11428, March 11, 2010); corrected May 4, 2010 (75 FR 23572); are approved as AMOCs for the corresponding provisions of this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2013–0136R1, dated July 30, 2013, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0648.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on September 12, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–22467 Filed 9–19–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2000–N–0158]

Reclassification of Iontophoresis Devices Intended for Any Other Purposes

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify iontophoresis devices intended for any other purposes, a preamendments class III device, into class II (special controls), and to amend the device identification. FDA is proposing this reclassification on its own initiative based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments by December 22, 2014. See section XII for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. (FDA–2000–N–0158) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael Ryan, Center for Devices and Radiological Health, Food and Drug Administration,10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 513(a)(1) of the FD&C Act defines class II devices as those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance.

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (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 preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. 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 administrative order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This

section provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 389–391 (D.D.C. 1991)) or in light of changes in ''medical science'' (see *Upjohn* v. *Finch,* supra, 422 F.2d at 951). Whether data before the Agency are past or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).)

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final reclassification order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed reclassification order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket.

In accordance with section 513(e)(1) of the FD&C Act, the Agency is proposing, based on new information that has come to the Agency's attention, to reclassify iontophoresis devices intended for any other purposes because general controls and special controls are sufficient to provide a reasonable assurance of safety and effectiveness. Therefore, this order proposes to reclassify iontophoresis devices intended for any other purposes into class II (special controls) and to amend the device identification.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to assure the safety and effectiveness of iontophoresis devices intended for any other purposes.

II. Regulatory History of the Device

On August 28, 1979, FDA published a proposed rule for classification of all iontophoresis devices in the **Federal Register** (44 FR 50520). This proposed classification was based on recommendations made during three panel meetings in 1978, of the Physical Medicine Panel; the Ear, Nose, and Throat Panel; and the Dental Products Panel. The 1979 rule proposed that iontophoresis devices should have a split classification; iontophoresis devices intended for diagnosis of cystic fibrosis, anesthetizing the intact tympanic membrane, and dental application of fluoride to the teeth would be class II, and iontophoresis devices intended for any other purposes would be class III. A second meeting of the Physical Medicine Panel in 1979 (the 1979 Panel) agreed with FDA's proposed rule, finding insufficient evidence of safety and effectiveness of iontophoresis except in the uses proposed for class II regulation. The 1979 Panel recommended that iontophoresis devices for general drug delivery and hyperhidrosis be classified in class III.

The Agency agreed with the 1979 Panel that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness and that insufficient information existed to establish a performance standard to provide this assurance when the device was used for any purpose other than the three uses proposed for class II regulation. However, FDA also regulates drugs for safety and effectiveness and, at the time, the Agency was unaware of any drug that had labeling providing adequate directions for its use with an iontophoresis device for the dental application of fluoride or the anesthetizing of the intact tympanic membrane. Therefore, in order to prevent conflicting regulatory requirements between the Center for Devices and Radiological Health (CDRH) and the Center for Drug Evaluation and Research (CDER), CDRH determined that iontophoresis devices for the dental application of fluoride or the anesthetizing of the intact tympanic membrane should be classified into class III.

On November 23, 1983, FDA published a final rule in the **Federal Register** classifying iontophoresis devices with a split classification (48 FR 53032 at 53045). The final rule revised the information that had been presented in the proposed rule to omit the dental application of fluoride and anesthetizing the intact tympanic membrane from the class II uses. The rule classified iontophoresis devices into class II when intended to 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 (§ 890.5525(a) (21 CFR 890.5525(a)). The rule classified iontophoresis devices into class III when intended for any other purposes (§ 890.5525(b)), but did not establish an effective date of requirement for premarket approval.

