

length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. FDA uses the information provided in the request to determine whether to grant the petition for stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action.

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the FD&C Act sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to Division of Dockets Management), an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion represents the formal position of FDA on a matter of general applicability. When making a request, the petitioner

must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Respondents to this collection of information are interested persons seeking an advisory opinion from the Commissioner on the Agency's formal position for matters of general applicability.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.30 .....	207	1	207	24	4,968
10.33 .....	4	1	4	10	40
10.35 .....	5	1	5	10	50
10.85 .....	4	1	4	16	64
<b>Total</b> .....					<b>5,122</b>

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

The burden estimates for this collection of information are based on Agency records and experience over the past 3 years. In 2010, FDA received approximately 207 petitions (§ 10.30), 4 administrative reconsiderations of action (§ 10.33), 5 administrative stays of action (§ 10.35), and 4 advisory opinions (§ 10.85).

Dated: August 30, 2011.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2011-22857 Filed 9-6-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0002]

**Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Vaccines and Related Biological Products 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 November 16, 2011, from 8 a.m. to approximately 5:30 p.m.

*Location:* Hilton Washington DC/ Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910, 301-589-5200. For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at <http://fda.yorkcast.com/webcast/Viewer/?peid=75dcd91903204870aff160cb9d5528151d>.

*Contact Person:* Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the 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 November 16, 2011, the committee will meet in open session to hear an overview of the research program in the Laboratory of Method Development, Division of Viral

Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA. The committee will also hear an update on the evaluation of Gullian-Barre Syndrome after Influenza Vaccine among Medicare population, 2010-2011. The committee will then discuss and make recommendations on the safety and immunogenicity (surrogate endpoint) of Pneumococcal 13-valent conjugate vaccine (Diphtheria CRM197 Protein) in adults aged 50 years and older using an accelerated approval regulatory pathway.

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 November 16, 2011, from 8 a.m. to approximately 9:30 a.m. and from 10:15 a.m. to approximately 5:30 p.m., the 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 November 9, 2011. Oral presentations from the public will be scheduled between approximately 3:30 p.m. and

4:30 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 November 1, 2011. 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 2, 2011.

*Closed Committee Deliberations:* On November 16, 2011, 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 program in the Laboratory of Method Development 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: August 31, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy*

[FR Doc. 2011-22766 Filed 9-6-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

#### Immunology Devices Panel of the Medical Devices Advisory Committee: Notice of Postponement of Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the meeting of the Immunology Devices Panel of the Medical Devices Advisory Committee scheduled for October 14, 2011. The meeting was announced in the *Federal Register* of August 9, 2011 (76 FR 48871). The meeting is postponed so that FDA can review and consider additional information that was submitted. Future meeting dates will be announced in the *Federal Register*.

**FOR FURTHER INFORMATION CONTACT:** Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1613, Silver Spring, MD 20993-0002, 301-796-6639, *e-mail:* [shanika.craig@fda.hhs.gov](mailto:shanika.craig@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

Dated: August 31, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

**AGENCY:** National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), HHS.

**ACTION:** 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

**SUMMARY:** As part of a Federal Government-wide effort to streamline the process to seek feedback from the

public on service delivery, NICHD has submitted a Generic Information Collection Request (Generic ICR): "Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery" to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

**DATES:** Comments must be submitted within 30 days after publication in FR.

**ADDRESSES:** Written comments may be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by E-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov), or by fax to 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** To request additional information, please contact Ms. Jamelle Banks, Public Health Analyst, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland 20892, or call a non-toll free number (301) 496-1877 or E-mail your request, including your address to [banksj@mail.nih.gov](mailto:banksj@mail.nih.gov).

#### **SUPPLEMENTARY INFORMATION:**

*Title:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

*Abstract:* The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over