DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket No. EERE–2012–BT–STD–0029]

RIN 1904–AC82

Energy Efficiency Program for Commercial and Industrial Equipment: Public Meeting and Availability of the Framework Document for Packaged Terminal Air Conditioners and Packaged Terminal Heat Pumps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Extension of public comment period.

SUMMARY: On February 22, 2013, the U.S. Department of Energy (DOE) published a document in the **Federal Register** initiating a rulemaking to evaluate energy conservation standards for packaged terminal air conditioners (PTACs) and packaged terminal heat pumps (PTHPs). In that document, DOE announced the availability of a framework document. This document announces an extension of the public comment period for submitting comments on the framework document or any other aspect of the rulemaking for PTACs and PTHPs. The comment period is extended to April 25, 2013.

DATES: DOE will accept comments, data, and information regarding the framework document received no later than April 25, 2013.

ADDRESSES: Any comments submitted must identify the framework document for packaged terminal air conditioners and packaged terminal heat pumps and provide docket number EERE–2012–BT–STD–0029 and/or RIN number 1904–AC82. Comments may be submitted using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: pkgTerminalAC-HP2012STD0029@ee.doe.gov.* Include EERE–2012–BT–STD–0029 in the subject line of the message.
- *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–2J, Framework Document for PTACs and PTHPs, Docket No. EERE–2012–BT–STD–0029 and/or RIN 1904–AC82, 1000 Independence Avenue SW., Washington, DC 20585– 0121. Phone: (202) 586–2945. Please submit one signed paper original.
- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 6th Floor, 950 L'Enfant Plaza SW., Washington, DC 20024. Phone: (202) 586–2945. Please submit one signed paper original.

Docket: For access to the docket to read background documents, or comments received, go to the Federal eRulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Ronald Majette, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–7935. Email: *PTACs@ee.doe.gov.*

In the Office of the General Counsel, contact Ms. Jennifer Tiedeman, U.S. Department of Energy, Office of the General Counsel, GC–71, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–6111. Email: *Jennifer.Tiedeman@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On February 22, 2013, DOE published a document in the **Federal Register** announcing a public meeting and the availability of a framework document as a first step in the rulemaking process to consider amending energy conservation standards for packaged terminal air conditioners and packaged terminal heat pumps. 78 FR 12252. The document provided for the submission of written comments by March 25, 2013, and oral comments were also accepted at a public meeting held on March 18, 2013. Stakeholders have requested an extension of the comment period to allow additional time for the preparation of their comments and to respond to issues raised at the public meeting.

DOE has determined that a brief extension of the public comment period is appropriate to allow stakeholders additional time to submit comments to DOE for consideration. DOE will consider any comments received by April 25, 2013 to be timely submitted.

Issued in Washington, DC, on March 19, 2013.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2013–06747 Filed 3–22–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2013–N–0234]

Effective Date of Requirement for Premarket Approval for Automated External Defibrillator System.

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

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 following class III preamendments devices: Automated external defibrillators systems (AEDs), which includes the AED device and its accessories (i.e., pad electrodes, batteries, and adapters). 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 this device to meet the statute's premarket approval requirements and the benefits to the public from the use of the device. In addition, FDA is announcing the opportunity for interested persons to request that the Agency change the classification of the automated external defibrillator based on new information. This action implements certain statutory requirements.

DATES: Submit either electronic or written comments by June 24, 2013. FDA intends that, if a final order based on this proposed order is issued, anyone who wishes to continue to market the device will need to submit a PMA within 90 days of the publication date of the final order. Please see section III for more information about submitting a PMA. Please also see section IX for the proposed effective date of any final order that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0234, 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 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–2013–N–0234 for this order. 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.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), 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: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993–0002, 301–796–5616, *Melissa.Burns@fda.hhs.gov.*

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 of 2004 (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) 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(d) 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 21 CFR part 807.

A preamendments device that has been classified into class III and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type may be marketed without submission of a PMA until FDA issues a final order 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 directs FDA to issue an order requiring premarket approval for a preamendments class III device.

Although, under the FD&C Act, the manufacturer of a class III preamendments device may respond to the call for PMAs by filing a PMA or a notice of completion of a PDP, in practice, the option of filing a notice of completion of a PDP has not been used. For simplicity, although corresponding requirements for PDPs remain available to manufacturers in response to a final order under section 515(b) of the FD&C Act, this document will refer only to the requirement for the filing and receiving approval of a PMA.

On July 9, 2012, FDASIA was enacted. Section 608(b) of FDASIA (126 Stat. 1056) amended section 515(b) of the FD&C Act, changing the process for requiring premarket approval for a preamendments class III device from rulemaking to an administrative order.

Section 515(b)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order requiring premarket approval for a preamendments class III device, the following must occur: publication of a proposed order in the **Federal Register**, a meeting of a device classification panel described in section 513(b) of the FD&C Act, and consideration of comments from all affected stakeholders, including patients, payors, and providers. FDA has held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to AEDs, and therefore, has met this requirement under section 515(b)(1) of the FD&C Act. As explained further in section IV, a meeting of a device classification panel described in section 513(b) of the FD&C Act took place in 2011 (Ref. 1) to discuss whether AEDs should be reclassified or remain in class III. The panel recommended that because AEDs are lifesaving devices it is appropriate to regulate them in class III. Furthermore, the problems with medical device reporting (MDR) systems and recalls indicate that having these devices regulated under 510(k) has not been successful. FDA also considered information it received, pertaining to AEDs, in response to the Agency's order (74 FR 16214, April 9, 2009) requiring manufacturers to submit information about a number of preamendments devices under section 515(i) of the FD&C Act. Moreover, FDA is not aware of new information that would provide a basis for a different recommendation or findings. Information received since the 2011 panel meeting and discussed further in section IV.B only further highlights the need to review these devices under a PMA and reinforces the recommendation and findings of the panel.

Section 515(b)(2) of the FD&C Act provides that a proposed order to require premarket approval shall contain: (1) The proposed order; (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 order 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)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed

order, consideration of any comments received, and a meeting of a device classification panel described in section 513(b) of the FD&C Act, issue a final order 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).

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order (a final rule issued under section 515(b) of the FD&C Act prior to the enactment of FDASIA is considered to be a final order for purposes of section 501(f) of the FD&C Act (21 U.S.C. 351(f))) 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 (section 501(f) of the FD&C Act). For AEDs, the preamendments class III devices that are the subject of this proposal, the later of these two time periods is the 90-day period. Since these devices were classified in 2003, the 30-month period has expired (see 68 FR 61342, October 28, 2003). If a PMA is not filed for such devices within 90 days after the issuance of a final order, the devices would be deemed adulterated under section 501(f) of the FD&C Act.

However, because of the widespread distribution of AEDs, we are proposing to consider exercising enforcement discretion for devices lawfully distributed before the requirement to have a PMA goes into effect as long as manufacturers of such devices timely notify FDA of their intent to file a PMA within 90 days from the issuance of the final order. FDA intends to consider exercising enforcement discretion for 15 months from the date the final order is issued.

In accordance with section 515(b) of the FD&C Act, interested persons are being offered the opportunity to request reclassification of AEDs and AED accessories, the preamendments class III devices that are the subject of this proposed order.

II. Regulatory History of the Device

Low energy DC-defibrillators are preamendment class II devices under 21 CFR 870.5300. Arrhythmia detectors and alarms are also preamendment devices that were once classified as class III devices under 21 CFR 870.1025. AEDs were found substantially equivalent to the preamendment class III arrhythmia detector and alarm devices in response to a 510(k) in 1985, because the submission was a combination of the class II low energy defibrillator and the class III arrhythmia detector and alarm. FDA found AEDs equivalent to the higher class of the combined devices, and thus, AEDs were classified as class III devices. On October 28, 2003 (68 FR 61342), FDA published a final rule reclassifying arrhythmia detector and alarm devices into class II (special controls). In that rule, FDA also established a separate classification regulation for AEDs under § 870.5310 (21 CFR 870.5310) that retained these devices in class III and stated that it would address, at a later date, the possible reclassification of AEDs.

III. Dates New Requirements Apply

In accordance with section 515(b) of the FD&C Act, FDA is proposing to require that a PMA be filed with the Agency for AED devices and accessories within 90 days after issuance of any final order 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 provided that a PMA is timely filed. FDA intends to review any PMA for the device within 180 days. 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.''

