Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2012–N–0378]

Effective Date of Requirement for Premarket Approval for Shortwave Diathermy for All Other Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the class III preamendments device, shortwave diathermy (SWD) for all other uses. This device applies to the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues. It is not intended for treatment of malignancies. The Agency is also summarizing its proposed 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. In addition, FDA is announcing the opportunity for interested persons to request that the Agency change the classification of any of the aforementioned devices based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments by October 4, 2012. Submit requests for a change in classification by July 23, 2012. FDA intends that, if a final rule based on this proposed rule is issued, anyone who wishes to continue to market the device will need to submit a PMA or a notice of completion of a PDP within 90 days of the effective date of the final rule. Please see section XII of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–0378, 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:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper or CD–ROM 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 Agency name and Docket No. FDA–2012–N–0378 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 J. Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1615, Silver Spring, MD 20993, 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 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (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), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), establish 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).

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 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).

A preamendments device that has been classified into class III may be marketed by means of premarket

notification procedures (510(k) process) without submission of a PMA until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) of the FD&C Act establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the FD&C Act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the FD&C Act provides that a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing the following information: (1) The regulation, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity for the submission of comments on the proposed rule and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the FD&C Act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change in reclassification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the FD&C Act. Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the FD&C Act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease since the device would be deemed adulterated under section 501(f) of the FD&C Act.

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, and the device does not comply with IDE regulations, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the FD&C Act, and subject to seizure and condemnation under section 304 of the FD&C Act (21 U.S.C. 334) if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the FD&C Act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the FD&C Act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA or PDP has been filed and may determine that such a request is appropriate for the class III devices that are the subjects of this regulation.

The FD&C Act does not permit an extension of the 90-day period after issuance of a final rule within which an application or a notice is required to be filed. The House Report on the 1976 amendments states that: ''[T]he thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval.'' (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976)).

The SMDA added section 515(i) to the FD&C Act requiring FDA to review the classification of preamendments class III devices for which no final rule requiring the submission of PMAs has been issued, and to determine whether or not each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, the SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval. The SMDA does not, however, prevent FDA from proceeding immediately to rulemaking under section 515(b) of the FD&C Act on specific devices, in the interest of public health, independent of the procedures of section 515(i). Proceeding directly to rulemaking under section 515(b) of the FD&C Act is consistent with Congress' objective in enacting section 515(i), i.e., that preamendments class III devices for which PMAs have not been previously required either be reclassified to class I or class II or be subject to the requirements of premarket approval. Moreover, in this proposal, interested persons are being offered the opportunity to request reclassification of any of the devices.

II. Dates New Requirements Apply

In accordance with section 515(b) of the FD&C Act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the Agency for class III devices within 90 days after issuance of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that under section 515(d)(1)(B)(i) of the FD&C Act, the Agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the Agency finds that ''the continued availability of the device is necessary for the public health.''

FDA intends that under § 812.2(d), the preamble to any final rule based on this proposal will state that, as of the date on which the filing of a PMA or a notice of completion of a PDP is required to be filed, the exemptions from the requirements of the IDE regulations for preamendments class III devices in § 812.2(c)(1) and (c)(2) will cease to apply to any device that is: (1) Not legally on the market on or before that

date, or (2) legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or notice of completion of a PDP for a class III device is not filed with FDA within 90 days after the date of issuance of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued under § 812.30. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period after the issuance of the final rule to avoid interrupting investigations.

III. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the FD&C Act, FDA is publishing its proposed 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 committee (panel) for the classification of these devices along with information submitted in response to the 515(i) Order (74 FR 16214, April 9, 2009), and any additional information that FDA has encountered. Additional information regarding the risks as well as classification associated with these device types can be found in the following proposed and final rules and notices published in the **Federal Register**: 44 FR 50512 (August 28, 1979), 48 FR 53032 (November 23, 1983), and 52 FR 17732 (May 11, 1987).

IV. Devices Subject to This Proposal

Shortwave Diathermy for All Other Uses (21 CFR 890.5290(b))

1. Identification

An SWD for all other uses except for the treatment of malignancies is a device that applies to the body electromagnetic energy in the radio frequency bands of 13 megahertz to 27.12 megahertz and that is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues as described in § 890.5290(a) (21 CFR 890.5290(a)).

