DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0650]

Cardiovascular Devices; Withdrawal of Proposed Rule of Reclassification of External Pacemaker Pulse Generator Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rule the Agency issued in the **Federal Register** of October 17, 2011. In that document, FDA proposed to reclassify the external pacemaker pulse generator (EPPG) devices, a preamendments class III device into class II (special controls). In response to the requirements under the Food and Drug Administration Safety and Innovation Act (FDASIA) and new information received during a panel meeting, FDA is withdrawing the proposed rule and issuing a proposed administrative order to reclassify EPPGs.

DATES: The proposed rule is withdrawn on September 15, 2014.

FOR FURTHER INFORMATION CONTACT: Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1652, Silver Spring, MD 20993, 301–796–6351.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

On October 17, 2011, FDA published in the **Federal Register** (76 FR 64223) a proposed rule proposing the reclassification of external pacemaker pulse generator (EPPG) devices from class III to class II with special controls. FDA identified special controls that the Agency believed would provide reasonable assurance of safety and effectiveness for the device type. FDA considered EPPGs in accordance with the reserved criteria and determined that the device type does require premarket notification.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (Pub. L. 112–144) amended section 513(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(e)) changing the process for reclassifying a device from rulemaking to an administrative order. Subsequent to the publication of the proposed rule, FDASIA's amendments to section 513 of the FD&C Act required FDA to hold a classification panel (an FDA advisory committee) meeting on the classification of this device. On September 11, 2013, a meeting of the Circulatory System Devices Panel (the Panel) was held to discuss whether EPPG devices should be reclassified or remain in class III (Ref. 1). There was Panel consensus that EPPG devices did not fit the regulatory definition of a class III device. Coupled with the rationale that special controls could be established to reasonably demonstrate an assurance of safety and effectiveness, the Panel recommended class II (special controls) for EPPG when intended for cardiac rate control or prophylactic arrhythmia prevention.

II. Withdrawal of the Proposed Rule

FDA provided an opportunity for interested parties to comment on the proposed rule for EPPG (76 FR 64223). FDA received three comments to the docket in response to the 2011 proposed rule. These comments were received and have been considered during the presentations to the Panel and in developing the proposed order. In response to these comments and findings at the Panel meeting, FDA is withdrawing the proposed rule for these devices and is issuing a proposed administrative order.

III. Proposed Reclassification

Elsewhere in this issue of the **Federal Register,** FDA is proposing in an order to reclassify EPPG devices, currently a preamendments class III device, into class II (special controls). FDA continues to review the merits of the submissions for requests for reclassification that meet the requirements under 21 CFR 860.123, submitted in response to the proposed rule.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. The panel transcript and other meeting materials for the September 11, 2013, Circulatory System Devices Panel are available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm342357.htm.*

Dated: September 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21816 Filed 9–12–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2011–N–0650]

Cardiovascular Devices; Reclassification of External Pacemaker Pulse Generator Devices; Reclassification of Pacing System Analyzers

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing in this administrative order to reclassify the external pacemaker pulse generator (EPPG) devices, a preamendments class III device into class II (special controls), and to amend the device identification and reclassify the pacing system analyzers (PSAs) into class II (special controls). Specifically, single and dual chamber PSAs, which are currently classified with EPPG devices, and triple chamber PSAs (TCPSAs), which are postamendments class III devices, are proposed to be reclassified to class II devices. FDA is proposing this reclassification based on new information pertaining to the device. This proposed action would implement certain statutory requirements.

DATES: Submit either electronic or written comments on the proposed order by December 15, 2014. See section XII for the effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0650, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions in the following ways:

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

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0650 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: Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1652, Silver Spring, MD 20993, 301–796–6351.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The 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 (Public Law 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) establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

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

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

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an 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 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 premarket approval (PMA) application until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended the device reclassification procedures under section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Prior to the enactment of FDASIA, FDA published a proposed rule under section 513(e) of the FD&C Act proposing the reclassification of EPPG devices (76 FR 64223, October 17, 2011). Three sets of comments were received on the proposed rule. The three sets of comments submitted in response to the proposed rule on EPPG devices will be considered under this proposed administrative order and do not need to be resubmitted. FDA is issuing this proposed administrative order to comply with the new procedural requirement created by FDASIA when reclassifying a preamendments class III device, as well as to reclassify a postamendments class III device. Also, as required by section 513(e) of the FD&C Act for preamendment devices, FDA convened a device classification panel meeting which discussed the proposed reclassification on September 11, 2013 (78 FR 49272). This action is intended solely to fulfill the procedural requirements for reclassification implemented by FDASIA.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) 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 Co.* v. *United States Dep't of Health, Educ., & Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified later into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) provides that FDA acting by administrative order can reclassify the device into class I or class II on its own initiative under section 513(f)(1) of the FD&C Act, or in response to the petition of the manufacturer or importer of the device. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of these class III devices. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

