

the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda item for the Commission's eleventh meeting is to continue discussing topics related to the ethical issues associated with the development of medical countermeasures for children.

The draft meeting agenda and other information about PCSBI, including information about access to the webcast, will be available at www.bioethics.gov.

The Commission welcomes input from anyone wishing to provide public comment on any issue before it.

Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Commission. The Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Commission may make a random selection.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233-3960, or email at Esther.Yoo@bioethics.gov in advance of the meeting. The Commission will make every effort to accommodate persons who need special assistance.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to info@bioethics.gov, or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C-100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business

information that they contain. Trade secrets should not be submitted.

Dated: September 28, 2012.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA-2012-N-0001]

Endocrinologic and Metabolic Drugs 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: Endocrinologic and Metabolic Drugs 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 8, 2012, from 8 a.m. to 5 p.m.

Location: DoubleTree by Hilton Hotel Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's telephone number is 301-589-5200.

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: EMDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of new drug

applications (NDAs) 203313, insulin degludec/insulin aspart [rDNA origin] injection and 203314, insulin degludec [rDNA origin] injection, manufactured by Novo Nordisk Inc. The proposed indication (use) for these applications is for the treatment of Type 1 and Type 2 diabetes mellitus.

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 October 24, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 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 16, 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 October 17, 2012.

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 Paul Tran 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 3, 2012.

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

[FR Doc. 2012-24861 Filed 10-9-12; 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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the

Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Office on (301) 443-1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Maternal and Child Health Bureau Performance Measures for Discretionary Grants (OMB No. 0915-0298): Revision

The Maternal and Child Health Bureau (MCHB) intends to continue to collect performance data for Special Projects of Regional and National Significance (SPRANS), Community Integrated Service Systems (CISS), and other grant programs administered by MCHB.

The Health Resources and Services Administration (HRSA) proposes to continue using reporting requirements

for SPRANS projects, CISS projects, and other grant programs administered by MCHB, including national performance measures previously approved by OMB, and in accordance with the “Government Performance and Results Act (GPRA) of 1993” (Pub. L. 103-62). This Act requires the establishment of measurable goals for federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in January 2003. Approval from OMB is being sought to continue the use of these measures. Some of these measures are specific to certain types of programs and will not apply to all grantees. Through the experience of utilizing these measures, we are enhancing them to better reflect program goals. Specifically, additional outcome measures that can be utilized by grantees that predominantly provide infrastructure services are being developed for submission to OMB.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Burden hours per response	Total burden hours
Grant Report	900	1	900	41	36,900

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395-5806. Please direct all correspondence to the “attention of the desk officer for HRSA.”

Dated: October 3, 2012.

Bahar Niakan,
Director, Division of Policy and Information Coordination.

[FR Doc. 2012-24889 Filed 10-9-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Coordinating Committee on the Validation of Alternative Methods Evaluation Report and Recommendations for Identifying Chemical Eye Hazards With Fewer Animals; Availability of Report; Notice of Transmittal to Federal Agencies

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces availability of an Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) test method evaluation report (TMER) that provides recommendations for identifying chemical eye hazards with fewer animals.

ICCVAM concludes that using a classification criterion of one or more positive animals in a three-animal test to identify chemicals and products that are eye hazards will maintain hazard classification equivalent to that provided by current testing procedures, while using up to 50% to 83% fewer animals. ICCVAM recommends

consideration of this classification criterion together with eye safety testing procedures that use a maximum of three animals per test substance. This recommendation also harmonizes the number of animals used for eye safety testing across U.S. regulatory agencies and international test guidelines.

The report and recommendations have been transmitted to Federal agencies for their review and response to ICCVAM.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, Mail Stop: K2-16, Research Triangle Park, NC 27709. Phone: 919-541-2384, Fax: 919-541-0947, Email: *niceatm@niehs.nih.gov*. Hand Deliver/Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: Eye safety testing procedures vary among U.S. agencies. Current testing procedures specified in the U.S. Code of Federal Regulations (16 CFR 1500.42) provide criteria and procedures for identifying eye hazards based on rabbit eye test results (CPSC,