

prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

**Agenda:** On February 28, 2012, the committee will meet in open session to hear an overview of the research program in the Laboratory of Mycobacterial Diseases and Cellular Immunology, Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA. The committee will then discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2012 to 2013 influenza season. On February 29, 2012, the committee will discuss licensure pathways for pandemic influenza vaccines.

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 link.

**Procedure:** On February 28, 2012, between approximately 8 a.m. and 9:45 a.m. and between approximately 10:15 p.m. and 4 p.m., the meeting is open to the public. On February 29, 2012, the entire meeting is open to the public. 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 February 21, 2012. Oral presentations from the public will be scheduled between approximately 2:40 p.m. and 3:10 p.m. on February 28, 2012, and between approximately 10:45 a.m. and 11:15 a.m. on February 29, 2012. 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 13, 2012. 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 14, 2012.

**Closed Committee Deliberations:** On February 28, 2012, between approximately 9:45 a.m. and 10:15 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

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 Donald W. Jehn or Denise Royster 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: January 17, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-1456 Filed 1-24-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0754]

#### Pediatric Medical Devices; Public Workshop; Reopening of Comment Period

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

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until March 5, 2012, the comment period for the notice entitled "Pediatric Medical Devices; Public Workshop; Request for Comments" that appeared in the **Federal Register** of Tuesday, November 1, 2011 (76 FR 67463). In the notice, FDA announced a public workshop to consider factors affecting the use of scientific research data to support pediatric medical device efficacy claims. This is part of an on-going effort to address the ways scientific research data can be used to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance; the scientific and regulatory limitations and issues of using existing scientific research data to support pediatric effectiveness claims and pediatric indication approvals for medical devices; and methods to overcome the pitfalls and data gaps, including statistical approaches and modeling. The agency is taking this action to allow interested persons additional time to submit comments on the use of scientific research data, including published scientific literature, to support and establish pediatric indications for medical devices.

**DATES:** Submit either electronic or written comments by March 5, 2012.

**ADDRESSES:** Submit electronic comments 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.

#### FOR FURTHER INFORMATION CONTACT:

Carol Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5437, Silver Spring, MD 20993-0002, (301) 796-3241, [Carol.Krueger@fda.hhs.gov](mailto:Carol.Krueger@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In 2007, Congress passed the Pediatric Medical Device Safety and Improvement

Act (the Act). The Act addresses pediatric device needs by providing financial incentives for development, production, approval and distribution of new devices for rare and unmet pediatric needs; allowing for a pediatric device approval pathway that permits extrapolation of adult effectiveness data to support a pediatric indication based on similar course of the disease or condition or a similar effect of the device; and providing grants to pediatric device consortia that provide technical support and assistance to pediatric device innovators.

FDA held a public workshop on December 5, 2011, to support FDA's efforts to define pathways for approving pediatric device indications by leveraging available scientific research data. An important, but not the only, focus was a discussion of how to determine when it is appropriate to use, and how to use, existing scientific research data to determine pediatric effectiveness based on a similar course of a disease or condition or a similar effect of a device on adults and similar extrapolation between pediatric subpopulations.

The demand by health care professionals and consumers for safe and effective pediatric medical devices continues to steadily increase. Pediatric medical devices treat or diagnose diseases and conditions occurring from birth through the 21st year of life. Some devices are designed specifically for pediatric use, while others are adopted from specific adult device applications or produced for more general use.

Designing pediatric medical devices can be challenging; children are often smaller and more active than adults; body structures and functions change throughout childhood, and children may be long-term device users—bringing new concerns about device longevity and long-term exposure to implanted materials. The current medical device market for children has a higher demand than supply. FDA is committed to supporting the development and availability of safe and effective pediatric medical devices.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments on the topics discussed at the Public Workshop.

## II. Topics Discussed at the Public Workshop

The public workshop discussed the following topic areas:

1. The use of existing scientific research data to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance,
2. The scientific and regulatory limitations and issues with the use of existing scientific research data, and
3. The methods to overcome the pitfalls and data gaps, including statistical approaches and modeling.

## III. Transcripts

Please be advised that a transcript of the public workshop is available at <http://www.regulations.gov> at FDA docket number FDA-2011-N-0754. The transcript may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript is also available online at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm278053.htm>.

## IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

Dated: January 19, 2012.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2012-1443 Filed 1-24-12; 8:45 am]

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## 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](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (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 Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Forms (OMB No. 0915-0044)—[Extension]**

The HPSL Program provides long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL program provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, or associate, baccalaureate, or graduate degrees in nursing.

Participating HPSL and NSL schools are responsible for determining the eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The Deferment Form (Deferment-HRSA Form 519) provides the schools with documentation of a borrower's eligibility for deferment. The Annual Operating Report (AOR-HRSA Form 501) provides the Federal Government with information from participating schools (schools that are no longer granting loans but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due to the Federal Government are returned) relating to HPSL and NSL program operations and financial activities.

The annual estimate of burden is as follows: