

regarding their request to speak by September 2, 2011.

Closed Committee Deliberations: On September 20, 2011, between approximately 10:15 a.m. and 10:45 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/ucm11462.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: July 18, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-18506 Filed 7-21-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Risk Communication 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: Risk Communication 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 August 15, 2011, from 8 a.m. to 5 p.m. and August 16, 2011, from 8 a.m. to 2 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You", click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Lee L. Zwanziger, Office of Policy, Planning and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3278, Silver Spring, MD 20993, 301-796-9151, FAX: 301-847-8611, *e-mail:* RCAC@fda.hhs.gov, 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 August 15, 2011, the Committee will discuss challenges of communicating about evolving methodology in the attribution of foodborne illness. Estimating the number of illnesses, hospitalizations, and deaths caused by major pathogens is the first step in the development of disease prevention strategies. Estimating the proportions of these illnesses due to specific food sources (food source attribution) is a necessary second step towards identifying the sources that cause substantial preventable human illness and measuring progress toward public health goals resulting from public health interventions applied to those food sources. Consequently, FDA, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture/Food Safety Inspection Service have begun a joint initiative, called the Interagency Food Safety Analytics Collaboration (IFSAC), to improve our collective understanding of source attribution of infections to specific foods and settings. While the

IFSAC works to improve methodology, we are also committed to keeping stakeholders informed and engaged, and are seeking advice about how to communicate most effectively. On August 16, 2011, the Committee will present "Communicating Risks and Benefits: An Evidence-Based User's Guide." This volume is the result of work, as discussed in previous meetings, by current and former members of the Risk Communication Advisory Committee.

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: 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 August 10, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on August 15, 2011, and 10:30 a.m. and 11:30 a.m. on August 16, 2011. 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 August 2, 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 August 3, 2011. Interested persons can also log on to <https://collaboration.fda.gov/rcac/> to hear and see the proceedings.

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Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 18, 2011.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-18507 Filed 7-21-11; 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, e-mail 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 Agency functions; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) the ways to enhance quality, utility, and clarity of the information to be collected; and (d) the ways to minimize the burden of the collection of information on respondents, through the use of automated collection techniques or other forms of information technology.

Proposed Project: ADAP Data Report—[NEW]

HRSA's AIDS Drug Assistance Program (ADAP) is funded through The Ryan White HIV/AIDS Program, Part B, Title XXVI of the Public Health Service Act, which provides grants to states and territories. ADAP provides medications for the treatment of HIV/AIDS. Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments.

Each of the 50 states, the District of Columbia, Puerto Rico, and several territories receive ADAP grants. As part of the funding requirements, ADAP grantees currently submit quarterly reports concerning aggregate information on patients served, pharmaceuticals prescribed, pricing, as

well as other sources of support to provide AIDS medication treatment, eligibility requirements, cost data, and coordination with Medicaid; however, aggregate data cannot be analyzed with the detail that is required to assess quality of care or to sufficiently account for the use of Ryan White HIV/AIDS Program Funds.

To address this limitation, HRSA's HIV/AIDS Bureau (HAB) is developing a client-level data system for ADAP grantees called the ADAP Data Report (ADR). The ADR consists of a grantee report and a client-level data file that will be submitted once every six months. Data collected through the ADR: Will enable HAB to answer specific questions about the utility of ADAP; will more precisely address program needs; and will monitor program performance.

Discussions were held with nine volunteer grantee agencies representing a variety of ADAP models, as a basis for the burden estimates for the ADR that are included. These burden estimates are presented in two tables. The first table represents the estimated burden for the first year, including the estimated time to adjust existing or develop new data collection systems to collect the elements that HAB is requesting. In the first year, grantees will be required to report the grantee and client reports twice. Therefore, the total number of grantees (57) is multiplied by the total number of times that each grantee must submit the specified report (2) to arrive at the total responses in a one year period (114). This total is multiplied by the number of hours to complete each report for each six month submission to calculate the total burden hours.

TABLE 1—ESTIMATE OF BURDEN FOR THE FIRST YEAR

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Grantee Report	57	2	114	12.50	1,425.00
Client Report	57	2	114	34.19	3,897.66
Data Collection System	57	1	57	826.00	47,082.00
Total	52,404.66

The second table represents the estimated burden for subsequent years. Given that data collection system updates only impact the first six month reporting period, it is not included in the subsequent years' total burden. The

grantee report burden remains unchanged, as the submission is consistent with current reporting requirements. The client report burden will decrease slightly in subsequent years as grantees become more

proficient with reporting client level data, based on feedback they receive, as well as technical assistance resources that HRSA will provide.