2. Summary of Data

The Agency first proposed classification of SWD devices for use in applying therapeutic deep heat as class II devices and SWD devices for any use other than applying therapeutic deep heat as class III devices in a proposed rule issued August 28, 1979 (44 FR 50512), based on recommendations made by the Physical Medicine Device Classification Panel of 1979 (The Physical Medicine Device Classification Panel). When a comment regarding the scope of the identifications for SWD devices in this proposed rule was received, the Agency asked the Physical Medicine Device Section of the Surgical and Rehabilitation Devices Panel (the Medicine Device Section) to review these devices in December 1979. Among their recommendations, the Medicine Device Section stated that to be therapeutically effective, a SWD device must be capable of providing energy sufficient to raise the temperature of tissues below the skin to 44 °C, and recommended that SWD devices be classified into class III when used in the treatment of malignancies because insufficient data exist concerning the safety and effectiveness of the device for this use (48 FR 53032). The Agency agreed with the Medicine Device Section that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device when it was used for any purpose other than applying therapeutic deep heat, and that insufficient information existed to establish a performance standard to provide this assurance, and finalized its classification of SWD devices for all other uses except the treatment of malignancies by means other than the generation of deep heat as class III devices (52 FR 17732). Current peer-reviewed literature suggests several risks to health for these devices (see the following section of this document), and the Agency continues to believe that there is insufficient evidence and information to determine that general controls would provide reasonable assurance of the safety and effectiveness or to establish a performance standard or special controls to provide this assurance.

3. Risks to Health

The Physical Medicine Device Classification Panel identified the following risks to health from all SWD devices: (1) Cellular or tissue injury, (2) pacemaker interference, (3) tissue necrosis (death) and burns, and (4) electrical shock. The Agency believes that these risks to health apply to SWD devices for all uses, and has also identified additional risks to health through review of peer-reviewed research and adverse event information. The Agency believes the following risks to health apply to SWD devices for all other uses.

- *Cellular or Tissue Injury:* There is uncertainty concerning the effects of electromagnetic flux on human cellular or tissue structures and functions. The cellular or tissue alterations may be induced by electromagnetic fields. The potential for and the effects of cellular changes by the electromagnetic field of the SWD device require further clinical study to show that the magnetic fields do not produce harmful effects on the cells.
- *Pacemaker Interference:* Several researchers have identified that the use of both thermal and nonthermal SWD can interfere with pacemaker function (Refs. 1 and 2). Electromagnetic fields generated by thermal and nonthermal SWD may interfere with the circuitry of a cardiac pacemaker or implantable defibrillator, which can lead to increased or decreased pacing rate, total loss of pacing, and/or cessation of pacemaker impulses.
- *Tissue Necrosis (Death) and Cutaneous Burns:* Excessive energy deposition into the tissue may cause excessive heating that results in tissue damage. In addition, a September 2011 review of Medical Device Reporting (MDR) and Manufacturer and User Facility Device Experience (MAUDE) databases identified two cases of burns associated with nonthermal SWD. Even though the therapeutic effect of nonthermal SWD appear to be nonthermal in mechanism, research has demonstrated that such devices do have a thermal effect and a direct correlation between pulse rate and thermal sensation exists (Refs. 3 and 4).
- Electrical Shock: Excessive leakage current could result in injury, or a malfunction of the device could result in electrical shock.
- Thermal Injury from Implanted Wire Leads and Metal Implants: Studies have shown that SWD can cause heating of implanted wire leads and presents the risk of thermal injury to patients with implanted wire leads (Refs. 5 and 6).

In a March 2003 public health notification (Ref. 7), FDA specifically warned that the danger of thermal injury can occur even when the SWD device is in non-heating mode, when the implanted device is not turned on, or when the implant has been removed

from the patient's body with the metal leads left behind.