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, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Flinch* supra, 422 F.2d at 951.) Whether data before the Agency are old 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 § 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Manufacturers Association* v. *FDA,* 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).

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

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final 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. In addition, the proposed order must set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risk of the device. (See section 513(e)(1)(A)(i) of 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. FDA has determined that premarket notification is necessary to reasonably assure the safety and effectiveness of EPPG and PSA devices.

II. Regulatory History of the Device

A. EPPG Devices

On March 9, 1979, FDA published a proposed rule in the **Federal Register** for classification of EPPG devices into class III based on the recommendation of the Cardiovascular Devices Panel (the Panel) (44 FR 13284 at 13372). The Panel meeting recommended EPPG devices be classified into class III because the device provided temporary life support and that certain kinds of failures could cause this device to emit inappropriate electrical signals, which could cause cardiac irregularities and death. The Panel indicated that general controls alone would not be sufficient and that there was not enough information to establish a performance standard. Consequently, the Panel believed that premarket approval was necessary to reasonably assure the safety and effectiveness of the device. In 1980, FDA classified EPPG into class III under § 870.3600 (21 CFR 870.3600) after receiving no comments on the proposed rule (45 FR 7907, February 5, 1980). In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for EPPG devices (52 FR 17732, May 11, 1987).

In 2009, FDA published an order in the **Federal Register** under section 515(i) of the FD&C Act to call for information on the remaining class III 510(k) preamendment devices, including EPPG devices (74 FR 16214, April 9, 2009). In response to that order, FDA received two reclassification petitions from one device manufacturer who requested that EPPG devices be reclassified into class II. The manufacturers stated that safety and effectiveness of these devices may be assured by performance standards, the intended use environment, postmarket surveillance to include Medical Device Reporting (MDRs), FDA inspections of manufacturing facilities, and premarket review of performance testing in a 510(k) submission. The manufacturers specifically noted that the FDA recognized consensus standard, International Electrotechnical Commission (IEC) 60601–2–31: 'Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source' provides adequate design and testing parameters for EPPG devices.

On October 17, 2011, FDA published a proposed rule proposing the reclassification of EPPG devices from class III to class II (76 FR 64223) and announcing the availability of a draft Special Controls Guidance Document that, if finalized, would serve as a special control, if FDA reclassified these devices. FDA believed that the special controls described in the draft special controls guidance document entitled ''Class II Special Controls Guidance Document: External Pacemaker Pulse Generator'' would be sufficient to mitigate the risks to health associated with EPPG (Ref. 1).

The proposed rule provided for a comment period that was open until January 17, 2012. FDA received three sets of comments. These comments stated that: (1) FDA should retain EPPG in class III, (2) FDA's reclassification proposed rule was not adequately supported by new publicly valid scientific evidence, (3) MDR data showed that existing performance standards are insufficient, (4) there were no publicly available performance standards that would apply to EPPG, (5) FDA should convene an advisory committee (the Panel) to seek a recommendation on the classification of EPPG, and (6) the recall process after reclassification of EPPG would need to be clarified. These comments were considered by FDA in drafting this proposed order.

B. PSA Devices

Single and dual chamber PSAs have historically been classified with EPPG devices. These devices combine the functionality of a single or dual chamber EPPG, which is currently class III and the functionality of a pacemaker electrode function tester, which is regulated as a class II device (under § 870.3720 (21 CFR 870.3720)). Single and dual chamber PSA devices have been found substantially equivalent to EPPG devices through the 510(k) process. Triple chamber PSA (TCPSA) devices have not been determined to be substantially equivalent through the 510(k) process, and since this technology was not on the market in 1976, TCPSAs have been reviewed through the PMA process as postamendment class III devices.

