U.S.C. app.2) and 21 CFR part 14 relating to advisory committees.

Dated: September 13, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–19130 Filed 9–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0155]

Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials,'' dated September 2007. The guidance document provides sponsors of vaccine trials with recommendations on assessing the severity of clinical and laboratory abnormalities in healthy adult and adolescent volunteers enrolled in clinical trials. In particular, the guidance includes toxicity grading scale tables to use as a guideline for selecting the assessment criteria. The guidance announced in this notice finalizes the draft guidance of the same title dated April 2005.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials,'' dated September 2007. The guidance provides sponsors of vaccine trials with toxicity grading scale tables as a guideline when selecting the criteria to assess the severity of clinical and laboratory abnormalities in healthy adult and adolescent volunteers enrolled in clinical trials of a preventive vaccine. FDA recommends the incorporation of such appropriate, uniform criteria into the investigational plan, case report forms, and study reports and correspondence with FDA, sponsors, monitors, investigators, and institutional review boards. The parameters in the tables are not necessarily applicable to every clinical trial of healthy volunteers. The parameters monitored should be appropriate for the specific study vaccine. In addition, the use of toxicity grading scales to categorize adverse events observed during clinical trials does not replace regulatory requirements to monitor, investigate, and report adverse events.

In the **Federal Register** of May 2, 2005 (70 FR 22664), FDA announced the availability of the draft guidance of the same title dated April 2005. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: (1) Clarification of the clinical toxicity parameters and (2) revision of laboratory parameter limit values based on additional published data. The guidance announced in this notice finalizes the draft guidance dated April 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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 the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19155 Filed 9–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket No. FEMA–2007–0008]

National Advisory Council; Notice of Federal Advisory Committee Meeting

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: This notice announces the date, time, location and agenda for the inaugural meeting of the National Advisory Council (NAC). At the meeting, members will be introduced and sworn in and the Chair and Vice Chair will be introduced. Members will also receive briefings on the status of the reorganized Federal Emergency Management Agency (FEMA) and its programs, and to discuss the vision, priorities and structure for the NAC. The meeting will be open to the public.

DATES: *Meeting Dates:* Monday, October 22, 2007, 9:45 a.m. to 5 p.m. and Tuesday, October 23, 2007, 9 a.m. to 4:30 p.m. A public comment period will

take place on October 23, 2007 between 3:15 p.m. and 4:30 p.m.

Comment Date: Written comments or requests to make oral presentations must be received by October 15, 2007.

ADDRESSES: The meeting will be held in Ballroom B/C of the Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, Virginia 22202. Persons wishing to make an oral presentation or who are unable to attend or speak at the meeting may submit written comments. Written comments and requests to make oral presentations at the meeting should reach Alyson Price at the address listed below and must be received by October 15, 2007. All submissions received must include the docket number FEMA–2007–0008 and may be submitted by any one of the following methods:

Federal Rulemaking Portal: http://www.regulations.gov. Follow instructions for submitting comments on the Web site.

E-mail: FEMA-RULES@dhs.gov. Include docket number in the subject line of the message.

Facsimile: (866) 466–5370.

Mail: Alyson Price, Designated Federal Officer, Federal Emergency Management Agency, 500 C Street, SW., (E Street, 3rd Floor), Washington, DC 20472.

Hand Delivery/Courier: National Advisory Council, DFO c/o Rules Docket Clerk, Office of the Chief Counsel, Federal Emergency Management Agency, Room 835, 500 C Street, SW., Washington, DC 20472.

Instructions: All submissions received must include the docket number: FEMA–2007–0008. Comments received will also be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may want to read the Privacy Act Notice located on the Privacy and Use Notice link on the Administration Navigation Bar of the Web site *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received by the National Advisory Council, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Alyson Price, Designated Federal Officer, Federal Emergency Management Agency, 500 C Street, SW., (E Street, 3rd Floor), Washington, DC 20472, telephone 202–646–3746, fax 202–646–3061, and e-mail *Alyson.Price@dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App. 1 *et seq.*). The NAC will be holding its first meeting on Monday and Tuesday, October 22 and 23, 2007, in Ballroom B/C of the Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, Virginia 22202.

Agenda of Council Meeting, October 22–23, 2007

The tentative agenda includes the following:

Monday, October 22, 2007

(1) Introduction of the Chair and Vice Chair;
(2) Introduction and swearing-in of members;
(3) FEMA Administrator's vision for the NAC;
(4) Introduction of FEMA leadership;
(5) FEMA programs overview; and
(6) Review of FEMA Strategic Plan.

Tuesday, October 23, 2007

(1) Summary of previous day;
(2) Structure and assignment of Subcommittee Chairs;
(3) Discussion Wrap-up/Next Steps;
(4) Public comment period; and
(5) Travel instructions/paperwork.

A public comment period will take place on October 23, 2007, between 3:15 p.m. and 4:30 p.m.

Public Attendance: The meeting is open to the public. Persons with disabilities who require special assistance should advise Alyson Price of their anticipated special needs as early as possible. Members of the public who wish to make comments on Tuesday, October 23 between 3:15 p.m. and 4:30 p.m. are requested to register in advance. In order to allow as many people as possible to speak, speakers are requested to limit their remarks to three minutes. For those wishing to submit written comments, please follow the procedure noted above.

Dated: September 20, 2007.

R. David Paulison,

Administrator, Federal Emergency Management Agency.

[FR Doc. E7–19063 Filed 9–26–07; 8:45 am]

BILLING CODE 9110–21–P

INTER-AMERICAN FOUNDATION BOARD MEETING

Sunshine Act Meetings

TIME AND DATE: October 1, 2007. 9 a.m.–1 p.m.

PLACE: 901 N. Stuart Street, Tenth Floor, Arlington, Virginia 22203.

STATUS: Open to the public except for the portion specified as closed session as provided in 22 CFR part 1004.4(b) and (f).

MATTERS TO BE CONSIDERED:

- Approval of the Minutes of the January 22, 2007, Meeting of the Board of Directors.
- President's Report.
- Program Update.
- Operations Update.
- External Affairs.
- Congressional Affairs.
- Advisory Council.

PORTIONS TO BE OPEN TO THE PUBLIC:

- Approval of the Minutes of the January 22, 2007, Meeting of the Board of Directors.
- President's Report.
- Program Update.
- Operations Update.
- External Affairs.
- Congressional Affairs.
- Advisory Council.

PORTIONS TO BE CLOSED TO THE PUBLIC:

- Closed session as provided in 22 CFR part 1004.4(b) and (f).

Dated: September 19, 2007.

Jennifer R. Hodges,

General Counsel, (703) 306–4320.

[FR Doc. 07–4804 Filed 9–25–07; 3:15 pm]

BILLING CODE 7025–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Sent to the Office of Management and Budget (OMB) for Approval; OMB Control Number 1018–0094; Federal Fish and Wildlife Permit Applications and Reports—Native Endangered and Threatened Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (Fish and Wildlife Service) have sent an Information Collection Request (ICR) to OMB for review and approval. The ICR, which is summarized below, describes the nature of the collection and the estimated burden and cost. This ICR is scheduled to expire on September 30, 2007. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. However, under OMB regulations, we may continue to conduct or sponsor this information collection while it is pending at OMB.

DATES: You must submit comments on or before October 29, 2007.

ADDRESSES: Send your comments and suggestions on this ICR to the Desk Officer for the Department of the Interior at OMB-OIRA at (202) 395–6566