that more accurately assess the safety and health hazards of chemicals and products and that refine (less pain and distress), reduce, or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 2851–2, 2851–5 [2000]), available at http://iccvam.niehs.nih.gov/about/PL106545.htm established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and coordinates international validation studies. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM, guidelines for nomination of test methods for validation studies, and guidelines for submission of test methods for ICCVAM evaluation are available at http://iccvam.niehs.nih.gov.


John R. Bucher,
Associate Director, National Toxicology Program.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting, in conjunction with the National Institutes of Health (NIH), to solicit comments from interested persons on how the agencies can more effectively collaborate to advance the translation of biomedical research discoveries into approved diagnostics and therapies as well as promote science to enhance the evaluation tools used for regulatory review. A newly formed NIH–FDA Joint Leadership Council will help ensure that regulatory considerations form an increasing component of biomedical research planning, and that the latest science is integrated into the regulatory review process.

DATES: The public meeting will be held on June 2, 2010, from 8:30 a.m. to 12:30 p.m. Persons interested in attending the meeting must register by Wednesday, May 26, 2010, at 5 p.m. e.s.t. (see section III of this document). Submit written or electronic comments by Wednesday, May 26, 2010, at 5 p.m. e.s.t.

ADDRESSES: The public meeting will be held at FDA, 10903 New Hampshire Ave., Bldg. 31, rm. 1503C, Silver Spring, MD 20993–0002.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All comments should be identified with the docket number found in brackets at the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rakesh Raghuwanshi, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4283, Silver Spring, MD 20993–0002, 301–796–4769, FAX: 301–847–8617, e-mail: rakesh.raghuwanshi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

With the dramatic breakthroughs occurring in biomedical research discovery, new public health challenges on the rise, an ever-changing economic landscape resulting from globalization, and the prospect for fundamental changes to healthcare delivery in the United States, there is a pressing need for greater collaboration between FDA and NIH. Both NIH and FDA have the goals of translating science discoveries into medical products and therapies, and both NIH and FDA have important roles and contributions to make towards these efforts. To address these important areas of common interest, NIH and FDA announced a new partnership effort that includes, among other initiatives, the regulatory science program and the NIH–FDA Joint Leadership Council.

The NIH–FDA Joint Leadership Council provides a forum for the leadership of both agencies to: (1) Work together on strategic planning at a high level; (2) stimulate an enhanced culture of collaboration between the agencies at all levels; and (3) further coordinate and target efforts to promote promising new therapies using the latest technological advances, such as stem cell biology, biomarkers, and computational sciences. NIH and FDA plan to work jointly to address the gap between biomedical research discoveries and new medical products. They can create new programs to support development of innovative therapies and promote personalized medicine, utilizing new clinical trial design strategies and regulatory review processes incorporating the use of genetic or other biomarkers and information technologies. These activities will also support postmarketing and/or other population-based surveys for safety assessments. Overall, there are many new avenues for NIH and FDA to explore such that we can deliver safer and more effective treatments faster.

II. Scope of the Meeting

FDA and NIH are interested in receiving comments from the public on the regulatory considerations that should be an integral part of the biomedical research program development and scientific tools or approaches that would enhance the ability to evaluate new medical products. The comments should focus on ways in which NIH and FDA can partner to promote interdisciplinary biomedical research through scientific exchange and new programs designed to advance innovation and development of new therapies incorporating many of the latest basic research discoveries.

Suggestions about the ways FDA and NIH can work together to promote an integrated biomedical research agenda including regulatory review approaches and/or processes on areas of common interest and mission are being sought. Some areas for which we are specifically interested in input are the following:

1. What steps should be taken to enhance the translation of biomedical research discoveries into new and approved preventatives, diagnostics, therapies, or devices for clinical use?

2. What are the priority scientific issues that currently need to be addressed (e.g., clinical trial design, endpoint selection and qualification, bioinformatics needs) in order to inform regulatory assessments and analyses of new products?

3. How could we enhance the exchange of scientific information across all sectors in order to better identify and prioritize scientific areas for emphasis in regulatory research?

4. What mechanisms for the support of regulatory science research would be most effective and efficient in addressing pressing priority areas in the translational pipeline?

III. Registration To Attend and/or To Participate in the Meeting

If you wish to attend the public meeting, you must register by e-mailing Rakesh Raghuwanshi.
(rakesh.raghuwanshi@fda.hhs.gov) by Wednesday, May 26, 2010, at 5 p.m. e.s.t. When registering, you must provide the following information: (1) Your name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) telephone number, and (6) e-mail address. If you wish to make a presentation, when you register, indicate the specific topic or issue to be addressed in your presentation. We will do our best to accommodate all persons who wish to make a presentation at the meeting. FDA and NIH encourage persons and groups having similar interests to consolidate their information for presentation through a single representative. After reviewing the requests to present, we will contact each participant prior to the meeting with the amount of time available and the approximate time the participant’s presentation is scheduled to begin. Presenters must then send the final electronic copies of their presentations in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) to Rakesh Raghuwanshi (rakesh.raghuwanshi@fda.hhs.gov) by Monday, May 31, 2010, at 12 noon e.s.t.

There is no fee to register for the public meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Registration on the day of the public meeting will be permitted on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please inform the meeting contact (see FOR FURTHER INFORMATION CONTACT) by Wednesday, May 26, 2010, at 5 p.m. e.s.t.

IV. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

V. Transcripts

Transcripts of the meeting will be available for review approximately 30 days after the meeting at http://www.regulations.gov and at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.


Leslie Kux,
Acting Assistant Commissioner for Policy.

[FR Doc. 2010–11008 Filed 5–7–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors (BSC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR)

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC and BSC, NCEH/ATSDR announce the following meeting of the aforementioned committee:

Times and Dates: 8:30 a.m.–6 p.m.,
May 27, 2010. 8 a.m.–2 p.m., May 28, 2010.

Place: Centers for Disease Control and Prevention, 4770 Buford Highway, Chamblee, Georgia 30341.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people. The public comment period is scheduled for Friday, May 28, 2010 from 8:45 a.m. until 9 a.m.

Purpose: The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC and Administrator, NCEH/ATSDR, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist States and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and well being; and (3) train State and local personnel in health work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency’s mission to protect and promote people’s health. The board provides advice and guidance that will assist NCEH/ATSDR in ensuring scientific quality, timeliness, utility, and dissemination of results. The board also provides guidance to help NCEH/ATSDR work more efficiently and effectively with its various constituents and to fulfill its mission in protecting America’s health.

Matters To Be Discussed: The agenda will include an update on NCEH/ATSDR’s Office of the Director; an overview of the Division of Laboratory Sciences (DLS); a presentation of DLS programs to the BSC peer review breakout groups; a presentation by the BSC peer review breakout groups of the key findings of DLS programs and activities; discussion of outstanding BSC Issues; Program Response to BSC Program Peer Review by NCEH/ATSDR Division of Emergency and Environmental Health Services (EHHE); an overview of the Division of Environmental Hazards and Health Effects; and presentations by EHHE Branches.

Agenda items are tentative and subject to change.

Contact Person for More Information:
Sandra Malcom, Committee Management Specialist, NCEH/ATSDR, 4770 Buford Highway, Mail Stop F–61, Chamblee, Georgia 30341; telephone 770/488–0575, Fax 770/488–3377; E-mail: smalcom@cdc.gov. The deadline for notification of attendance is May 25, 2010.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.


Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2010–10971 Filed 5–7–10; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2010–0035]

DHS Data Privacy and Integrity Advisory Committee

AGENCY: Privacy Office, DHS.