Under the FD&C Act, AEDs and AED accessories currently in distribution for which no PMA is submitted within 90 days of a final order calling for PMAs, or for which a denial is rendered on its filed PMA, will be considered adulterated under section 501(f)(1) of the FD&C Act. As discussed in the paragraphs that follow, FDA believes that most AED manufacturers already have the clinical data they need to support a PMA. Nonetheless, because FDA recognizes that continued access to AEDs is important to the public health, FDA is proposing to consider exercising enforcement discretion for manufacturers of currently marketed AEDs, AED devices or accessories who cannot timely submit a PMA, but instead notify FDA of their intent to file a PMA within 90 days from the issuance of the final order based on this proposal. The notification of the intent to file a PMA submission should include a list of all model numbers for which a manufacturer plans to seek marketing approval through its PMA. FDA proposes further to consider exercising enforcement discretion for 15 months from the issuance of a final order requiring the filing of a PMA for such devices. Manufacturers should be able to collect additional scientific evidence, to the extent any is necessary, and prepare PMA submissions, in this time. No new devices will be allowed into interstate commerce without approval of a PMA. We request comment on whether it is appropriate to exercise enforcement discretion and, if so, whether the 15-month period proposed is reasonable.

FDA intends that under § 812.2(d) (21 CFR 812.2(d)), the publication in the **Federal Register** of any final order based on this proposal will include a statement that, as of the date on which the filing of a PMA is required, the exemptions from the requirements of the investigational device exemption (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 is not filed by that date, or for which PMA approval has been denied or withdrawn.

However, FDA intends to exercise enforcement discretion concerning IDE and PMA requirements for manufacturers of AEDs, AED devices and/or accessories who notify FDA of their intent to file a PMA for such devices within 90 days and file a PMA within 15 months after the date of issuance of any final order requiring premarket approval for these devices. FDA is aware that many existing AED manufacturers have already obtained significant clinical data on their devices. In most cases, FDA believes the clinical data that has been submitted for AEDs in 510(k) applications will suffice as valid scientific evidence necessary to support a PMA. However, a small number of manufacturers may need to conduct an additional investigation to support approval. In those circumstances, FDA will consider the least burdensome means of gathering information, and will consider whether reliance on post-market controls can reduce the extent of data that would otherwise be required to show effectiveness. FDA recommends that manufacturers file a pre-submission to discuss data requirements that may be necessary to support their individual PMA submission.

IV. Benefits of AED Systems

A. 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 this device have an approved PMA, and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the advisory committee for the classification of this device along with information submitted in response to the 515(i) order (74 FR 16214) and any additional information that FDA has obtained. Additional information regarding the risks as well as classification associated with this device type can be found in the following proposed and final orders and notices published in the **Federal Register** on the following dates: October 28, 2003 (68 FR 61342) and March 8, 2004 (69 FR 10615).

B. Device Subject to This Proposal—Automated External Defibrillator (§ 870.5310)

1. Identification

An AED system consists of an AED device and its accessories, i.e., battery, pad electrode and, if applicable, an adapter. An AED system analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

2. Summary of Data

In response to the 515(i) order (74 FR 16214), manufacturers provided information to FDA that they believe supports reclassification of AED devices from class III to class II. One manufacturer submitted a reclassification petition to the Docket (FDA–2009–M–0101). The primary basis presented by the manufacturer for reclassification was that special controls could provide reasonable assurance of the safety and effectiveness of AEDs. Examples of applicable special controls that were cited include testing to industry standards, guidelines, device labeling, guidance documents, and postmarket surveillance.

A meeting of the Circulatory System Devices Panel (''Panel'') was held on January 25, 2011 (Ref. 1). The Panel discussed and made recommendations regarding the regulatory classification of AEDs to either reconfirm to class III (subject to premarket approval application) or reclassify to class II (subject to special controls), as directed by section 515(i) of the FD&C Act (21 U.S.C. 360e(i)).

FDA's presentation to the Panel included a summary of the adverse event reports and recalls received by FDA on AED systems. This summary indicated that the total number of MDRs submitted annually more than doubled from 2005 to 2010. A review of reports submitted from 2011 and 2012 shows that the number of submitted adverse events reports has continued to increase. Annual reporting (which occurs with PMA devices) would improve overall surveillance by providing denominator data for device distribution as well as current trend information on issues being followed by the manufacturer.

FDA's analysis of recalls associated with AEDs systems indicated that the majority of recalls were associated with a manufacturer's handling of purchasing controls (21 CFR 820.50) or design controls (21 CFR 820.30). In addition, FDA's analysis also noted the significant number of violative AED manufacturing facility inspections. FDA concluded from the recall and inspection information that the following requirements that are a part of the PMA process should be placed on AED manufacturers: (1) Premarket review of manufacturing information, including procedures and processes to ensure compliance with the requirements of 21 CFR part 820 (Quality System (QS) Regulation), (2) pre-approval inspections to determine manufacturers' compliance with the QS regulation to assure that the manufacturer's quality system is in place and appears to be adequate prior to manufacture and distribution of devices, (3) review of changes in manufacturing facilities to ensure facility, procedures, and systems are adequate, and (4) additional postmarket assurances available for PMA devices including the postmarket review of significant manufacturing changes to ensure that the changes are adequately evaluated.