On July 9, 2012, FDASIA was enacted, which amended the device reclassification procedures under sections 513 and 515 of the FD&C Act. Accordingly, FDA is issuing a proposed administrative order to comply with the new procedural requirement created by FDASIA when reclassifying a preamendments class III device. Further, FDA intends to codify the proposed special controls within the § 870.3600 classification regulation for EPPG and to create a separate

classification regulation for PSA devices.

As explained further in section VII, a meeting of the Circulatory System Devices Panel (the 2013 Panel) took place on September 11, 2013, to discuss whether EPPG and TCPSA devices should be reclassified or remain in class III (Ref. 2). FDA included a discussion of TCPSA devices in the 2013 Panel discussion because the risks to health and proposed special controls were very similar to those being proposed for the EPPG devices already under consideration. The 2013 Panel recommended that EPPG devices be reclassified to class II with special controls when intended for cardiac rate control or prophylactic arrhythmia prevention. The 2013 Panel also recommended that TCPSA devices be reclassified to class II with special controls when intended for use during the pulse generator implant procedure. FDA is not aware of new information that would provide a basis for a different recommendation or finding.

III. Device Description

A. EPPG Devices

An EPPG is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following events such as cardiac surgery or a myocardial infarction. The device may have adjustments for pacing rate, pulse amplitude, pulse width (duration), R-wave sensitivity, and other pacing variables.

An EPPG device is designed to be used with cardiac pacing lead systems for temporary atrial and/or ventricular pacing. An EPPG system generally includes the pulse generator, extension cables, and adaptors which connect the extension cable to the implanted pacing lead and are critical to the functionality of the EPPG system. The pacing leads for use with EPPG may be for temporary or permanent use for either tranvenous or epicardial uses. The pacing leads are not considered part of the EPPG device because they have their own regulatory designations (21 CFR 870.3680) depending on their design and intended use.

EPPG devices are used exclusively in hospital environments with the patients supervised by qualified medical personnel. The electrical and heart rhythm of patients are continuously monitored using EPPG-independent electrocardiogram (ECG) monitors usually with alarm functions. Independent ECG monitoring requirements are identified in international standards, such as IEC 60601–2–31 for device design.

FDA is also proposing in this order to slightly modify the identification language from the way it is presently written in § 870.3600(a) to clarify that these are prescription devices in accordance with § 801.109 (21 CFR 801.109).

B. PSA Devices

A PSA combines the functionality of a pacemaker electrode function tester (under § 870.3720) and an EPPG. A pacemaker electrode function tester is a device that is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential. A PSA can temporarily take over pacing functions while simultaneously testing one or more implanted pacing leads. PSA devices can be single, dual, or triple chamber, translating into the measurement capabilities/functionalities of the device. Single chamber PSAs typically measure pacing capture threshold, whereas in the case of dual chamber PSAs, the device can also measure conduction times or intrinsic atrioventricular delay. In the case of a TCPSA, the device can also function as a biventricular external pacemaker and measure the intrinsic intra-ventricular (VV) interval.

IV. Proposed Reclassification

A. EPPG Devices

FDA is proposing that EPPG devices be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls (including prescription-use restrictions) applicable to the devices, would provide reasonable assurance of their safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device. Since the time of the 1979 classification, new information about use and pacing technology for this device has become sufficiently available to establish special controls. FDA believes that this new information is sufficient to demonstrate that the proposed special controls, when finalized, can effectively mitigate the risks to health identified in section V, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for EPPG devices.

B. PSA Devices

FDA is proposing to create a separate classification regulation for PSA devices, including single, dual, and triple chamber PSA devices that will be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls (including prescription-use restrictions) applicable to the devices, would provide reasonable assurance of their safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device. Since the 1979 classification of temporary external pacing devices, new information about device use and pacing technology has become available to establish special controls. FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for PSA devices.

Section 510(m) of the FD&C Act authorizes the Agency to exempt class II devices from premarket notification (510(k)) submission. FDA has considered EPPG and PSA devices in accordance with the reserved criteria set forth in section 513(a) and determined that both devices require premarket notification (510(k) of the FD&C Act). Therefore, the Agency does not intend to exempt these proposed class II devices from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

V. Risks to Health

A. EPPG Devices

After considering available information for the classification of these devices, 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 EPPG devices and determined the following risks to health are associated with its use:

- *Failure to pace:* Improper settings, electromagnetic interference, or failure

of mechanical/electrical components of the device can prevent pacing of the patient's heart.