• *Radiation Hazards:* Several researchers have expressed concern about the potential hazard from stray radiation and unintended exposure of the therapist or of non-treated areas of the patient (Refs. 8, 9, and 10). The majority of SWD units in clinical use do not have shielded leads to transmit the high frequency generated to the applicator. Most SWD units have no provision to minimize radiation loss from the applicator in directions away from the patient. Hence, if the user or operator stays near the energized SWD unit and treat several patients daily, he or she could absorb significant electric and magnetic field radiation (Ref. 8). The International Commission on Non-ionizing Radiation Protection has established limits to reduce radio frequency exposure in workers and the general public. Shields et al. (Ref. 9) studied stray electric and magnetic field strengths from 10 SWD units. Findings demonstrated that, under a worst-case scenario, emissions from SWD exceed the guidelines for operators at distances currently recommended as safe.

• *Abnormal Cell Growth:* Cellular proliferation caused by nonthermal SWD in human and rat cell lines has been reported in in vitro studies (Ref. 11).

V. PMA Requirements

A PMA for this device must include the information required by section 515(c)(1) of the FD&C Act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on the following: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA must include valid scientific evidence to demonstrate reasonable assurance of the safety and effectiveness of the device for its intended use (see § 860.7(c)(2) (21 CFR 860.7(c)(2))). Valid scientific evidence is ''evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. * * * Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness.'' (§ 860.7(c)(2)).

VI. PDP Requirements

A PDP for any of these devices may be submitted in lieu of a PMA, and must follow the procedures outlined in section 515(f) of the FD&C Act. A PDP must provide: (1) A description of the device, (2) preclinical trial information (if any), (3) clinical trial information (if any), (4) a description of the manufacturing and processing of the devices, (5) the labeling of the device, and (6) all other relevant information about the device. In addition, the PDP must include progress reports and records of the trials conducted under the protocol on the safety and effectiveness of the device for which the completed PDP is sought.

VII. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the FD&C Act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the FD&C Act.

A request for a change in the classification of these devices is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device.

The Agency advises that to ensure timely filing of any such petition, any request should be submitted to the Division of Dockets Management (see **ADDRESSES**) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of these devices is submitted, the Agency will, within 60 days after receipt of the petition, and after consultation with the appropriate FDA resources, publish an order in the **Federal Register** that either denies the request or gives notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the FD&C Act and 21 CFR 860.130 of the regulations.

VIII. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

IX. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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 not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Agency believes that the final rule will 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, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Need for Regulation

The SWD devices that would be affected by this rule use electromagnetic energy in radio frequency bands to treat medical conditions other than malignancies through means other than heat. The devices are regulated under

§ 890.5290(b). These are currently class III preamendments devices and can be approved through premarket notification (510(k)) submissions rather than costlier PMA or PDP applications. Devices cleared through 510(k) submissions may be subject to general and special controls designed to provide reasonable assurance of safety and effectiveness. FDA has determined that insufficient information exists to develop such controls for these devices and therefore the devices should be approved through PMA or PDP applications.

Health care providers and patients rely on FDA determinations of safety and effectiveness when making treatment decisions. An FDA finding that current premarket requirements are inadequate to establish safety and effectiveness implies that health care providers and patients have inadequate information on these devices. We expect that at least some health care providers and patients who would have used these devices will make different consumption decisions if they possess more information.

This proposed rule, should it be issued as a final rule, would require manufacturers of affected devices to file a PMA or a notice of completion of a PDP within 90 days. Under section 501 of the FD&C Act, a PMA or a notice of completion of a PDP must be filed either within 90 days of the issuance of the final rule or within 30 months after the final classification of the device under section 513 of the FD&C Act, whichever is later. Because the final classification of SWD devices occurred in 1983, the 30-month period has elapsed. If a manufacturer failed to file a PMA or a notice of completion of a PDP within 90 days of the issuance of the final rule, the device would be deemed adulterated under section 501 of the FD&C Act.

B. Benefits

The primary benefit of this rule would be the more efficient allocation of resources. We believe that health care providers and patients currently have incomplete information concerning the safety and effectiveness of these devices. This lack of information causes them to direct resources toward treatments they would not otherwise choose. Even extensive use of a medical product by physicians may not provide physicians with enough information to determine the safety and effectiveness of that product (Ref. 12).