On August 22, 2000, FDA published a proposed rule in the **Federal Register** (65 FR 50949) (the August 2000 proposed rule) to amend the iontophoresis regulation to remove paragraph (b), the class III identification, such that only paragraph (a) of the regulation, the class II identification, would remain. In this rule, FDA stated that it believed it had made an error in the original classification and that there were no iontophoresis devices on the market prior to the Medical Device Amendments of 1976 (preamendments devices) that met the class III identification. Although several devices had been cleared under this regulation between 1976 and the publication of the proposed rule, FDA believed that those devices could meet the definition of a class II iontophoresis device with modifications to their labeling. Any device that could not meet the class II definition (i.e., for any other use than the diagnosis of cystic fibrosis or with a specific drug approved for iontophoretic delivery) would require submission of a PMA.

FDA received seven comments in response to the August 2000 proposed

rule (see Docket No. FDA–2000–N–0158). Several comments disagreed with FDA's assertion that no class III preamendments iontophoresis devices existed. Two comments asserted that the assumption that there are differences between different iontophoresis devices that would warrant linking a particular device to a particular drug is in error, and suggested that FDA should consider reclassification of iontophoresis devices into either class I or class II as drug delivery systems comparable to syringes and pumps. In contrast, another comment rejected what it perceived as the implication that all iontophoresis drug delivery systems were the same and that any iontophoresis device could be relabeled to reference any drug approved for iontophoretic administration, whether or not the drug had actually been tested for use with that particular device.

As a result of these comments, FDA withdrew the August 2000 proposed rule on November 4, 2004 (69 FR 64266). In the same issue of the **Federal Register**, FDA also published a notice of its intent to initiate a proceeding to reclassify class III iontophoresis devices intended for any other purposes into class II (special controls) (69 FR 64313).

In 2009, FDA published an order in the **Federal Register** under section 515(i) of the FD&C Act (21 U.S.C. 360e(i)) to call for information on the remaining class III 510(k) devices (74 FR 16214, April 9, 2009). FDA received 10 submissions regarding iontophoresis devices in response to that order (see Docket No. FDA–2009–M–0101). One response stated that the company was only a repackager/relabeler of the device and did not have a recommended classification or information on safety and effectiveness. The remaining nine responses were all from manufactures of iontophoresis devices. Eight of the manufacturers recommended that the devices be reclassified into class II with special controls. The other manufacturer provided only safety and effectiveness information and did not recommend a classification. The risks to health identified by the manufacturers are included as part of the discussion in section V.

On February 21, 2014, FDA held a classification panel meeting of the Orthopaedic and Rehabilitation Devices Panel (the 2014 Panel) in accordance with section 513(b) of the FD&C Act to discuss the reclassification of iontophoresis devices intended for any other purposes (Ref. 1). This device classification panel meeting discussed the relevant data and information described in this order, the risks to health for iontophoresis devices intended for any other purposes, whether they should be reclassified or remain in class III, and possible special controls for these devices if reclassified into class II. The Panel believed that iontophoresis devices intended for any other purposes present a potential unreasonable risk of illness or injury and recommended that general controls alone are not sufficient to ensure the safety and effectiveness of these devices. In deliberating whether sufficient information exists to establish special controls for these devices, the Panel voiced significant concerns over possible systemic effects that might be produced by some drugs, particularly fentanyl, or by misuse of drugs. The Panel consensus was that if this issue could be addressed, sufficient information exists to establish special controls for these devices that would mitigate the risks to health identified by FDA and the Panel, and that special controls, in combination with general controls, could provide a reasonable assurance of safety and effectiveness and these devices could be classified in class II.

In order to address the Panel's concerns regarding systemic effects of the delivered drug, FDA is proposing to amend the identification of iontophoresis devices intended for any other purposes to clarify that devices intended to deliver specific drugs that may have adverse systemic effects, like fentanyl, are not considered part of this regulatory classification, and that only iontophoresis devices not labeled for use with a specific drug, or labeled for use with a non-drug solution, are included. An iontophoresis device intended to deliver a specific drug with systemic effects, such as fentanyl, would be regulated as a combination product in CDER under section 503(g) of the FD&C Act (21 U.S.C. 353(g)) and § 3.2(e) (21 CFR 3.2(e)) or under § 890.5525(a)) (the iontophoresis regulation). FDA believes this will also help clarify the difference between the two regulatory subsets of iontophoresis devices. In addition, FDA is proposing a special control that will require iontophoresis device manufacturers to include labeling warnings regarding adverse systemic effects.

