contacting components and the shelf-life of these components;

(4) Non-clinical performance evaluation of the device must provide a reasonable assurance of safety and effectiveness for mechanical integrity, durability, and reliability;

(5) In-vivo evaluation of the device must demonstrate device performance; and

(6) Labeling must include a detailed summary of the nonclinical and clinical evaluations pertinent to use of the device and adequate instructions with respect to anticoagulation, circuit set up, and maintenance during a procedure.

Dated: January 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00086 Filed 1–7–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2012–N–1173]

Cardiovascular Devices; Reclassification of External Cardiac Compressor

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the external cardiac compressor, including cardiopulmonary resuscitation (CPR) aids, from class III devices into class II (special controls). FDA is proposing this reclassification on its own initiative based on new information. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended.

DATES: Submit either electronic or written comments on this proposed order by April 8, 2013. See section XII of this document for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–1173, 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 way:

- *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–1173 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 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: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1646, Silver Spring, MD 20993, 301–796–5616, *melissa.burns@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

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 (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 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), 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).

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 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).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) 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 preamendments devices. This section provides that FDA may, by administrative order, reclassify a device (in a proceeding that parallels the initial classification proceeding) 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 (DC 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 section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (DC Cir. 1985); *Contact Lens Assoc.* v. *FDA,* 766 F.2d 592 (DC Cir.), cert. denied, 474 U.S. 1062 (1985).)

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 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed 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 from all affected stakeholders, including patients, payors, and providers.

FDAMA added section 510(m) to the FD&C Act. 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.

II. Regulatory History of the Device

On March 9, 1979 (44 FR 13424), FDA published a proposed rule for classification of external cardiac compressors as class III requiring premarket approval. The Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel recommended class III because the device is life supporting and is potentially hazardous to life or health even when properly used, and the Panel believed that there was not sufficient information to develop a performance standard to provide a reasonable assurance of safety and effectiveness. No comments were received on the proposed rule and on February 5, 1980 (45 FR 7966), a final rule was published for external cardiac compressors, classifying these devices as class III. In 1987, FDA published a final rule amending the codified language for this device to clarify that no effective date had been established for the requirement for premarket approval for external cardiac compressor devices (52 FR 17732 at 17737; May 11, 1987). In 2009, FDA published an order under sections 515(i) and 519 of the FD&C Act (21 U.S.C. 360e and 360i) for the submission of safety and effectivness information on external cardiac compressors (74 FR 16214; April 9, 2009). In response to that order, FDA received information from four manufacturers of external cardiac compressor devices.

III. Device Description

External cardiac compressors (ECCs), also known as chest compressors, assist in the act of CPR. The devices in this classification are divided into two types: (1) Devices that provide automatic chest compressions at a fixed compression rate and depth (automated external cardiac compressors), which are placed directly on the patient's chest and are powered manually, pneumatically, or electrically and (2) devices that aid the emergency medical professional in delivering manual compressions at a compression depth and rate that are consistent with current guidelines (CPR Aids). These devices are placed beneath the hands of the emergency medical professional or in the vicinity of the cardiac arrest victim and provide audio and/or visual feedback to assist emergency personnel in following the recommended steps for CPR and maintaining the recommended rate and depth of compressions for the duration of CPR.

IV. Proposed Reclassification

FDA is proposing that the device subject to this proposed order be reclassified from class III to class II. FDA believes CPR Aid devices and automated external cardiac compressor devices when used as indicated can supplement the effective delivery of CPR.

FDA believes that the identified special controls, in addition to general controls, would provide reasonable assurance of safety and effectiveness. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and 21 CFR 860.130, based on new information with respect to the devices, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. FDA believes that this information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V of this document, and that these special controls in addition to the general controls will provide a reasonable assurance of safety and effectiveness for ECCs.

FDA has considered automated external cardiac compressor devices in accordance with the reserved criteria and has determined that the device should be subject to the premarket notification (510(k) of the FD&C Act) requirements as provided for under section 510(m) of the FD&C Act. However, the Agency does intend to exempt a CPR Aid device when it is a prescription use device and when the feedback provided to the rescuer is consistent with the current version of the American Heart Association (AHA) guidelines for CPR (Ref. 1) from premarket notification (section 510(k) of the FD&C Act) submission as provided for under section 510(m) of the FD&C Act. The AHA guidelines recommend that chest compressions be the highest priority and the initial action when starting CPR in the adult victim of sudden cardiac arrest. Chest compressions are an especially critical component of CPR because perfusion during CPR depends on these compressions.