FDA has determined that the devices regulated by § 890.5290(b) have not been shown to be safe and effective. Approval of a device through PMA procedures or PDP applications would require that safety and effectiveness be demonstrated. This demonstration of safety and effectiveness would increase the information available to health care providers and patients and enable them to allocate resources more efficiently. For example, this rule may improve the health of patients by causing resources to be redirected toward more effective treatment.

FDA has insufficient data to estimate the size of the benefits from requiring PMA or PDP applications. The size of the benefits would vary with changes in the safety and effectiveness of treatment received as well as changes in the cost of treatment. Little information is available concerning the effectiveness of these devices, making estimation of the changes in the effectiveness of treatment received difficult.

FDA does not expect the rule to result in large improvements in the safety of treatment received. FDA's MAUDE database records adverse events associated with medical devices. Few adverse events have been reported for the devices that would be affected by the rule.

C. Costs

This rule would require the manufacturers of affected devices to prepare and submit PMAs. PMA approval procedures are substantially more costly than 510(k) clearance procedures. Furthermore, those manufacturers of devices already cleared through 510(k) submissions would be required to incur the additional costs of preparing and submitting PMAs to continue marketing their devices.

The primary cost of preparing and submitting a PMA is typically the cost of clinical trials that demonstrate the safety and effectiveness of a device. These clinical trials typically cost between $10,000 and $20,000 per patient (Refs. 13 and 14). FDA estimates that the clinical trials necessary to demonstrate the safety and effectiveness of these devices would include between 50 and 150 patients. We therefore estimate that the clinical trials would cost between about $500,000 and $3 million per PMA.

In addition to the cost of conducting the clinical trials, manufacturers would incur the cost of completing and submitting the applications. We estimate that the total cost of completing and submitting an application is between 25 and 35 percent of the cost of the clinical trials (Ref. 15).

Additional costs would be incurred by FDA in reviewing any PMAs. The average cost of reviewing a PMA is estimated to be over $600,000 (Ref. 16). Part of the cost of review would be borne by manufacturers through user fees. For fiscal year 2011, the PMA user fee was typically $236,298 for large firms and $59,075 for small firms (75 FR 45641, August 3, 2010).

The total cost per PMA is therefore estimated to be between about $1.2 million and $4.7 million, with a primary estimate of $2.6 million. Not all of that cost would be a net social cost, however. A portion of the cost would be incurred as a result of the provision of additional medical care to clinical trial participants and therefore would be a transfer from manufacturers to health care providers or patients rather than a cost to society.

We are uncertain about the number of PMAs that would be submitted. A manufacturer's decision to submit a PMA for a currently marketed device would involve considering the cost of the PMA, the probability of the PMA's approval, and the profits that would be lost were the device to be withdrawn from the market. We are unaware of data for these devices that would enable us to estimate the potential loss in profits from withdrawal. While the potential loss in profits would affect the decisions of manufacturers, lost profits would not generally be net social costs. Health care providers and patients would direct their financial resources elsewhere, resulting in additional profits, consumption or savings for other entities that would offset the lost profits for manufacturers of affected devices.

FDA expects to receive one or fewer PMAs for affected devices should a final rule be issued. If one PMA were to be submitted, the total cost of preparing, submitting, and reviewing PMAs as a result of this rule would be between about $1.2 million and about $4.7 million, with a primary estimate of about $2.6 million.

D. Regulatory Flexibility Analysis

Firms involved in the manufacture of medical devices are required to register with FDA and list the devices that they produce. FDA's Establishment Registration & Device Listing database contains nine firms that registered with FDA in 2011 and listed devices that would be affected by this rule. Eight of those firms were based in the United States. The U.S. Small Business Administration (SBA) defines a business in the Surgical and Medical Instrument Manufacturing industry (NAICS code 339112) as small if it has 500 or fewer employees (Ref. 17). Seven of the eight domestic firms are small according to the SBA definition.

It is anticipated that most of the devices manufactured by these firms

would cease to be marketed if a final version of this rule were issued. Any manufacturers that remained in this market or entered in the future would be required to incur the cost of about $2 million associated with preparing and submitting a PMA. Therefore, FDA predicts that this rule would have a significant economic impact on a substantial number of small firms. This analysis together with other sections of this document serve as the Initial Regulatory Flexibility Analysis.