III. Device Description

Iontophoresis is a noninvasive transdermal delivery method in which a substance bearing a charge is propelled through the skin by an electric current. Iontophoresis devices generally consist of a controller, active and return electrode(s), and a power supply used to deliver currents to transport drugs, soluble salts, ionic solutions, or other drugs into the body for medical purposes as an alternative to hypodermic injections. Iontophoresis systems consist of the iontophoresis device and the drug or other solution to be administered. If the system is marketed as a complete product that includes both a device and drug component, then it would be regulated as a drug-device combination product (see § 3.2(e)), and CDER would have the lead jurisdictional authority because the primary mode of action of the combination product is attributable to the drug component (see § 3.2(m) and 21 CFR 3.4(a)). Alternatively, if the device component is marketed separately from a drug, or as a complete system with a non-drug solution, then it would be regulated as a medical device by CDRH.

The iontophoresis classification regulation is split into two parts, as described previously. Iontophoresis devices intended for use in the diagnosis of cystic fibrosis or for use with a specific drug that has been approved for delivery by iontophoresis are class II devices regulated under § 890.5525(a). These devices are not the subject of this proposed order. Iontophoresis devices intended for any other purposes are currently class III devices regulated under § 890.5525(b). ''Any other purposes'' means that these devices are not intended for use in the diagnosis of cystic fibrosis and not indicated for use with a specific drug; that is, these devices are intended for general iontophoretic delivery of drugs that are approved for that route of administration. This device subset also includes devices indicated for use with specific non-drug solutions, such as tap water (e.g., for treatment of hyperhidrosis). FDA is proposing in this order to reclassify iontophoresis devices intended for any other purposes from class III to class II. FDA is also proposing in this order to amend the device identification in order to clarify the difference between the two subsets of iontophoresis devices in § 890.5525, to emphasize that iontophoresis devices intended and labeled for use with specific drugs are regulated under § 890.5525(a), and to clarify that these are prescription devices in accordance with § 801.109 (21 CFR 801.109).

IV. Proposed Reclassification

FDA is proposing that iontophoresis devices intended for any other purposes be reclassified from class III to class II (special controls). FDA is also proposing, in response to the concerns voiced by the 2014 Orthopaedic and Rehabilitation Devices Classification Panel regarding adverse systemic effects of drug delivery via iontophoresis

devices, to amend the identification of these devices to clarify that iontophoresis devices intended for any other purposes do not include devices labeled for use with specific drugs. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, if finalized, together with general controls (including prescription use restrictions) applicable to the devices, would provide reasonable assurance of their safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that iontophoresis devices may benefit patients by improving the noninvasive transdermal delivery of drugs or other solutions intended to treat various medical ailments or issues.

Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130 (21 CFR 860.130), based on new information with respect to the devices and taking into account the public health benefit of the use of the device and the nature and known incidence of the risks of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V, and that these special controls, together with general controls (including prescription use restrictions), will provide a reasonable assurance of safety and effectiveness for iontophoresis devices intended for any other purposes.

Section 510(m) of the FD&C Act authorizes the Agency to exempt class II devices from premarket notification (510(k)) requirements. FDA has considered iontophoresis devices intended for any other purposes and has determined that the device does require premarket notification (510(k)). Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submission requirements as provided for under section 510(m) of the FD&C Act.

V. Risks to Health

After considering available information, including a comprehensive review of relevant literature and the recommendations of the 2014 Orthopaedic and Rehabilitation Devices Classification Panel (Ref. 1), FDA has determined that the following risks to health are associated with the use of iontophoresis devices intended for any other purposes.

