

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 Ionotophoresis Device**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the physical medicine devices regulations to remove the class III (premarket approval) iontophoresis device identification. FDA is taking this action because the agency believes that there were no preamendments iontophoresis devices marketed for uses other than those described in the class II identification. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the FDA Modernization Act of 1997.

**DATES:** Submit written comments by [*insert date 90 days after date of publication in the Federal Register*]. See section IV of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Russell P. Pagano, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2196.

DMB

Display Date	8-21-00
Publication Date	8-22-00
Certifier	S. N. Reese

**SUPPLEMENTARY INFORMATION:****I. Classification of Devices**

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94-295), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory control needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices under the 1976 amendments were class I (general controls), class II (performance standards), and class III (premarket approval). The SMDA changed the class II designation to "special controls."

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendment devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without FDA rulemaking. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807.

## II. The Existing Rule

In the **Federal Register** of November 23, 1983 (48 FR 53032), FDA issued a final rule classifying the iontophoresis device into class II (performance standards before the SMDA of 1990 and now special controls) and class III (premarket approval), depending on its intended use. 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 diagnostic use. The regulation defines a class II iontophoresis device as a device intended 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. The regulation also states that, "When used in the diagnosis of cystic fibrosis, the sweat is collected and its composition and weight are determined." Although the foregoing sentence is accurate, FDA is removing it from the "Identification" section of the regulation because it is unnecessary for description of the iontophoresis device. A class III iontophoresis device is intended for uses other than those specified for the class II device.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA published a notice that set forth the agency's strategy for implementing section 515(i) of the act (21 U.S.C. 360e(i)) to review the classification of certain class III devices, and either reclassify the devices into class I or class II or retain them in class III. In reviewing the iontophoresis classification as part of this process, FDA realized that it made an error in its identification of the class III iontophoresis device when the device was classified in 1983. Specifically, there were no preamendments devices that met the class III identification, because the definition had the unintended consequence of placing into class III all those iontophoresis devices intended for use with a drug whose labeling cannot bear adequate directions for the device's use with the drug (i.e., a drug that had not been approved for iontophoretic delivery). Nevertheless, from 1977 to 1998, FDA cleared 41 510(k) submissions from 21 firms for devices that met the class III identification because they were not labeled for the diagnosis of cystic fibrosis or for use with a drug approved for iontophoretic delivery. Most of the 41 letters of substantial equivalence stated that these devices could not be labeled for use

with a drug that had not been approved for iontophoretic delivery. During this same time, one manufacturer obtained drug approval for iontocaine; and that manufacturer's substantial equivalence determination for its class III iontophoresis device now meets the definition of the class II iontophoresis device because its device's labeling now bears adequate directions for iontophoretic delivery of iontocaine.

### **III. Proposed Revision of the Classification**

FDA is proposing to correct this error by revoking the class III identification. Any device that is not substantially equivalent to the class II device would be considered a postamendments device that is automatically classified in class III under section 513(f) of the act. Under section 501(f) of the act (21 U.S.C. 351(f)), a class III postamendments device may not be introduced into interstate commerce for commercial distribution, unless it has in effect an approved premarket approval application or a notice of completion of a product development protocol.

FDA is notifying all manufacturers who market iontophoresis devices that have been cleared as class III 510(k)'s by letter of this proposed action. FDA believes that manufacturers of these iontophoresis devices can revise the labeling of their devices to meet the class II identification and submit such revised labeling to the agency, referencing their 510(k) number. Upon satisfactory review of this revised labeling, FDA will issue a revised order that will establish that the device is equivalent to a legally marketed predicate within the class II identification. A new premarket notification will not be necessary.