Accordingly, FDA stated that the devices should remain in class III, and require PMAs, because of the level of regulatory control necessary to provide reasonable assurance of safety and effectiveness, including: premarket review of manufacturing information; pre-approval inspections; review of changes in manufacturing facility location where finished devices are manufactured; postmarket review of significant manufacturing changes to ensure that the changes are adequately evaluated and tested prior to implementation; and annual reporting of device performance. The majority of the Panel members recommended the reconfirmation of AEDs as class III devices. The Panel expressed significant concerns that the number of adverse events reported in MDRs and the increase in recalls indicate that regulating these devices under premarket notification has not been successful. Therefore, increased regulatory oversight would be prudent. The panel transcript and other meeting materials are available on FDA's Web site (Ref. 1).

The AED system is composed of the AED device and its accessories, i.e., pad electrodes, battery, and adapters. The reports of MDRs and recalls associated with AED devices have also included failures related to pad electrodes, batteries and adapters. Because failure of the pad electrode, battery or adapter results in the same risks to health as failure of the AED, these devices should be subject to the same regulatory oversight as the AEDs themselves to provide reasonable assurance of safety and effectiveness for the entire AED system. Thus, this proposed order confirms the classification of AED accessories as class III devices and requires that manufacturers of AED accessories submit PMAs for their devices.

3. Risks to Health

AEDs are devices that diagnose life-threatening abnormal heart rhythms, and treat them by delivering defibrillation shocks to the heart to restore its normal rhythm. Defibrillation shocks are used to treat patients with ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT). AEDs should be able to be deployed quickly to provide defibrillation shocks to patients with VF or pulseless VT. These patients' survival depends upon a rapid sequence of rescue events that includes the successful delivery of a defibrillation shock from an AED. Rescuers have only minutes before these patients' heart rhythms degenerate beyond rescue capabilities.

a. Failure or delay to deliver a defibrillation shock. One risk to health associated with AEDs is that these devices can malfunction and fail to deliver a defibrillation shock to a patient in VF or pulseless VT. Such failure can result in permanent injury or prevent the rescue of the patient.

b. Inappropriate cardiac rhythm detection. AEDs should be able to recognize shockable and non-shockable algorithms. Shockable rhythms include VF and pulseless VT. Non-shockable

rhythms include normal sinus rhythm, supraventricular tachycardia, asystole, atrial fibrillation, sinus bradycardia, atrial flutter, and pulseless electrical activity. If the AED does not appropriately recognize a patient's cardiac rhythm it can fail to deliver or recommend a defibrillation shock to a shockable rhythm, or deliver or recommend a defibrillation shock to a non-shockable rhythm. Failure to deliver a defibrillation shock to a patient in VF or VT may result in death or permanent impairment of the patient. If the device delivers an inappropriate defibrillation shock to a patient in normal sinus rhythm it may induce ventricular fibrillation.

c. Inadvertent shocks to rescuers or bystanders. There is the potential risk of delivering an electrical shock during defibrillation of a patient to a rescuer or bystander if there is physical contact between them and the patient, or if there is a malfunction in the pad electrodes or device. There is concern that an inadvertent shock to a rescuer or bystander could induce cardiac arrhythmias or ventricular fibrillation.

4. Benefits of AED Systems

AEDs have a rhythm recognition detection system that delivers an electrical shock to treat VF or pulseless VT. The delivery of this therapy can be either fully automatic or semiautomatic. These devices are intended to be used on suspected victims of sudden cardiac arrest who are unresponsive and not breathing normally. AEDs are an important tool in providing a rapid response to victims of cardiac arrest and are successful at resuscitating victims of cardiac arrest by restoring normal cardiac rhythm.

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: (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 (§ 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)).

For those manufacturers with multiple AED devices in their portfolio, a single PMA may be submitted for AEDs that are intended for lay users (public access AEDs) and another PMA for AEDs that incorporate additional functionality for medical professionals such as manual defibrillation, monitoring features, etc. (hospital use and emergency responder AEDs). Manufacturers of pad electrodes, batteries, and adapters may submit PMAs for the accessories they manufacture, which must be supported by valid scientific evidence that these accessory devices operate as intended when paired with a given AED(s) and are appropriately labeled to ensure use only with supported AEDs.