- *Electric shock:* Electrical shock hazards may pose a hazard to both operators and users. Excessive leakage current from the device could result in injury, or a malfunction of the device could result in electrical shock. Possible adverse events include cardiac events such as arrhythmias and cardiac arrest.
- *Burns:* Patient or user burns could result from a large electrical current density or a highly acidic solution.
- *Insufficient or excessive delivery of drug or solution:* Device malfunction (such as inaccurate current measurement), use error, or inadequate information on the drug or solution being used may result in inappropriate drug or solution delivery.
- *Interference with other medical devices:* Electromagnetic interference could interfere with other devices in the treatment environment, such as pacemakers implanted in either the patient or user.
- *Adverse tissue reactions:* Device materials that are not biocompatible may either directly or through the release of their material constituents or through a reaction with the ionic solution: (1) Produce adverse local or systemic effects such as contact dermatitis and scarring, (2) be carcinogenic, or (3) produce adverse reproductive and developmental effects. Although medical devices may have myriad biocompatibility issues, the biocompatibility concerns from iontophoresis devices are likely limited to skin reactions.
- *Infection:* Infection can occur from use of a non-sterile iontophoresis device, or from improper device design or use error. This risk is particularly relevant for devices used in the ear.
- *Ear Trauma (when used in the ear):* Use error or improper device design can lead to ear trauma, when used in the ear. This includes perforation of the tympanic membrane and middle or inner ear injuries.

VI. Summary of Reasons for Reclassification

Based on the comments from the 2014 Panel meeting and FDA's assessment of new, valid scientific data related to the health benefits and risks associated with iontophoresis devices intended for any other purposes, FDA is proposing that these devices should be reclassified from class III to class II because sufficient information exists to establish specials controls, which, in addition to general controls, would provide a reasonable assurance of safety and effectiveness of the device, and because general controls themselves are insufficient to provide a reasonable assurance of its safety and effectiveness.

FDA does not believe that iontophoresis devices not intended for use with a specific drug or solution are life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health. FDA does believe these devices may present a potential unreasonable risk of illness or injury, as a review of the relevant clinical literature indicates. However, FDA believes that special controls, in combination with general controls, would provide reasonable assurance of safety and effectiveness.

VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls (including prescription use restrictions), are necessary to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130, based on new information with respect to the device and taking into account the public health benefit(s) of the use of the device and the nature and known incidence of the risk(s) of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. The Agency has identified special controls that would provide reasonable assurance of their safety and effectiveness. FDA's review of the clinical literature has been previously summarized in the Executive Summary to the 2014 Panel meeting to discuss iontophoresis device classification (Ref. 1).

In addition, the 2014 Panel reviewed and discussed recent information presented by FDA, a manufacturer of iontophoresis devices, and members of the public. This information included recent literature regarding the possible risks to health and a review of FDA's Manufacturer and User Facility Device Experience (MAUDE) database.

The 2014 Panel agreed that iontophoresis devices not intended for use with specific drugs or solutions are not ''life-supporting or life-sustaining, or of substantial importance in preventing impairment of human health.'' The 2014 Panel agreed on the potential risks to health identified by FDA with some proposed clarifications, which were incorporated in section V. However, the 2014 Panel also expressed concerns regarding adverse systemic effects that might potentially result from use of iontophoresis devices to deliver drugs such as fentanyl, repeated treatments with certain drugs, or

misuse. In order to address the Panel's concerns regarding systemic effects, FDA is proposing to amend the identification of iontophoresis devices intended for any other purposes to clarify that devices intended to deliver specific drugs that may have adverse systemic effects, like fentanyl, are not considered part of this regulatory classification. An iontophoresis device intended to deliver a specific drug with systemic effects, such as fentanyl, would be regulated as a combination product in CDER or under § 890.5525(a). FDA believes this will help clarify the difference between the two regulatory subsets of iontophoresis devices. In addition, FDA is proposing a special control that will require iontophoresis device manufacturers to include labeling warnings regarding adverse systemic effects. Regarding the benefits of iontophoresis devices not intended for use with a specific drug or solution, the 2014 Panel indicated that they believe that the benefit provided by these devices outweigh the probable risks, as long as their concern about potential adverse systemic events could be addressed.

