

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

*For devices regulated by CDRH:*  
Gregory Campbell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2110, Silver Spring, MD 20993-0002, 301-796-5750.

*For devices regulated by CBER:*  
Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**I. Background**

The guidance document is intended to provide guidance to those involved in designing clinical studies that support premarket submissions for medical devices and FDA staff who review those submissions. Although the Agency has articulated policies related to design of studies intended to support specific device types, and a general policy of tailoring the evidentiary burden to the regulatory requirement, the Agency has not attempted to describe the different clinical study designs that may be appropriate to support a device premarket submission, or to define how a sponsor should decide which pivotal clinical study design should be used to support a submission for a particular device. The guidance document describes different study design principles relevant to the development of medical device clinical studies that can be used to fulfill premarket clinical data requirements. The guidance is not intended to provide a comprehensive tutorial on the best clinical and statistical practices for investigational medical device studies.

A medical device pivotal study is a definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use. Evidence from one or more pivotal clinical studies generally serves as the primary basis for the determination of reasonable assurance of safety and effectiveness of the medical device of a premarket approval application (PMA) and FDA's overall risk-benefit assessment. In some cases, a PMA may include multiple studies designed to answer different scientific questions.

The guidance describes principles that should be followed for the design

of premarket clinical studies that are pivotal in establishing the safety and effectiveness of a medical device. Practical issues and pitfalls in pivotal clinical study design are discussed, along with their effects on the conclusions that can be drawn from the studies concerning safety and effectiveness.

In the **Federal Register** of August 15, 2011 (76 FR 50484), FDA announced the availability of the draft guidance. Interested persons were invited to comment by November 14, 2011. FDA considered the comments and revised the guidance, as appropriate.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on pivotal clinical investigations for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>. To receive "Device Considerations for Pivotal Clinical Investigations for Medical Devices," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1776 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This guidance 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 807, subpart E have been approved under 0910-0120; the collections of information in 21 CFR part 812 have been approved under

0910-0078; the collections of information in 21 CFR part 814 have been approved under 0910-0231.

**V. 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>.

Dated: November 1, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0001]

**Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on December 12, 2013, from 8 a.m. to 6:30 p.m.

*Location:* Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

*Contact Person:* Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring, MD 20993, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301 796-7047; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC

area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On December 12, 2013, during Session I, the committee will discuss and make recommendations regarding the classification of spinal sphere devices. These devices are spheres manufactured from metallic (e.g., cobalt chromium molybdenum) or polymeric (e.g., polyetheretherketone) materials. They are intended to be inserted between the vertebral bodies into the disc space from L3–S1 to help provide stabilization and to help promote intervertebral body fusion. During the arthrodesis procedure, they are to be used with bone graft. These devices are not intended for use in motion-sparing, non-fusion procedures.

Spinal sphere devices are considered preamendment devices because they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. Spinal sphere devices are currently regulated under the heading of "Intervertebral Fusion Device with Bone Graft, Solid-Sphere, Lumbar", Product Code NVR, as unclassified devices and reviewed under the 510(k) premarket notification authority. FDA is seeking committee input on the safety and effectiveness of spinal sphere devices and the regulatory classification for spinal sphere devices.

On December 12, 2013, during Session II, the committee will discuss and make recommendations regarding the reclassification petition received on November 20, 2012, from DEKA Research & Development Corp. requesting that FDA reclassify stair climbing wheelchairs (21 CFR 890.3890) from Class III to Class II. A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs. On June 12, 2013 (78 FR 35173), FDA issued a proposed order which, if made final, would reclassify stair-climbing wheelchairs as Class II subject to premarket notification (510(k)) and special controls. The petitioner has one stair-climbing wheelchair approved, the iBot (P020033), and it is indicated for the following: to provide indoor and

outdoor mobility in confined spaces, at an elevated height, climb curbs, ascend/descend stairs, traverse obstacles, travel over a wider variety of terrain, and negotiate uneven/inclined surfaces.

Stair-climbing wheelchairs are preamendment devices because they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. Stair-climbing wheelchairs are currently regulated as Class III devices. A call for premarket approval (PMA) applications was issued on April 13, 2000 (effective July 12, 2000) (65 FR 19834).

The committee's discussion will include recommendations regarding the regulatory classifications noted above. The committee will also discuss whether the proposed special controls are adequate to reasonably ensure the safety and effectiveness of stair-climbing wheelchairs.

On December 12, 2013, during Session III, the committee will discuss and make recommendations regarding the possible reclassification of mechanical wheelchairs (21 CFR 890.3850) from Class I, currently subject to premarket notification (510(k)), to Class II, subject to special controls. The mechanical wheelchairs are being considered for exemption from premarket notification (510(k)) requirements. A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. No proposed order has been issued for this proposed change in classification.

Mechanical wheelchairs are preamendment devices because they were in commercial distribution prior to May 28, 1976, when the Medical Device Amendments became effective. Mechanical wheelchairs are currently regulated as Class I devices that are subject to premarket notification (510(k)) requirements (48 FR 53041).

The committee will discuss whether general and/or special controls are appropriate to demonstrate a reasonable assurance of safety and effectiveness of mechanical wheelchairs and whether, if reclassified to Class II, these devices should be exempt from premarket notification (510(k)) requirements.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is

available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 21, 2013. Oral presentations will be scheduled between approximately 9:15 a.m. and 9:35 a.m. for Session I and between approximately 2:40 p.m. and 3:20 p.m. for Session II and Session III. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of the proposed participants, and an indication of the approximate time requested to make their presentation on or before November 13, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 14, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, [James.Clark@fda.hhs.gov](mailto:James.Clark@fda.hhs.gov) or 301-796-5293, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 4, 2013.  
**Jill Hartzler Warner,**  
*Acting Associate Commissioner for Special Medical Programs.*  
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**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request**

**AGENCY:** Health Resources and Services Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received within 30 days of this notice.

**ADDRESSES:** Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA\_submission@omb.eop.gov* or by fax to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the

HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

**Information Collection Request Title: Scholarships for Disadvantaged Students Application and Performance Report (SDSPR); OMB No. 0915-0149—Revision**

*Abstract:* The purpose of the Scholarships for Disadvantaged Students (SDS) Program is to promote diversity among health profession students and practitioners by providing funds to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions and nursing programs.

To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups (section 737(d)(1)(B) of the PHS Act). A school must meet the eligibility criteria to demonstrate that the program has achieved success based on the number and/or percentage of disadvantaged students who graduate from the school. In awarding SDS funds to eligible schools, funding points must be given to schools based on the proportion of graduate students practicing in primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities (section 737(c) of the PHS Act).

Information collected from the SDS application and SDS report is needed by the Department to determine whether applicant schools meet the statutory and

regulatory requirements, to determine eligibility for program participation, and to establish priority points for funding. Applicant schools are requested to complete an application for each discipline or program. Data are provided on numbers of full-time student enrollment and the applicant schools' racial/ethnicity data, disadvantaged full-time enrollment by class year, full-time students graduated, full-time disadvantaged students graduated, and full-time graduates serving in Medically Underserved Communities. Numbers of full-time graduates serving in primary care must be provided only for schools of medicine, osteopathic medicine, dentistry, nursing (graduate degree program), physician assistants, dental hygiene, and mental and behavioral health.

Each school will determine the eligibility of students based on financial need and whether a student is from a disadvantaged background.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS**

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
SDS Application Program Specific form .....	400	1	400	13	5,200
SDS Performance Report Form .....	99	1	99	24	2,376
Total .....	499	.....	499	.....	7,576