AED manufacturers will need to submit performance testing, including clinical trials of their device, in order to support PMA approval. FDA anticipates that many existing AED manufacturers have already obtained significant clinical data that may be sufficient to support PMA approval. Existing published clinical literature may also be leveraged as part of the PMA submission. Manufacturers of batteries, adapters, and pad electrode manufacturers may need to submit non-clinical performance testing with confirmatory animal studies in order to support independent PMA approval. Battery and adapter manufacturers may need to submit only bench testing. However, pad electrode manufacturers may need to submit animal studies in addition to bench testing if concerns arise during the premarket review process on defibrillation success or post-shock dysfunction. We request comment on the performance and clinical data requirements for AEDs and related devices.

VI. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA, FDA is required by section 515(b)(2)(D) of the FD&C Act 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 this device is to be in the form of a reclassification petition containing the information required by 21 CFR 860.123, including new information relevant to the classification of the device.

VII. 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.

VIII. Paperwork Reduction Act of 1995

This proposed order refers to collections of information that 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 21 CFR part 814 have been approved under OMB control number 0910–0231. The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120. The effect of this order, if finalized, is to shift certain devices from the 510(k) premarket notification process to the PMA process. To account for this change, FDA intends to transfer some of the burden from OMB control number 0910–0120, which is the control number for the 510(k) premarket notification process, to OMB control number 0910–0231, which is the control number for the PMA process. As noted previously, FDA estimates that it will receive 12 new PMAs for AED devices and 21.5 for AED accessories as a result of this order, if finalized. Based on FDA's most recent estimates, this will result in 22,378 hours burden increase to OMB control number 0910–0231. FDA also estimates that there will be 3.4 fewer 510(k) submissions as a result of this order, if finalized. Based on FDA's most recent estimates, this will result in a 269 hours burden decrease to OMB control number 0910–0120. Therefore, on net, FDA expects a burden hour increase of

22,109 hours due to this proposed regulatory change.

IX. Proposed Effective Date

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

X. Codification of Orders

Prior to the amendments by FDASIA, section 515(b) of the FD&C Act provided for FDA to issue regulations to require approval of an application for premarket approval for preamendments devices or devices found substantially equivalent to preamendments devices. Section 515(b) of the FD&C Act, as amended by FDASIA, provides for FDA to require approval of an application for premarket approval for such devices by issuing a final order, following the issuance of a proposed order in the **Federal Register**. FDA will continue to codify the requirement for an application for premarket approval, resulting from changes issued in a final order, in the Code of Federal Regulations (CFR). Therefore, under section 515(b)(1)(A) of the FD&C Act, as amended by FDASIA, in this proposed order, we are proposing to require approval of an application for premarket approval for AEDs and if this proposed order is finalized, we will make the language in 21 CFR 870.5310 consistent with the final version of this proposed order.

XI. 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.*

XII. 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 FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. The panel transcript and other meeting materials are available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm240575.htm.*

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 870 be amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

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

■ 2. Section 870.5310 is amended by revising the section heading and paragraphs (a) and (c) to read as follows:

§ 870.5310 Automated external defibrillator system.

(a) *Identification.* An automated external defibrillator (AED) system consists of an AED device and its accessories, i.e., battery, pad electrode and, if applicable, an adapter. An AED system analyzes the patient's electrocardiogram, interprets the cardiac rhythm, and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA is required to be submitted to the Food and Drug Administration by [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE **FEDERAL REGISTER**], for any automated external defibrillator that was in commercial distribution before May 28, 1976, or that has, by [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE **FEDERAL REGISTER**], been found to be substantially equivalent to any automated external defibrillator that was in commercial distribution before May 28, 1976. Any other automated external defibrillator and automated external defibrillator accessories, i.e., pad electrodes, adaptors, and batteries shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: March 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–06723 Filed 3–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–370]

Schedules of Controlled Substances: Placement of Alfaxalone into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes the placement of 5α-pregnan-3α-ol-11,20-dione (alfaxalone) including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule IV of the Controlled Substances Act (CSA). This proposed action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking.

DATES: DEA will permit interested persons to file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted and written comments must be postmarked on or before April 24, 2013. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined at 21 CFR 1300.01 as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may file a request for hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and 1316.47. Requests for hearing and waivers of participation must be received on or before April 24, 2013.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA 370'' on all electronic and written correspondence. DEA encourages all comments be submitted electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document and supplemental