Regarding classification, there was general panel consensus that iontophoresis devices not intended for use with a specific drug or solution should be class II devices subject to special controls, unless the devices were used to deliver a treatment with potential adverse systemic effects. The Panel believed that such devices should be class III. However, iontophoresis devices intended to deliver specific drugs are not included in this regulatory subset of iontophoresis devices, and are regulated separately under § 890.5525(a) or as combination products in CDER. FDA believes that its proposal to amend the identification of iontophoresis devices regulated under § 890.5525(b), as well as its proposed special controls, will address the Panel's concern. There was general consensus among the Panel that if that concern could be addressed that the special controls identified by FDA were appropriate. The Panel agreed that general controls alone are not sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

VIII. Proposed Special Controls

FDA believes that the following special controls, in addition to general controls (including applicable prescription use restrictions), are sufficient to mitigate the risks to health described in section V:

1. Performance testing must provide a reasonable assurance of safety and effectiveness of the device, including:

a. Testing using a drug approved for iontophoretic delivery, or a non-drug solution if identified in the labeling;

b. testing of the ability of the device to maintain a safe pH level; and

c. if used in the ear, testing of the mechanical safety of the device.

2. Labeling must include adequate instructions for use, including sufficient information for the health care provider to determine the device characteristics that affect delivery of the drug or solution and to select appropriate drug or solution dosing information for administration by iontophoresis. This includes the following:

a. A description and/or graphical representation of the electrical output;

b. a description of the electrode materials and pH buffer;

c. when intended for general drug delivery, language referring the user to approved drug labeling to determine if the drug they intend to deliver is specifically approved for use with that type of device and to obtain relevant dosing information; and

d. a detailed summary of the device-related and procedure-related complications pertinent to use of the device, and appropriate warnings and contraindications, including the following warning:

Warning: Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.

3. Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety. The requirement would, in concert with other special controls, help ensure the mitigation of cardiac events and discomfort, pain, and tenderness resulting from burns to the skin due to excessive energy deposition. In addition, this requirement would ensure the device does not interfere with other electrical equipment or medical devices and would also ensure that both operators and users are properly protected from electrical hazards such as electrical shock.

4. Appropriate software verification, validation, and hazard analysis must be performed. This requirement would help mitigate the risk of insufficient or excessive delivery of drugs or non-drug solutions.

5. The elements of the device that may contact the patient must be demonstrated to be biocompatible. These devices can contact users' and patients' skin directly; therefore, a demonstration of biocompatibility would mitigate the risks of skin reactions. Conditions of device operation, such as application of electrical current, may influence biocompatibility and should be considered in any biocompatibility determination.

6. The elements of the device that may contact the patient must be assessed for sterility to ensure the risk of infection is mitigated.

7. Performance data must support the shelf life of the elements of the device that may be affected by aging by demonstrating continued package integrity and device functionality over the stated shelf life.

Table 1 shows how FDA believes that the risks to health identified in section V can be mitigated by the proposed special controls. Under § 807.81 (21 CFR 807.81), these devices would also continue to be subject to 510(k) notification requirements.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR § 890.5525(b) IONTOPHORESIS DEVICES

Identified risk	Mitigation measures
Burns	Performance Testing.
	Electrical Safety Testing.
	Shelf Life Testing.
	Labeling.
Electrical Shock	Electrical Safety Testing.
	Shelf Life Testing.
	Labeling.
Insufficient or Excessive Delivery.	Performance Testing.
	Software Verification, Validation and Hazards Analysis.
	Labeling.
Interference with Other Medical Devices.	Electromagnetic Compatibility Testing.
	Labeling.
Adverse Tissue Reactions.	Biocompatibility.
Infection	Sterility.
	Shelf Life Testing.
Ear Trauma (only when used in the ear).	Performance Testing.
	Labeling.

In addition, iontophoresis devices are restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed § 890.5525(b); § 801.109 (*Prescription devices*)). Under § 807.81,

these devices would continue to be subject to 510(k) notification requirements.

IX. 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.

X. Paperwork Reduction Act of 1995

This proposed order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485. In addition, FDA concludes that the labeling statement proposed in this order does not constitute a ''collection of information'' under the PRA. Rather, the labeling statement is ''public disclosure(s) of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public . . .'' (5 CFR 1320.3(c)(2)).