- *Improperly high pacing rate:* Undersensing during demand pacing, unintended asynchronous pacing, or improper use of burst/overdrive pacing can cause harmful acceleration of heart rate or induce harmful arrhythmias such as ventricular tachycardia.
- *Improperly low pacing rate:* Oversensing or use error can result in stimulation pulses being delivered at an unwanted low pacing rate, which can result in untreated symptomatic bradycardia.
- *Improper pacing leading to unwanted stimulation:* Pacing during vulnerable periods of the cardiac cycle or at higher than programmed amplitude can induce arrhythmias.
- *Micro/macro shock:* Uncontrolled leakage currents or patient auxiliary currents can cause an electric shock resulting in an arrhythmia or cardiac tissue damage.

B. PSA Devices

After considering available information for the classification of these devices, 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 PSA devices and determined the following risks to health are associated with its use:

- *Failure to pace:* Improper settings, electromagnetic interference, or failure of mechanical/electrical components of the device can prevent pacing of the patient's heart.
- *Improperly high pacing rate:* Undersensing during demand pacing, unintended asynchronous pacing, or improper use of burst/overdrive pacing can cause harmful acceleration of heart rate or induce harmful arrhythmias such as ventricular tachycardia.
- *Improperly low pacing rate:* Oversensing or use error can result in stimulation pulses being delivered at an unwanted low pacing rate, which can result in untreated symptomatic bradycardia.
- *Improper pacing leading to unwanted stimulation:* Pacing during vulnerable periods of the cardiac cycle or at higher than programmed amplitude can induce arrhythmias. For TCPSAs, this risk includes VV dyssynchrony.
- *Micro/macro shock:* Uncontrolled leakage currents or patient auxiliary currents can cause an electric shock resulting in an arrhythmia or cardiac tissue damage.
- *Misdiagnosis:* If the zero or calibration of the device is inaccurate or unstable the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

VI. Summary of Reasons for Reclassification

FDA believes that EPPG devices and PSA devices should be reclassified from class III to class II because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of the devices, and because general controls themselves are insufficient to provide reasonable assurance of their safety and effectiveness. In addition, there is now sufficient information to establish special controls to provide such assurance. FDA also believes that TCPSA devices—as a subset of PSA devices—can achieve a reasonable assurance of safety and effectiveness using the same special controls proposed for EPPG and PSA devices with the addition of limiting use to the duration of the implant procedure in order to mitigate the risk of unwanted interventricular stimulation leading to arrhythmia (captured as misdiagnosis and improper pacing leading to unwanted stimulation in the list of risks to health in section V).

VII. Summary of Data Upon Which the Reclassification Is Based

A. EPPG Devices

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130, based on new information with respect to the device and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. The Agency has identified special controls that would provide reasonable assurance of their safety and effectiveness. EPPG are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. Since 1979 when FDA classified EPPG devices into class III, sufficient evidence has been developed to support a reclassification to class II with the establishment of special controls. FDA has been reviewing these devices for many years and their risks are well known. The risks to health are identified in section V, and FDA believes these risks can be adequately mitigated by special controls.

EPPG devices that use temporary cardiac pacing for the purposes of rate control or treatment of bradycardia use mature technology with well-established evidence of effectiveness (Refs. 3, 8, 9, 11, 13). A review of 14 clinical studies published over four decades shows that temporary external pacing is generally safe and has an electrophysiologic as well as hemodynamic benefit when used as indicated (Refs. 3 to 17).

The low frequency of serious adverse events as evidenced through FDA's Manufacturer and User Facility Device Experience (MAUDE) database, the low rate of postmarket recalls, the established scientific evidence to support pacing for specific indications, the hospital use environment, and FDA's review experience with these devices, all support the reclassification of these devices to class II. In addition, several key performance standards (such as IEC 60601–1 and IEC 60601–2–31) that address various aspects of design and performance have been developed and used to support marketing applications since the original classification. In light of these considerations, FDA has tentatively concluded that the identified special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of EPPG devices.

