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 The guidance announced in this notice finalizes the draft guidance of the same title dated April 2005.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]

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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