FDA has analyzed regulatory options that would provide regulatory relief for small business compared with this rule. The only viable alternatives to the proposed reclassification would be options involving the reclassification of affected devices from class III to class II accompanied by the implementation of general and special controls. The costs associated with reclassification to class II vary with the costs of complying with the special controls. The more extensive the special controls, the costlier would be the reclassification. FDA has not estimated the costs of various levels of stringency of special controls but all levels would be far less costly than the $2 million for a PMA.

As stated elsewhere in this document, however, FDA has determined that it has insufficient information to implement adequate general and special controls. The Agency has concluded that this rule is necessary to provide a reasonable assurance that SWD devices marketed in the United States are safe and effective for their intended use.

X. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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 tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Paperwork Reduction Act of 1995

This proposed rule refers to previously 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 812 have been approved under OMB Control No. 0910–0078; the collections of information in part 807, subpart E have been approved under OMB Control No. 0910–0120; the collections of information in 21 CFR part 814, subpart B have been approved under OMB Control No. 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB Control No. 0910–0485.

XII. Proposed Effective Date

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

XIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to submit 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.

XIV. References

The following references have 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. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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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. Section 890.5290 is amended by revising paragraph (c) to read as follows:

§ 890.5290 Shortwave diathermy.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [date 90 days after date of publication of the final rule in the **Federal Register**], for any shortwave diathermy for all other uses (as described in paragraph (b)(1) of this section) that was in commercial distribution before May 28, 1976, or that has, on or before [date 90 days after date of publication of the final rule in the **Federal Register**], been found to be substantially equivalent to any shortwave diathermy for all other uses (as described in paragraph (b)(1) of this section) that was in commercial distribution before May 28, 1976. Any other shortwave diathermy for all other uses (as described in paragraph (b)(1) of this section) shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: June 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–16487 Filed 7–5–12; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50 and 51

[EPA–HQ–OAR–2011–0887; FRL–9696–1]

RIN 2060–AN40

Draft Guidance To Implement Requirements for the Treatment of Air Quality Monitoring Data Influenced by Exceptional Events

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and public comment period.

SUMMARY: Notice is hereby given that the EPA has posted its draft non-binding guidance titled, *Draft Guidance to Implement Requirements for the Treatment of Air Quality Monitoring Data Influenced by Exceptional Events* and associated attachments, on the agency's Internet Web site. The EPA invites public comments on this guidance document and plans to issue an updated version of the guidance after reviewing timely submitted comments. The EPA intends to hold a conference call to provide interested stakeholders with an overview of the Exceptional Events draft guidance.

DATES: Comments must be received on or before September 4, 2012. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the comment period.

ADDRESSES: *Access to the draft guidance:* Please see the EPA's Web site at *http://www.epa.gov/ttn/analysis/exevents.htm* for additional details on the draft non-binding guidance titled, *Draft Guidance to Implement Requirements for the Treatment of Air Quality Monitoring Data Influenced by Exceptional Events* and associated attachments and the conference call for interested stakeholders.

Comments: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2011–0887, by one of the following methods:

- *http://www.regulations.gov.* Follow the online instructions for submitting comments. Attention Docket ID No. EPA–HQ–OAR–2011–0887.
- *Email: a-and-r-docket@epa.gov.* Attention Docket ID No. EPA–HQ–OAR–2011–0887.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2011–0887.
- *Mail:* Air Docket, Attention Docket ID No. EPA–HQ–OAR–2011–0887, U.S. Environmental Protection Agency, Mail Code: 6102T, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery:* EPA Docket Center, 1301 Constitution Avenue NW., Room 3334, Washington, DC, Attention Docket ID No. EPA–HQ–OAR–2011–0887. Such deliveries are only accepted during the Docket Center'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–HQ–OAR–2011–0887. The 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 the 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 the EPA without going through *www.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, the 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 the EPA is unable to read your comment and cannot contact you for clarification due to technical difficulties, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to Section II of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket. All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* 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 at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Beth W. Palma, U.S. EPA, Office of Air