FDA's presentation to the 2013 Panel included a summary of the available safety and effectiveness information for EPPG devices, including adverse event reports from FDA's MAUDE database and available literature. Based on the available scientific literature, which supports that use of EPPG devices may be beneficial for patients needing temporary atrial and/or ventricular pacing, FDA recommended to the 2013 Panel that EPPG devices be reclassified to class II (special controls). The 2013 Panel discussed and made recommendations regarding the regulatory classification of EPPG devices to either reconfirm to class III (subject to premarket approval application) or reclassify to class II (subject to special controls). The 2013 Panel agreed with FDA's conclusion that the available scientific evidence is adequate to support the safety and effectiveness of EPPG devices. The 2013 Panel also acknowledged that EPPG devices are life-supporting devices and provided the following rationale per

§ 860.93 for recommending that EPPG devices be reclassified to class II: (1) These devices are used exclusively in the hospital environment where backup monitoring is available, hazards can be recognized and treated immediately, and where there is a reasonable expectation that users are adequately trained; (2) there is sufficient clinical experience that attests to the benefit of the device; and (3) the recommended special controls will mitigate the health risks associated with the device.

The 2013 Panel also agreed with the identified risks to health presented at the meeting; however, it recommended that FDA consider rewording some of the language for clarity and also to ensure that certain hazards, such as asynchronous pacing and arrhythmia induction, are included in the risks to health. FDA agrees with the 2013 Panel's recommendations and modified the risks to health accordingly as outlined in section V. The 2013 Panel also agreed with FDA's proposed special controls outlined in section VIII; however, the 2013 Panel further recommended that FDA add labeling requirements for proper training, proper maintenance of the device, and remedial actions for failures due to lead connections. FDA agrees with the 2013 Panel and the proposed special controls have been modified to reflect more specific labeling requirements.

The 2013 Panel transcript and other meeting materials are available on FDA's Web site (Ref. 2).

B. PSA Devices

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and § 860.130, based on new information with respect to the device and taking into account the public health benefit of the use of the device and the nature and known incidence of the risks of the device, FDA, on its own initiative, is proposing to reclassify these class III devices into class II. The Agency has identified special controls that would provide reasonable assurance of their safety and effectiveness.

Single and dual chamber PSA devices combine the functions of a pacemaker electrode function tester (class II) and an EPPG device (proposed class II). No new risks have been identified from the combination of these devices and the 2013 Panel likewise did not identify new concerns with regulating single and dual chamber PSAs in a manner consistent with EPPG devices. The low frequency of serious adverse events as evidenced through FDA's MAUDE database, the low rate of postmarket recalls, the established scientific evidence to support pacing for specific indications, the hospital use environment, and FDA's review experience with these devices, all supports the reclassification of these devices to class II. These devices are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device.

Sufficient evidence has been developed to support a reclassification of single and dual chamber PSA devices, to class II with special controls. FDA has been reviewing these devices for many years and their risks are well known. The risks to health are identified in section V, and FDA believes these risks can be adequately mitigated by general and special controls.

Sufficient evidence has also been developed to support a reclassification of TCPSA devices. FDA has not identified any additional risks to the patient due to the availability to pace three chambers in terms of failure to pace or improper pacing rate during the implant procedure. The longer-term hemodynamic issues associated with biventricular pacing are not relevant to the acute implant procedure. The use of TCPSAs is limited by labeling to use only during implant of a pacemaker or implantable cardioverter defibrillator (ICD). Accordingly, the proposed special controls for TCPSA devices contain the same requirements as EPPG devices with the addition of labeling that indicates TCPSA use only during the implant procedure.

FDA's presentation to the 2013 Panel included a summary of the available safety and effectiveness information for TCPSA devices, including adverse event reports from FDA's MAUDE database and a search of the available literature. The searches did not identify any safety issues for this device type.

Based on the available evidence, FDA recommended to the 2013 Panel that TCPSA devices be reclassified to class II (special controls). The 2013 Panel discussed and made recommendations regarding the regulatory classification of TCPSA devices to either reconfirm to class III (subject to premarket approval application) or reclassify to class II (subject to special controls) as directed by section 513(e) of the FD&C Act. The 2013 Panel agreed with FDA's conclusion that the available scientific evidence is adequate to support the safety and effectiveness of TCPSA devices and reclassify them to class II. The 2013 Panel also acknowledged that TCPSA devices are life-supporting devices and provided the following rationale per § 860.93 for recommending that TCPSA devices be reclassified to class II: (1) These devices are used only during the implant procedure where backup monitoring is continuous, hazards can be recognized and treated immediately, and where there is a reasonable expectation that users are adequately trained; (2) these devices are not intended to provide the long-term hemodynamic benefit of biventricular pacing or cardiac resynchronization therapy; and (3) the recommended special controls will mitigate the health risks associated with the device.

The 2013 Panel also agreed with the identified risks to health presented at the meeting; however, the 2013 Panel recommended that FDA consider the same modifications as recommended for EPPG devices. FDA agrees with the 2013 Panel's recommendations and modified the risks to health accordingly as outlined in section V. The 2013 Panel also agreed with FDA's proposed special controls outlined in section VIII; however, the 2013 Panel further recommended that FDA add labeling requirements for proper training, proper maintenance of the device, and remedial actions for failures due to lead connections. FDA agrees with the 2013 Panel.

The 2013 Panel transcript and other meeting materials are available on FDA's Web site (Ref. 2).

VIII. Proposed Special Controls

A. EPPG Devices

FDA believes that the following special controls, together with general controls (including applicable prescription-use restrictions and continuing 510(k) notification requirements), are sufficient to mitigate the risks to health described in section V for EPPG devices:

1. Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

2. Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

3. Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

- Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable

or programmable parameters as identified in labeling;

- mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;
- simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g. data storage, printing), and indicator(s) functionality under intended use conditions; and
- methods and instructions for cleaning the pulse generator and connection cables must be validated.

4. Appropriate software verification, validation, and hazard analysis must be performed.

5. Labeling must include the following:

- The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in its use;
- connector terminals should be clearly, unambiguously marked on the outside of the EPPG device. The markings should identify positive (+) and negative (−) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals;
- the labeling must list all pacing modes available in the device;
- labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching); and
- appropriate electromagnetic compatibility information must be included.

Table 1 shows how FDA believes that the risks to health identified in section V can be mitigated by the proposed special controls.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR EPPG DEVICES

Identified risk	Mitigation measures
Failure to Pace	Use Environment. EMC Testing. Electrical Safety Testing. Non-Clinical Performance Evaluation. Software Verification, Validation & Hazards Analysis. Labeling.
Improper High Rate Pacing	Use Environment. EMC Testing. Electrical Safety Testing. Non-Clinical Performance Evaluation. Software Verification, Validation & Hazards Analysis. Labeling.
Pacing at an Improperly Low Rate	Use Environment. EMC Testing. Electrical Safety Testing. Non-Clinical Performance Evaluation. Software Verification, Validation & Hazards Analysis. Labeling.
Improper Pacing Leading to Unwanted Stimulation.	Non-Clinical Performance Evaluation. Software Verification, Validation & Hazards Analysis. Labeling.
Micro/Macro Shock	Electrical Safety Testing. Non-Clinical Performance Evaluation. Labeling.

In addition, under § 801.109, the sale, distribution, and use of EPPG devices are restricted to prescription use. Prescription use restrictions are a type of general control in section 513(a)(1)(A)(i) of the FD&C Act. Also, under § 807.81, the device would continue to be subject to 510(k) notification requirements.

B. PSA Devices

FDA believes that the following special controls, together with general controls (including applicable prescription-use restrictions and continuing 510(k) notification requirements), are sufficient to mitigate the risks to health described in section V for single, dual, and triple chamber PSA devices:

1. Appropriate analysis/testing must validate EMC within a hospital environment.

2. Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

3. Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

- Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;
- mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;
- simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g. data storage, printing), and indicator(s) functionality under intended use conditions; and
- methods and instructions for cleaning the pulse generator and connection cables must be validated.

4. Appropriate software verification, validation, and hazard analysis must be performed.

5. Labeling must include the following:

- The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in its use;
- connector terminals should be clearly, unambiguously marked on the outside of the EPPG device. The markings should identify positive (+) and negative (−) polarities. Dual

chamber devices should clearly identify atrial and ventricular terminals. Triple chamber devices should clearly identify atrial, right ventricular, and left ventricular terminals;

- the labeling must list all pacing modes available in the device;
- labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching);
- labeling must limit the use of external pacing to the implant procedure; and
- appropriate electromagnetic compatibility information must be included.

Table 2 shows how FDA believes that the risks to health identified in section V can be mitigated by the proposed special controls.

