submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden on the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure

The draft guidance suggests that applicants who submit certain medical device applications include, if readily available, pediatric use information for diseases or conditions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 in order 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 FD&C Act;

2. Any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act;

3. Any product development protocol submitted under section 515 of the FD&C Act.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Description	Number of respondents	Annual frequency per response	Total annual responses	Hours per responses	Total hours
Uses outside approved indication	148	1	148	.5	74
Totals	148		148		74

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

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.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 814 (21 CFR part 814), subpart B have been approved under OMB control number 0910–0231 and the collections of information in part 814, subpart H have been approved under OMB control number 0910–0332.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that requires, under section 515A of the FD&C Act, the submission of readily available information on any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients.

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: February 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03652 Filed 2–15–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Neonatal Subcommittee of the Pediatric 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: Neonatal Subcommittee of the Pediatric 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 Friday, March 15, 2013, from 8 a.m. to 4 p.m.

Location: Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910, 301–589–0800, *www.sheratonsilverspring.com.*

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301–796–0885, *walter.ellenberg@fda.hhs.gov,* 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 Food and Drug Administration Safety and Innovation Act identified the need to expand current pediatric science to include the neonatal population. On March 15, 2013, FDA's Neonatal Subcommittee of the Pediatric Advisory Committee will convene a non-voting session to establish an operational framework for the subcommittee as well as discuss and comment on nonspecific matters pertaining to neonatology. The subcommittee will also comment on ways to approach the challenges and identify different programmatic strategies for advancing the knowledge necessary to developing neonatal regulatory science.

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 March 7, 2013. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 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 February 27, 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 February 28, 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 Walter Ellenberg, 301–796–0885, 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 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–03613 Filed 2–15–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The National Health Service Corps Site Retention Assessment Questionnaire (OMB #)—New

The National Health Service Corps (NHSC) provides health professionals with loan repayment and scholarships in return for their service to underserved areas. The NHSC's mission is to improve access to primary care, which is supported by clinicians who remain in their sites well beyond their contracted periods of service. However, many sites are unaware of their influence and impact on clinician retention levels. The purpose of this project is to gather survey information from administrative officials at NHSC-approved sites that will guide NHSC initiatives and assist sites in improving their retention outcomes. The survey will ask site administrators to rate: (1) How difficult it is to retain clinicians; (2) their general attitudes about the feasibility of good retention and awareness of its principles; (3) their practices' current approaches to promoting retention; (4) various aspects of their practices' organizational culture and administrative style; and (5) their sites' interest in and preferred ways of learning how to bolster retention. Survey data will be gathered anonymously and presented in-aggregate, to promote administrators' participation and full disclosure.

The annual estimate of burden is as follows: