

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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

**Science Advisory Board to the National Center for Toxicological Research; 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:* Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

*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 8, 2011, from 8:15 a.m. to 5:30 p.m. and on November 9, 2011, from 8:30 a.m. to 1 p.m.

*Location:* NCTR SAB Conference Room B-12, 3900 NCTR Rd., Jefferson, AR 72079.

*Contact Person:* Margaret Miller, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 2208, Silver Spring, MD. 20993-0002, 301-796-8890, 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 8, 2011, the NCTR Director will welcome the participants and provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will then briefly review the subcommittee report on the Division of Neurotoxicology, which was adopted by the full committee at the last meeting. The Director of the Division of Neurotoxicology will provide a response to the report, noting the changes that

have been implemented based on the recommendations in the report.

A representative from FDA's Office of Science will present the Agency's Regulatory Science Strategic Plan and speak about the Agency's Medical Countermeasure Initiative.

The Directors for the Division of Microbiology and the Division of Personalized Nutrition and Medicine will update the SAB on the major research accomplishments of the past year, the important implications of their findings for FDA, and the research direction of the division, including issues requiring input from the Committee. The SAB will then discuss the research direction and provide advice on the state of the science, future research directions, and impact of the findings on the public health.

The Center representatives from the Center for Veterinary Medicine and the Center for Food Safety and Applied Nutrition will describe their Center's regulatory mandate, public health mission, and strategic research needs, and discuss opportunities for collaboration to help address these needs. This information will be considered by NCTR's SAB in their recommendations for the future direction of NCTR's research activities. Next, a member of the SAB will present future research needs in the area of regulatory science for personalized nutrition.

Following the public session, the SAB will hear a presentation by the representative from the National Toxicology Program (NTP) on the current and future research collaborations between the National Institute of Environmental Health Sciences (NIEHS) and the NCTR. This presentation will be followed by an update from NCTR's Office of Science Coordination on the NTP studies being conducted at NCTR and those studies that will commence during the next year.

Next, the Chair of the Nanotechnology Core Facility Subcommittee will present an overview of the Nanotechnology Core Facility and subcommittee report. On August 16-17, 2011, the subcommittee convened to conduct an in-depth review of the NCTR/ORA Nanotechnology Core Facility. The Nanotechnology Core Facility is jointly sponsored by FDA's NCTR and Office of Regulatory Affairs, and NIEHS/NTP to support nanotechnology-related scientific studies through the characterization and detection of nanomaterials in toxicology studies and to develop analytical methods to accurately monitor nanotechnology-based FDA-regulated products. Representatives from FDA's

Office of the Commissioner and product Centers, as well as a representative from the NTP/NIEHS, participated in the evaluation. The site visit report will be presented to the full Committee and then open for discussion by all participants before a vote for adoption by the full SAB. All members of the NCTR SAB and the Center representatives will have an opportunity to comment on the Nanotechnology Core Facility Subcommittee report.

Following consideration of the Nanotechnology Core Facility Subcommittee Review report, a member of the SAB will present a vision for research needs to advance regulatory science in the area of pharmaceuticals.

On November 9, 2011, the Center representatives from the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research will describe their Center's regulatory mandate, public health mission, and strategic research needs; and discuss opportunities for collaboration to help address these needs. Again, this information will be considered by NCTR's SAB in their recommendations for the future direction of NCTR's research activities.

The Directors for the Division of Biochemical Toxicology and the Division of Systems Biology will update the SAB on the major research accomplishments of the past year, the important implications of the findings for FDA, and the research direction of the division, including issues needing input from the Committee. The SAB will then discuss the research direction and provide advice on the state of the science, future research directions, and impact of the findings on the public health.

NCTR's Center Director will discuss research priorities, alignment of NCTR with the Agency's regulatory science initiative, and the strategic focus for future research at NCTR.

The Center representative from the Center for Devices and Radiological Health and the Center for Tobacco Products will present their regulatory mandate, public health mission, and strategic research needs; and discuss opportunities for collaboration to help address these needs. Again, this information will be considered by NCTR's SAB in their recommendations for the future direction of NCTR's research activities.

The Director for the Division of Genetic and Molecular Toxicology will update the SAB on the major research accomplishments of the past year, the important implications of the findings for FDA, and the research direction of the division, including issues needing

input from the Committee. The SAB will then discuss the research direction and provide advice on the state of the science, future research directions, and impact of the findings on the public health.

Following an open discussion of all the information presented, the open session of the meeting will close so that the SAB members can discuss personnel issues at NCTR.

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 8, 2011, from 8:15 a.m. to 4:20 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 October 28, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 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 October 20, 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 October 21, 2011.

**Closed Committee Deliberations:** On November 9, 2011, 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)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

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 Margaret Miller 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: October 11, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-26891 Filed 10-17-11; 8:45 am]

**BILLING CODE 4160-01-P**

## 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, National Institute on Drug Abuse (NIDA), 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, NIDA 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 Genevieve deAlmeida-Morris, Health Research Evaluator, Office of Science Policy and Communications, National Institute on Drug Abuse, 6001 Executive Boulevard, Bethesda, MD 20892-9557, or call non-toll-free number (301) 594-6802 or E-mail your request, including your address to [dealmeig@nida.nih.gov](mailto:dealmeig@nida.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 time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be