TABLE 2—HEALTH RISKS AND MITIGATION MEASURES FOR PSA DEVICES

Identified risk	Mitigation measures
Misdiagnosis	Non-Clinical Performance Evaluation. Labeling.
Failure to Pace	Use Environment. EMC Testing. Electrical Safety Testing. Non-Clinical Performance Evaluation. Software Verification, Validation & Hazards Analysis. Labeling.
Improper High Rate Pacing	Use Environment. EMC Testing. Electrical Safety Testing. Non-Clinical Performance Evaluation. Software Verification, Validation & Hazards Analysis. Labeling.
Pacing at an Improperly Low Rate	Use Environment. EMC Testing. Electrical Safety Testing. Non-Clinical Performance Evaluation. Software Verification, Validation & Hazards Analysis. Labeling.
Improper Pacing Leading to Unwanted Stimulation.	Non-Clinical Performance Evaluation. Software Verification, Validation & Hazards Analysis. Labeling.
Micro/Macro Shock	Electrical Safety Testing. Non-Clinical Performance Evaluation. Labeling.

In addition, under § 801.109, the sale, distribution, and use of these single and dual chamber PSA devices are restricted to prescription use. Prescription use restrictions are a type of general controls in section 513(a)(1)(A)(i) of the FD&C Act. Also, under § 807.81, the device would continue to be subject to 510(k) notification requirements.

IX. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XI. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended authorizes FDA to issue orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this proposed order we are proposing to: (1) Revoke the requirements in § 870.3600 related to the classification of EPPG devices as class III devices and to codify the reclassification of EPPG devices into class II (special controls) and (2) codify the reclassification of PSA devices into class II (special controls).

XII. Proposed Effective Date

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

XIII. Comments

Comments already submitted to the docket (FDA–2011–N–0650) have been officially noted and do not need to be resubmitted. FDA will consider previous docket comments in issuing any final orders for these devices. Interested persons may submit either electronic comments regarding this document or the associated guidance 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. Class II Special Controls Draft Guidance Document: External Pacemaker Pulse Generator, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM275703.pdf.*
2. The panel transcript and other meeting materials for the September 11, 2013, Circulatory System Devices Panel are available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/CirculatorySystemDevicesPanel/ucm342357.htm.*
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13. Kratz, J. and J. Tyler, ''Clinical Experience with a New DDD External Pacemaker,'' *Pacing and Clinical Electrophysiology,* December; 16(12):2227–2234, 1993.
14. Nimetz, A. A., S. J. Shubrooks, A. M. Hutter, and R. W. DeSanctis, ''The Significance of Bundle Branch Block During Acute Myocardial Infarction,'' *American Heart Journal,* October; 90(4):439–444, 1975.
15. Pinneri, F., S. Frea, K. Najd, et al., ''Echocardiography-Guided Versus Fluoroscopy-Guided Temporary Pacing in the Emergency Setting: An Observational Study,'' *Journal of Cardiovascular Medicine* (Hagerstown), March; 14(3):242–246, 2013.
16. Siddons, H., ''Transvenous Long-Term Pacing With an External Pacemaker. What Are the Risks?'', *Pacing and Clinical Electrophysiology,* April; 1(2):163–165, 1978.
17. Voigtländer T., B, Nowak, P. Bärenfänger, et al., ''Feasibility and Sensing Thresholds of Temporary Single-Lead VDD Pacing in Intensive Care,'' *American Journal of Cardiology,* May 15; 79(10):1360–1363, 1997.

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 870.3600 is revised to read as follows:

§ 870.3600 External pacemaker pulse generator.

(a) *Identification.* An external pacemaker pulse generator (EPPG) is a prescription device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

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

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g. data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

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

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use; and

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the EPPG device. The markings should identify positive (+) and negative (-) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals; and

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching); and

(v) Appropriate electromagnetic compatibility information must be included.

■ 3. In Subpart D, add § 870.3605 to read as follows:

§ 870.3605 Pacing system analyzer.

(a) *Identification.* A pacing system analyzer (PSA) is a prescription device that combines the functionality of a pacemaker electrode function tester (§ 870.3720) and an external pacemaker pulse generator (EPPG) (§ 870.3600). It is connected to a pacemaker lead and uses a power supply and electronic circuits to supply an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and intracardiac R-wave potential. A PSA may be a single, dual, or triple chamber system and can simultaneously deliver pacing therapy while testing one or more implanted pacing leads.