On the effective date of a final rule based on this proposed rule, FDA will issue letters to those manufacturers of previously cleared class III iontophoresis devices who have not submitted revised labeling for their 510(k)'s to the agency and received a revised substantial equivalence order. 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 [insert date 90 days after date of publication in the **Federal Register**]. 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:

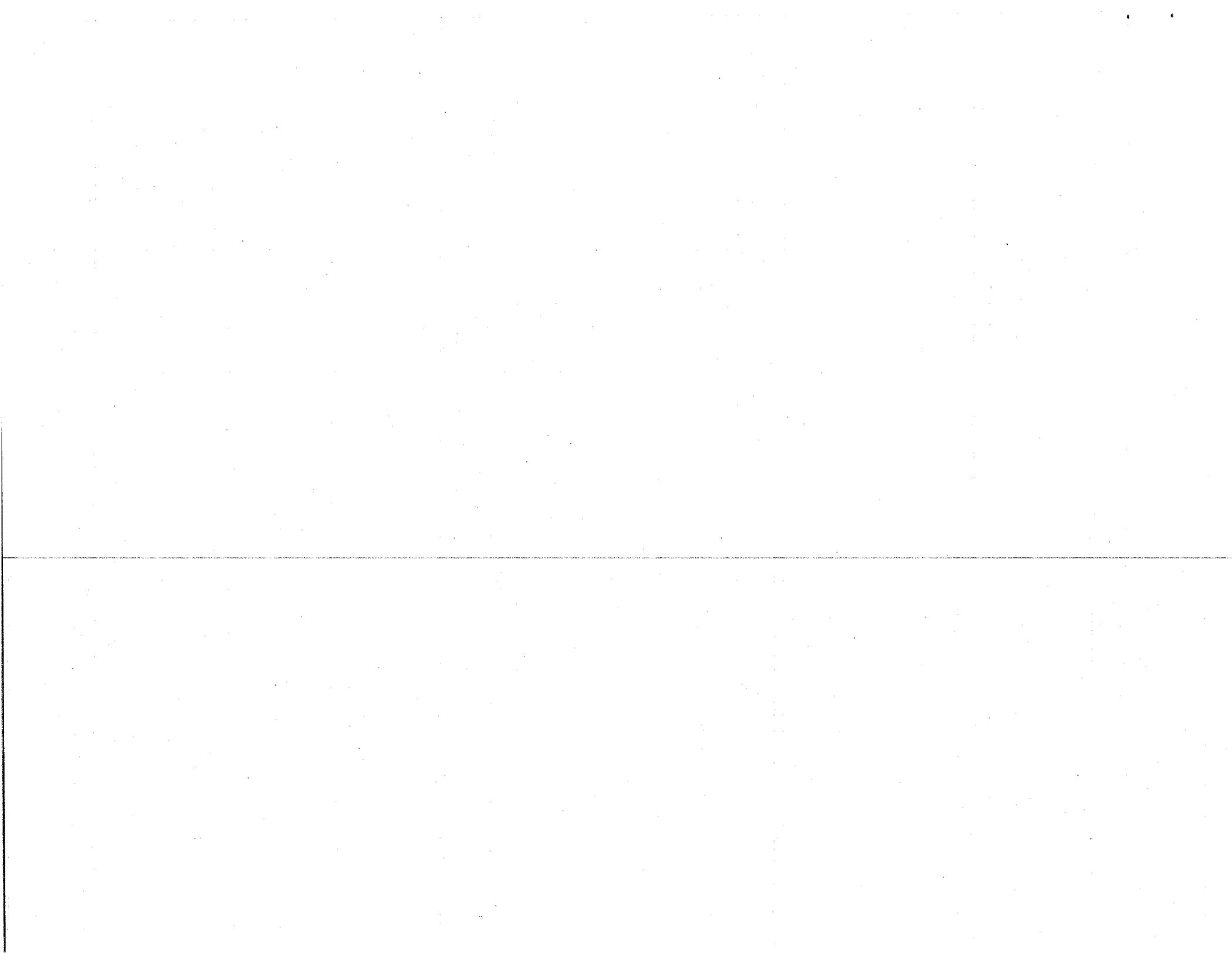
**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