V. Risks to Health

After considering available information, including the recommendations of the advisory committees (panels) for the classification of these devices, FDA has evaluated the risks to health associated with the use of external cardiac compressor devices and determined that the following risks to health are

associated with use of the automated external cardiac compressor devices:

- *Tissue damage or bone breakage, or inadequate blood flow.* Damage to the heart, other organs or tissues, can result from poor mechanical design, improper surface area of the plunger, improper vertical excursion of the plunger, improper force applied by the plunger, or improper energy transmission by the device.
- *Cardiac arrhythmias or electrical shock.* Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias.
- *Adverse skin reactions.* Lack of biocompatibility in materials contacting skin may cause an adverse immunological or allergic reaction in a patient.

FDA has evaluated the risks to health associated with the use of CPR Aid devices and determined that the following risks to health are associated with use of CPR Aid devices:

- *Suboptimal CPR delivery.* Inaccurate rate or depth feedback from the device or inadequate labeling may result in suboptimal delivery of CPR.
- *Adverse skin reactions.* Lack of biocompatibility in materials contacting skin may cause an adverse immunological or allergic reaction in a patient.

VI. Summary of Reasons for Reclassification

FDA believes that automated external cardiac compressor devices indicated for adjunctive use with manual CPR (e.g., during transport—to assure more consistent and continuous therapy; or prolonged CPR—to avoid/replace rescuer fatigue) and CPR Aid devices should be reclassified into class II because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of the device. In addition, there is now adequate effectiveness information sufficient to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification Is Based

Since the time of the Panel recommendation, sufficient evidence has been developed to support a reclassification of automated external cardiac compressors indicated for adjunctive use with manual CPR and CPR Aid devices into class II with special controls.

Automated external cardiac compressors are tools used by emergency medical personnel to automate chest compressions during CPR. These devices are typically used in situations where extended CPR is required, such as during patient transport or when there are an inadequate number of trained personnel during extended CPR. The review of the available literature on mechanical versus manual chest compressions both by AHA (Ref. 1) and in a recent systematic literature review (Ref. 2) provided mixed results on whether mechanical compressions are as effective as manual chest compressions. However, it is well established that chest compressions are crucial to maintaining perfusion and that compressions of adequate rate and depth are necessary to increase the probability of survival in victims of sudden cardiac arrest (Ref. 1). As such, FDA believes that these devices, when indicated for use as an adjunct to manual CPR during patient transport or for use in situations where fatigue of or inaccessibility to emergency medical personnel may otherwise prevent adequate chest compressions, can be regulated as class II devices. These devices should not be used as a replacement for manual CPR. FDA believes that the special controls, including adequate labeling of the device for the appropriate use population, use conditions, and use by appropriately trained personnel, and performance testing of the device to ensure adequate chest compression rate and depth, adequately mitigate the risks.

CPR Aid devices are used to remind emergency medical personnel of appropriate CPR steps and technique and to provide feedback on the rate and depth of compressions. AHA guidelines on CPR and emergency cardiovascular care (Ref. 1) conclude that ''real-time CPR prompting and feedback technology such as visual and auditory prompting devices can improve the quality of CPR.'' In addition, these devices have been reviewed by FDA for many years, and their risks are well-known. Between January 2000 and June 2012, FDA has not received any adverse event reports (medical device reports) associated with CPR Aid devices. FDA believes that the identified special controls, in addition to the general controls, provide reasonable assurance of safety and effectiveness.

VIII. Proposed Special Controls

FDA believes that the following special controls, in addition to general controls, are sufficient to mitigate the risks to health described in section V of this document for automated external cardiac compressor devices:

- Performance testing under simulated physiological conditions must demonstrate the reliability of the delivery of specific compression depth and rate over the intended duration and environment of use;
- Labeling must include the clinical training for the safe use of this device and information on the patient population for which the device has been demonstrated to be effective;
- For devices that incorporate electrical components, appropriate analysis and testing must validate electrical safety and electromagnetic compatibility;
- For devices containing software, software verification, validation, and hazard analysis must be performed; and
- Any elements of the device that may contact the patient must be demonstrated to be biocompatible;

In addition, under 21 CFR 801.109, the sale, distribution, and use of the automated external cardiac compressor device are restricted to prescription use.

