabotage, or other unlawful interference;

(10) Safety inspectors of the National Transportation Safety Board or the FAA in their official duties;

(11) Postal employees on duty in charge of the mails or traveling to or from such duty;

(12) Technical representatives of companies that have been engaged in the manufacture, development or testing of a particular type of aircraft or aircraft equipment, when the transportation is provided for the purpose of in-flight observation and subject to applicable FAA regulations;

(13) Persons engaged in promoting transportation; and

(14) Other authorized persons, when such transportation is undertaken for promotional purpose.

* * * * *

Revenue passenger means a passenger for whose transportation an air carrier receives commercial remuneration. This includes for example:

(1) Passengers traveling under publicly available tickets including promotional offers (for example two-for-one) or loyalty programs (for example, redemption of frequent flyer points);

(2) Passengers traveling on vouchers or tickets issued as compensation for denied boarding or in response to consumer complaints or claims;

(3) Passengers traveling at corporate discounts;

(4) Passengers traveling on preferential fares (Government, seamen, military, youth student, etc.);

(5) Passengers traveling on barter tickets; and

(6) Infants traveling on confirmed-space tickets.

* * * * *

Issued in Washington, DC on August 16, 2000.

Susan McDermott,

Deputy Assistant Secretary for Aviation and International Affairs.

Donald W. Bright,

Acting Director, Office of Airline Information.
[FR Doc. 00-21313 Filed 8-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. 00N-1409]

Physical Medicine Devices; Revision of the Identification of the Iontophoresis Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the physical medicine devices regulations to remove the class III

FDA's letters to those manufacturers will rescind their previously cleared substantial equivalence orders. At that time, the manufacturer may no longer place the device into commercial distribution.

IV. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 180 days after the date of publication of the final rule in the **Federal Register**.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

VI. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of the device from class III into class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. The FDA analysis determined that 21 manufacturers have 41 510(k)'s that will be affected by this proposed rule. FDA believes that submissions for the class III iontophoresis device will involve only changes in device labeling in the existing 510(k)'s and that preparation of these changes will require minimal cost. FDA believes that most of these devices

will remain on the market as class II devices. The agency believes that the cost of complying with the labeling requirements for each manufacturer will be approximately \$1,000. The agency, therefore, certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this rule, because the rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation.

VII. Paperwork Reduction Act of 1995

FDA concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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.

IX. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposed rule by November 20, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 890 be amended to read as follows:

PART 890—PHYSICAL MEDICINE DEVICES

1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 890.5525 is amended by adding paragraphs (d) and (e) to read as follows:

§ 890.5525 Iontophoresis device.

* * * * *

(d) *Identification.* An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug.

(e) *Classification.* Class II (special controls).

Dated: August 3, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–21251 Filed 8–21–00; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 00–1797, MM Docket No. 00–138, RM–9896]

Digital Television Broadcast Service; Boca Raton, FL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition jointly filed by Palmetto Broadcasters Associated for Communities, Inc., licensee of noncommercial educational station WPPB–TV, NTSC Channel 63, Boca Raton, Florida, and Channel 63 of Palm Beach, Inc., the proposed assignee of WPPB. Petitioners request the substitution of DTV Channel *40 for DTV Channel *44 at Boca Raton. DTV Channel *40 can be allotted to Boca