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

(1) Appropriate analysis/testing must validate electromagnetic compatibility (EMC) within a hospital environment.

(2) Electrical bench testing must demonstrate device safety during intended use. This must include testing with the specific power source (i.e., battery power, AC mains connections, or both).

(3) Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:

(i) Testing must demonstrate the accuracy of monitoring functions, alarms, measurement features, therapeutic features, and all adjustable or programmable parameters as identified in labeling;

(ii) Mechanical bench testing of material strength must demonstrate that the device and connection cables will withstand forces or conditions encountered during use;

(iii) Simulated use analysis/testing must demonstrate adequate user interface for adjustable parameters, performance of alarms, display screens, interface with external devices (e.g. data storage, printing), and indicator(s) functionality under intended use conditions; and

(iv) Methods and instructions for cleaning the pulse generator and connection cables must be validated.

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

(5) Labeling must include the following:

(i) The labeling must clearly state that these devices are intended for use in a hospital environment and under the supervision of a clinician trained in their use;

(ii) Connector terminals should be clearly, unambiguously marked on the outside of the EPPG. The markings should identify positive (+) and negative (-) polarities. Dual chamber devices should clearly identify atrial and ventricular terminals. Triple chamber devices should clearly identify atrial, right ventricular, and left ventricular terminals;

(iii) The labeling must list all pacing modes available in the device;

(iv) Labeling must include a detailed description of any special capabilities (e.g., overdrive pacing or automatic mode switching);

(v) Labeling must limit the use of external pacing to the implant procedure; and

(vi) Appropriate electromagnetic compatibility information must be included.

Dated: September 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21814 Filed 9–12–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 41

[145A2100DD.AADD001000.A0E501010.999900]

RIN 1076–AF08

Grants to Tribally Controlled Colleges and Universities, Diné College, and Tribally Controlled Postsecondary Career and Technical Institutions

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of tribal consultation sessions.

SUMMARY: The Bureau of Indian Education provides financial and technical assistance to tribally controlled colleges and universities and Diné College. In collaboration with the American Indian Higher Education Consortium, we have prepared a discussion draft that updates the policies and procedures for administration and oversight of these assistance programs and revises regulatory language to conform to statutory amendments. This notice announces tribal consultation sessions and a comment period on the preliminary discussion draft.

DATES: Comments must be received by November 15, 2014. See the **SUPPLEMENTARY INFORMATION** section of this notice for dates of the tribal consultation sessions.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section of this notice for locations of the tribal consultation sessions and the Web site where the preliminary discussion draft is available. You may submit comments by either of the following methods:

—Federal Rulemaking Portal: *http://www.regulations.gov.* This rule is listed under the agency name ''Bureau of Indian Affairs'' and Docket ID ''BIA–2011–0002.''

—Mail or Hand-Delivery: Ms. Juanita Mendoza, Program Analyst, Bureau of Indian Education, U.S. Department of the Interior, 1951 Constitution Ave. NW., MS 312, Washington, DC 20240. Include ''1076–AF08'' on the cover of the submission.

FOR FURTHER INFORMATION CONTACT: Ms. Juanita Mendoza, Program Analyst, Bureau of Indian Education, U.S. Department of the Interior, 1951 Constitution Ave. NW., MS 312, Washington, DC 20240; or email to *juanita.mendoza@bie.edu.*

SUPPLEMENTARY INFORMATION: The BIE supports and encourages the establishment, operation, and improvement of tribally controlled colleges and universities (TCUs) to ensure continued and expanded educational opportunities for Indian students. The TCUs are both integral and essential to their communities, creating environments that foster American Indian culture, languages, and traditions. The TCUs serve a variety of people from young adults to senior citizens. The TCUs offer 358 total programs, including apprenticeships, diplomas, certificates, and degrees. These programs include 181 associate degree programs at 23 TCUs, 40 bachelor's degree programs at 11 TCUs, and 5 master's degree programs at 2 TCUs.

The BIE is revising the regulations at 25 CFR Part 41 and has prepared a preliminary discussion draft. Subpart B of the preliminary discussion draft concerns financial and technical assistance to tribal colleges and universities funded under the Tribally Controlled Colleges and Universities Assistance Act of 1978, as amended (25 U.S.C. 1801 et seq.). Subpart B does not concern financial assistance to Diné College or to tribally controlled postsecondary career and technical institutions. Subpart C of the