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

Raton, Florida, in compliance with the principal community coverage requirements of Section 73.625(a) at reference coordinates (25–59–34 N. and 80–10–27 W.). As requested, we propose to allot DTV Channel *40 to Boca Raton with a power of 1000 and a height above average terrain (HAAT) of 310 meters.

DATES: Comments must be filed on or before October 10, 2000, and reply comments on or before October 25, 2000.

ADDRESSES: Federal Communications Commission, 445 12th Street, S.W., Room TW–A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Kevin C. Boyle, Nandan M. Joshi, Latham & Watkins, 1001 Pennsylvania Avenue, NW., Suite 1300, Washington, DC 20004 (Counsel for Palmetto Broadcasters Associated for Communities, Inc.); and John R. Feore, Jr., Margaret L. Miller, Christine J. Newcomb, Dow, Lohnes & Albertson, PLLC, 1200 New Hampshire Avenue, Suite 800, Washington, DC 20036 (Counsel for Channel 63 of Palm Beach, Inc.).

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 00–138, adopted August 17, 2000, and released August 25, 2000. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center 445 12th Street, SW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW., Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 00–21405 Filed 8–21–00; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 243

[FRA Docket No. HST–1; Notice No. 3]

RIN 2130–AB14

FOX High Speed Rail Safety Standards

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Termination of rulemaking.

SUMMARY: This document terminates rulemaking action in FRA Docket No. HST–1. In its Notice of Proposed Rulemaking (NPRM) published on December 12, 1997, FRA proposed to establish safety standards for the Florida Overland eXpress (FOX) high speed rail system. Termination of this rulemaking is based on Florida's decision not to develop the FOX high speed rail system.

FOR FURTHER INFORMATION CONTACT: Christine Beyer, Deputy Assistant Chief Counsel for Safety, Office of Chief Counsel, FRA, 1120 Vermont Avenue, N.W., Stop 10, Washington, D.C. 20590 (telephone: 202–493–6027).

SUPPLEMENTARY INFORMATION: The State of Florida was planning to develop a high speed rail system that would utilize high speed technology and equipment modeled on the French TGV, that would run from Miami to Tampa, via Orlando. On February 18, 1997, the developer of the high speed system, the Florida Overland eXpress (FOX), filed a petition for rulemaking with FRA that proposed safety standards for the proposed high speed rail system. After analyzing the Petition, FRA published a notice of proposed rulemaking (NPRM) (62 FR 65478, December 12, 1997) on the subject that incorporated many of the standards proposed by the FOX Petition and proposed new standards. The funding for this project was to be shared by the public and private sector. However, after publication of the NPRM, the State of Florida decided to withdraw its financial support for the high speed rail system. Consequently, the proposed system will not be constructed.

Termination of Rulemaking

Based on the foregoing information FRA has decided to terminate this rulemaking, as it would have been solely applicable to the FOX high speed rail project. We note that this rulemaking has been a worthwhile first step in addressing the safety concerns inherent in the implementation of certain high speed rail operations. We are confident that further steps in addressing these concerns will build upon the information and discussion generated by this proceeding. In light of the foregoing, FRA is hereby terminating this rulemaking.

Issued in Washington, DC on August 11, 2000.

Jolene M. Molitoris,

Administrator.

[FR Doc. 00–21261 Filed 8–21–00; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 697

[I.D. 081500A]

Atlantic Coastal Fisheries Cooperative Management Act Provision; Atlantic Coast Horseshoe Crab Fishery; Public Hearings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public hearings; request for comments.

SUMMARY: NMFS is considering implementing a closed area to provide conservation for horseshoe crabs near the mouth of Delaware Bay. NMFS will hold three public hearings to receive comments from fishery participants and other members of the public regarding its proposal to prohibit fishing for, and possession of, horseshoe crabs (*Limulus polyphemus*) in a designated area in Federal waters (EEZ) off the mouth of the Delaware Bay, with a limited exception for vessels fishing for whelk and conch (whelk).

DATES: NMFS will take comments at public hearings in September 2000. See **SUPPLEMENTARY INFORMATION** for dates and times of the public hearings.

ADDRESSES: Copies of a Draft Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (EA/RIR/IRFA) and a draft proposed rule are available from Richard H. Schaefer, Chief, Staff Office for Intergovernmental and Recreational Fisheries, National Marine Fisheries Service, 8484 Georgia Avenue, Suite