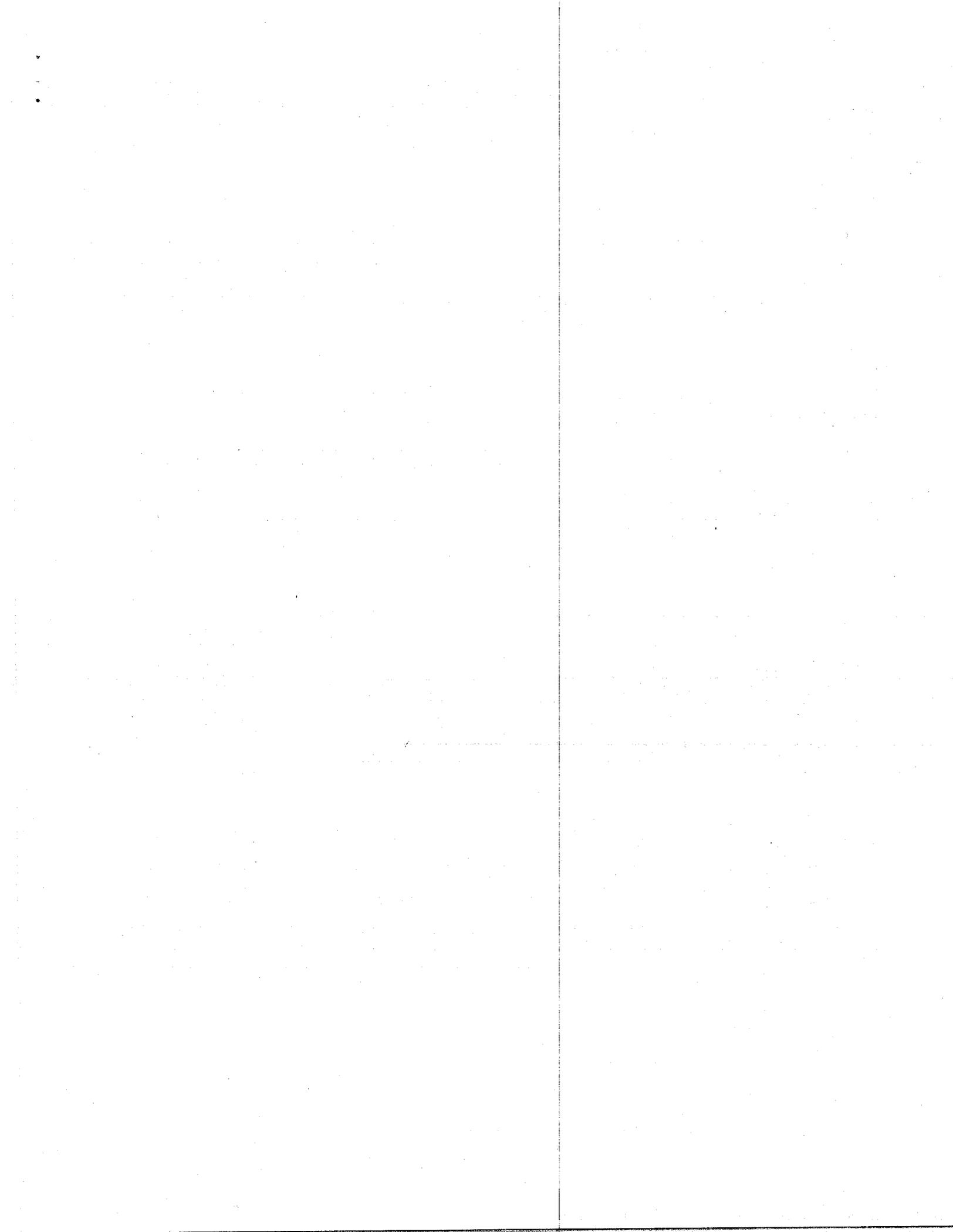
2. Section 890.5525 is amended by adding paragraphs (d) and (e) to read as follows:

#### § 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: 8/3/00  
August 3, 2000

Linda S. Kahan

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

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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COPY OF THE ORIGINAL

Suzette N. Reese