

submitter may request status reports every 30 days following the initial status request. To obtain a 510(k) status report, the submitter should complete the status request form, Form FDA 3541,

and fax it to the Center for Devices and Radiological Health office identified on the form.

In the **Federal Register** of November 18, 2016 (81 FR 81772), FDA published a 60-day notice requesting public

comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| Activity and 21 CFR part/section | Form FDA No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|--------------|-----------------------|------------------------------------|------------------------|-----------------------------|----------------|
| 510(k) submission (807 subpart E) | | 3,900 | 1 | 3,900 | 79 | 308,100 |
| Summary cover sheet (807.87) | 3514 | 1,956 | 1 | 1,956 | .5 (30 minutes) | 978 |
| Status request (807.90(a)(3)) | 3541 | 218 | 1 | 218 | .25 (15 minutes) | 55 |
| Standards (807.87(d) and (f)) | 3654 | 2,700 | 1 | 2,700 | 10 | 27,000 |
| 510(k) statement (807.93) | | 225 | 10 | 2,250 | 10 | 22,500 |
| Total | | | | | | 358,633 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 13, 2017.
Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2017-05300 Filed 3-16-17; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0117]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Information About Pediatric Uses of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 17, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX:

202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0762. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0762—Extension

The guidance document entitled “Providing Information About Pediatric Uses of Medical Devices—Guidance for Industry and Food and Drug Administration Staff” suggests that applicants who submit certain medical device applications include, if readily available, pediatric use information for diseases or conditions that the device is being used to treat, diagnose, or cure that are outside the device’s approved or proposed indications for use, as well as an estimate of the number of pediatric patients with such diseases or

conditions. The information submitted will allow FDA to identify pediatric uses of devices outside their approved or proposed indication for use to determine areas where further pediatric device development could be useful. This recommendation applies to applicants who submit the following applications: (1) Any request for a humanitarian device exemption submitted under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)); (2) any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act (21 U.S.C. 360e); and (3) any product development protocol submitted under section 515 of the FD&C Act.

Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20 percent of respondents submitting information required by section 515A of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

In the **Federal Register** of December 5, 2016 (81 FR 87575), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| Description | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Uses outside approved indication | 148 | 1 | 148 | 0.5 (30 minutes) | 74 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-05302 Filed 3-16-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the National Advisory Committee on Rural Health and Human Services (NACRHHS). This meeting will be open to the public. Information about NACRHHS and the agenda for this meeting can be obtained by accessing the following Web site: <http://www.hrsa.gov/advisorycommittees/rural>.

DATES:

April 10, 2017, 9:00 a.m.–5:00 p.m. EDT
 April 11, 2017, 8:30 a.m.–5:00 p.m. EDT
 April 12, 2017, 9:00 a.m.–11:00 a.m. EDT

ADDRESSES: This meeting will be held in-person at the Hyatt Place Hotel. The address for the meeting is 400 E Street SW., Washington, DC 20024. The meeting will also be held in-person at the Hubert H. Humphrey Building, located at 200 Independence Avenue SW., Washington, DC, on April 11.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, Administrative Coordinator, NACRHHS, HRSA, 5600 Fishers Lane, Room 17W41C, Rockville, Maryland 20857, telephone (301) 443-0835, fax (301) 443-2803 or by email at shirsch@hrsa.gov.

Persons interested in attending any portion of the meeting, including the April 11 portion at the Hubert H. Humphrey Building, should contact Adam Cohen at the Federal Office of Rural Health Policy before April 7, 2017

by telephone at (301) 443-0445 or by email at acohen@hrsa.gov.

SUPPLEMENTARY INFORMATION:

NACRHHS provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

The meeting on Monday, April 10, will be called to order at 9:00 a.m. by the Chairperson of the Committee, the Honorable Ronnie Musgrove. The Committee will examine the current delivery of health care and human services in rural areas. The day will conclude with a period of public comment at approximately 5:00 p.m.

The Committee will visit the Hubert H. Humphrey Building on Tuesday, April 11. The day will conclude with a period of public comment at approximately 5:00 p.m.

The Committee will meet to summarize key findings and develop a work plan for the next quarter and its future meeting on Wednesday, April 12, at 9:00 a.m., at the Hyatt Place Hotel.

The Hubert H. Humphrey Building requires a security screening on entry. To facilitate your access to the building, please contact Adam Cohen before April 7, 2017 at (301) 443-0445. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Adam Cohen by telephone at (301) 443-0445 or by email at acohen@hrsa.gov at least 10 days prior to the meeting.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017-05298 Filed 3-16-17; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Board of Scientific Advisors, March 21, 2017, 08:30 a.m. to 05:00 p.m., National Institutes of Health, 31

Center Drive, Building 31, Conference Room 10, Bethesda, MD, 20892 which was published in the **Federal Register** on March 3, 2017, 82 FR 12459.

The meeting notice is amended to change the meeting start and end time to 9:00 a.m. to 4:30 p.m. The date and location remain the same. The meeting is open to the public.

Dated: March 14, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-05391 Filed 3-16-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

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 meeting.

The meeting 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 Human Genome Research Institute Special Emphasis Panel: Gabriella Miller Kids First.

Date: April 24, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Grand Thomas Boardroom, 2350 M Street NW., Washington, DC 20037.

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Ste. 4076, MSC 9306, Bethesda, MD 20892-9306, 301-402-0838, barbara.thomas@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)