DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–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 Wednesday, April 20, 2016, from 8 a.m. to 6 p.m.

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

Contact Person: S.J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, rm. 1643, 10903 New Hampshire Ave., Silver Spring, MD 20993, email: *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: The Committee will discuss, make recommendations, and vote on the premarket approval application for the Cartiva Synthetic Cartilage Implant (SCI), sponsored by Cartiva, Inc. The Cartiva Synthetic Cartilage Implant (SCI) is an organic polymer-based biomaterial to mimic biologic cartilage. The device is to be indicated for treatment of degenerative and post-traumatic arthritis in the first metatarsophalangeal joint in the presence of good bone stock along with the following clinical conditions: hallux valgus or hallux limitus, hallux rigidus, and an unstable or painful metatarsophalangeal joint.

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 April 13, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 proposed participants, and an indication of the approximate time requested to make their presentation on or before April 5, 2016. 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 April 6, 2016.

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 disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at 301–796–5966 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: February 29, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–04927 Filed 3–4–16; 8:45 am]

BILLING CODE 4164–01–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

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). 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. To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office at (301) 443–1984.

DATES: *Deadline:* Comments on this ICR should be received no later than April 6, 2016.

ADDRESSES: Submit your comments to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Health Center Controlled Networks (OMB No. 0915–0360) Extension.

Abstract: One goal of the Health Resources and Services Administration (HRSA) is to ensure that all Health Center Program grantees effectively implement health information technology (HIT) systems that enable all providers to adopt and implement HIT, including Electronic Health Records (EHRs); to become meaningful users of EHRs and use HIT systems to increase access to care, improve quality of care, and reduce the costs of care delivered.

The Health Center Controlled Network (HCCN) Program serves as a major component of HRSA's HIT initiative to support these goals. The HCCN model focuses on the integration of certain functions and the sharing of skills, resources, and data to improve health center operations and care provision, and generating efficiencies and economies of scale. Through this grant, HCCNs will provide support for the adoption and implementation of HIT, including meaningful use of EHRs, to improve the quality of care provided by existing Health Center Program grantees (*i.e.,* Section 330 funded health centers) by engaging in the following program components:

- *Adoption and Implementation:* Assist participating health centers with effectively adopting and implementing certified EHR technology.
- *Meaningful Use:* Support participating health centers in meeting Meaningful Use requirements and accessing incentive payments under the Medicare and Medicaid Electronic Health Records Incentive Programs.
- *Quality Improvement (QI):* Advance participating health centers' QI initiatives to improve clinical and operational quality, including their obtaining of Patient Centered Medical Home (PCMH) recognition.

HRSA collects and evaluates network outcome measures. HRSA requires that HCCNs report such measures to HRSA in annual work plan updates as part of their annual, non-competing continuation progress reports through an electronic reporting system. The work plan includes information on grantees' plans and progress on the following:

- Adoption and Implementation of HIT (including EHR);
- Attainment of Meaningful Use Requirements; and
- Improvement of quality measures (*e.g.,* Healthy People 2020 clinical quality measures, PCMH recognition status, etc.).

The annual, non-competing continuation progress reports describe each grantee's progress in achieving key activity goals such as quality improvement, data access and exchange, efficiency and effectiveness of network services, and the ability to track and monitor patient outcomes, as well as emerging needs, challenges and barriers encountered customer satisfaction, and plans to meet goals for the next year. Grantees submit their work plan updates and annual, non-competing continuation progress reports each fiscal year of the grant; the submission and subsequent HRSA approval of each report triggers the budget period renewal and release of each subsequent year of funding.

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.

The annual estimate of burden is as follows:

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Work Plan Update	43	1	43	10.9	468.7
Annual Progress Report	43	1	43	44.5	1913.5
Total	86				2382.2

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–04984 Filed 3–4–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Bioreactors for Reparative Medicine (STTR).

Date: March 24, 2016.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Tony L Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, *creazzotl@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Bioreactors for Reparative Medicine (SBIR).

Date: March 24, 2016.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Tony L Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, *creazzotl@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 1, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–04915 Filed 3–4–16; 8:45 am]

BILLING CODE 4140–01–P