FDA believes that the following special controls, in addition to general controls, are sufficient to mitigate the risks to health described in section V of this document for CPR Aid devices:

- Performance testing under simulated physiological or use conditions must demonstrate the accuracy and reliability of the feedback to the user on specific compression rate and/or depth over the intended duration of use;
- Labeling must include the clinical training, if needed, for the safe use of this device and information on the patient population for which the device has been demonstrated to be effective;
- For devices that incorporate electrical components, appropriate analysis and testing must validate electrical safety and electromagnetic compatibility;
- For devices containing software, software verification, validation, and hazard analysis must be performed;
- Any elements of the device that may contact the patient must be demonstrated to be biocompatible; and
- For over-the counter-devices, human factors testing and analysis must validate that the device design and labeling are sufficient for lay use.

IX. Exemption From Premarket Notification Requirements

FDA, on its own initiative, is also proposing to exempt CPR Aid devices that provide feedback consistent with the current AHA guidelines for CPR from premarket notification, subject to limitations. The AHA guidelines are intended to support emergency medical personnel with a series of sequential assessments and actions for resuscitation of the victim. The intent of

the AHA guideline is to provide recommendations on the most effective CPR practices, rather than specific instructions for using CPR Aid or other devices on a victim of sudden cardiac arrest.

FDA may consider a number of factors in determining whether premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff'' (Ref. 3).

FDA believes that a CPR Aid, when it is a prescription use device that provides feedback compliant with the current AHA guidelines for CPR, is appropriate for exemption from premarket notification, subject to the limitations of exemptions identified in 21 CFR 870.9, because the applicable special controls and general controls provide reasonable assurance of safety and effectiveness if device manufacturers follow the special controls requirements.

FDA advises that exemption from the requirement of premarket notification for prescription CPR Aids does not mean that these devices would be exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. Indeed, FDA's proposal to exempt these devices from the requirement of premarket notification is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements (21 CFR part 820) and the identified special controls, provide.

X. 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.

XI. Paperwork Reduction Act of 1995

This proposed order 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 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in part 807, subpart E, are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, are approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 are approved under OMB control number 0910–0485.

XII. Proposed Effective Date

FDA is proposing that any final order based on this proposal become effective 30 days after date of publication of the final order in the **Federal Register**.

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. 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, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Berg R. A., R. Hemphill, B. S. Abella, *et al.*, ''2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Circulation,'' vol. 122, issue 18, suppl. 3, 2010, available at *http://circ.ahajournals.org/content/122/18_suppl_3/S685.full.pdf+html.*

2. Brooks S. C., B. L. Bigham, and L. J. Morrison, ''Mechanical Versus Manual Chest Compressions for Cardiac Arrest (Review),'' *The Cochrane Library,* issue 1, 2011, available at *http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD007260.pub2/pdf.*

3. FDA guidance, ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff,'' 1998, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080198.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 870.5200 is revised to read as follows:

§ 870.5200 External cardiac compressor.

(a) *Identification.* An automated external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest. Automated external cardiac compressor devices are used as an adjunct to manual cardiopulmonary resuscitation (CPR) during patient transport or extended CPR. This also includes CPR Aid devices, which are external devices intended to provide audio and/or visual feedback to the rescuer regarding compression rate and/or depth, to aid in the consistent application of manual CPR.

(b) *Classification.* (1) Class II (special controls) for the automated external cardiac compressor device. The special controls for this device are:

(i) Performance testing under simulated physiological conditions must demonstrate the reliability of the delivery of specific compression depth and rate over the intended duration of use;

(ii) Labeling must include the clinical training for the safe use of this device and information on the patient population for which the device has been demonstrated to be effective;

(iii) For devices that incorporate electrical components, appropriate analysis and testing must validate electrical safety and electromagnetic compatibility;

(iv) For devices containing software, software verification, validation, and hazard analysis must be performed; and

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

(2) Class II (special controls) for the CPR Aid device. The special controls for this device are:

(i) Performance testing under simulated physiological conditions must demonstrate the accuracy and reliability of the feedback to the user on specific compression rate and/or depth

over the intended duration and environment of use;

(ii) Labeling must include the clinical training, if needed, for the safe use of this device and information on the patient population for which the device has been demonstrated to be effective;

(iii) For devices that incorporate electrical components, appropriate analysis and testing must validate electrical safety and electromagnetic compatibility;

(iv) For devices containing software, software verification, validation, and hazard analysis must be performed;

(v) Any elements of the device that may contact the patient device must be demonstrated to be biocompatible; and

(vi) For over-the-counter devices, human factors testing and analysis must validate that the device design and labeling are sufficient for lay use.