No burden shift is associated with the reclassification of the device. This is currently a class III device for which manufacturers must submit a premarket notification (510(k)). This order proposes to reclassify the device into class II, therefore, respondents would continue to submit a premarket notification.

XI. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i), as amended by FDASIA, in this proposed order we are proposing to revoke the requirements in § 890.5525(b)(1) related to the classification of iontophoresis devices not intended for use with a specific drug as class III devices and to codify their reclassification into class II (special controls).

XII. Proposed Effective Date

FDA is proposing that any final order based on this proposed order become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

XIII. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

XIV. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Meeting Materials for the February 21, 2014, meeting of the Orthopaedic and Rehabilitation Devices Panel, available at: *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm386335.htm.*

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine 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 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. Amend § 890.5525 by revising paragraph (b) and removing paragraph (c) to read as follows:

§ 890.5525 Iontophoresis device.

* * * * *

(b) *Iontophoresis device intended for any other purposes*—(1) *Identification.* An iontophoresis device intended for any other purposes is a prescription device that is intended to use a current to introduce ions of drugs or non-drug solutions into the body for medical purposes other than those specified in paragraph (a) of this section, meaning that the device is not intended for use in diagnosis of cystic fibrosis, and a specific drug is not specified in the labeling of the iontophoresis device. Iontophoresis devices included in this classification may be intended to deliver non-drug solutions.

(2) *Classification.* Class II (special controls). The special controls for this device are:

(i) Performance testing must provide a reasonable assurance of safety and effectiveness of the device, including:

(A) Testing using a drug approved for iontophoretic delivery, or a non-drug solution if identified in the labeling;

(B) testing of the ability of the device to maintain a safe pH level; and

(C) if used in the ear, testing of the mechanical safety of the device.

(ii) Labeling must include adequate instructions for use, including sufficient information for the health care provider to determine the device characteristics that affect delivery of the drug or solution and to select appropriate drug or solution dosing information for administration by iontophoresis. This includes the following:

(A) A description and/or graphical representation of the electrical output;

(B) a description of the electrode materials and pH buffer;

(C) when intended for general drug delivery, language referring the user to approved drug labeling to determine if the drug they intend to deliver is specifically approved for use with that type of device and to obtain relevant dosing information; and

(D) a detailed summary of the device-related and procedure-related complications pertinent to use of the device, and appropriate warnings and contraindications, including the following warning:

Warning: Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.

(iii) Appropriate analysis/testing must demonstrate electromagnetic compatibility, electrical safety, thermal safety, and mechanical safety.

(iv) Appropriate software verification, validation, and hazard analysis must be performed.

(v) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(vi) The elements of the device that may contact the patient must be assessed for sterility.

(vii) Performance data must support the shelf life of the elements of the device that may be affected by aging by demonstrating continued package integrity and device functionality over the stated shelf life.

Dated: September 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22453 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2014–0596; FRL–9916–81–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; West Virginia; 2014 Amendments to West Virginia's Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of West Virginia for the purpose of amending their Legislative Rule on Ambient Air Quality Standards. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because EPA views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

DATES: Comments must be received in writing by October 22, 2014.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2014–0596 by one of the following methods:

A. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. Email: *fernandez.cristina@epa.gov.*

C. Mail: EPA–R03–OAR–2014–0596, Cristina Fernandez, Associate Director, Office of Air Program Planning, Air Protection Division, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2014–0596. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *ww.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street SE., Charleston, West Virginia 25304.

FOR FURTHER INFORMATION CONTACT: Ellen Schmitt, (215) 814–5787, or by email at *schmitt.ellen@epa.gov.*

SUPPLEMENTARY INFORMATION: For further information, please see the information provided in the direct final action, with the same title, that is located in the ''Rules and Regulations'' section of this **Federal Register** publication. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

Dated: September 2, 2014.

William C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2014–22414 Filed 9–19–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2014–0623, 0624, and 0625; FRL–9916–73–OSWER]

National Priorities List, Proposed Rule No. 61

AGENCY: Environmental Protection Agency (EPA).