(c) *Premarket notification.* The CPR aid device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if it is a prescription use device that provides feedback to the rescuer consistent with the current American Heart Association guidelines for CPR and in compliance with the special controls under paragraph (b)(2) of this section, subject to the limitations of exemptions in § 870.9.

Dated: January 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–00085 Filed 1–7–13; 8:45 am]

BILLING CODE 4160–01–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1195

[Docket No. ATBCB–2012–0003]

RIN 3014–AA40

Medical Diagnostic Equipment Accessibility Standards Advisory Committee

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of advisory committee meeting.

SUMMARY: The Medical Diagnostic Equipment Accessibility Standards Advisory Committee will hold its third meeting. On July 5, 2012, the Architectural and Transportation Barriers Compliance Board (Access Board) established the advisory committee to make recommendations to the Board on matters associated with comments received and responses to questions included in a previously published Notice of Proposed Rulemaking (NPRM) on Medical Diagnostic Equipment Accessibility Standards.

DATES: The Committee will meet on January 22, 2013, from 10:00 a.m. to 5:00 p.m. and on January 23, 2012, from 9:00 a.m. to 2:30 p.m.

ADDRESSES: The meeting will be held at the Access Board's Conference Room, 1331 F Street NW., Suite 800, Washington, DC 20004–1111.

FOR FURTHER INFORMATION CONTACT: Rex Pace, Office of Technical and Information Services, Architectural and Transportation Barriers Compliance Board, 1331 F Street NW., Suite 1000, Washington, DC 20004–1111. Telephone number (202) 272–0023 (Voice); (202) 272–0052 (TTY). Electronic mail address: *pace@access-board.gov.*

SUPPLEMENTARY INFORMATION: On July 5, 2012, the Architectural and Transportation Barriers Compliance Board (Access Board) established an advisory committee to make recommendations to the Board on matters associated with comments received and responses to questions included in a previously published NPRM on Medical Diagnostic Equipment Accessibility Standards. See 77 FR 6916 (February 9, 2012). The NPRM and information related to the proposed standards are available on the Access Board's Web site at: *http://www.access-board.gov/medical-equipment.htm.*

The advisory committee will hold its third meeting on January 22 and 23, 2013. The agenda includes the following:

- Review of previous committee work;
- Presentations by medical practitioners and clinicians on the use of medical diagnostic equipment in relation to transfer surfaces;
- Continued discussion on subcommittees based on medical diagnostic equipment type;
- Continued discussion on transfer surface height and size;
- Review and discussion on transfer support location and configuration;
- Consideration of issues proposed by committee members; and
- Discussion of administrative issues.

The preliminary meeting agenda, along with information about the committee, is available at the Access Board's Web site (*http://www.access-board.gov/medical-equipment.htm*).

Committee meetings are open to the public and interested persons can attend the meetings and communicate their views. Members of the public will have opportunities to address the committee on issues of interest to them during public comment periods scheduled on each day of the meeting.

The meetings will be accessible to persons with disabilities. An assistive listening system, computer assisted real-time transcription (CART), and sign language interpreters will be provided. Persons attending the meetings are requested to refrain from using perfume, cologne, and other fragrances for the comfort of other participants (*see www.access-board.gov/about/policies/fragrance.htm* for more information). Also, persons wishing to provide handouts or other written information to the committee are requested to provide electronic formats to Rex Pace via email prior to the meetings so that alternate formats can be distributed to committee members.

David M. Capozzi,

Executive Director.

[FR Doc. 2013–00071 Filed 1–7–13; 8:45 am]

BILLING CODE 8150–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 27

[WT Docket No. 12–357; FCC 12–152]

Service Rules for the Advanced Wireless Services in the H Block—Implementing Section 6401 of the Middle Class Tax Relief and Job Creation Act of 2012 Related to the 1915–1920 MHz and 1995–2000 MHz Bands

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Commission proposes rules for the Advanced Wireless Services (AWS) H Block that would make available ten megahertz of spectrum for flexible use. The proposal would extend the widely-deployed Personal Communications Services (PCS) band, which is used by the four national providers as well as regional and rural providers to offer mobile service across the nation. The additional spectrum for mobile use will help ensure that the speed, capacity, and ubiquity of the nation's wireless networks keeps pace with the skyrocketing demand for mobile service.

DATES: Submit comments on or before February 6, 2013. Submit reply