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 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In the Federal Register of May 2, 2005 (70 FR 22664), FDA announced the availability of the draft guidance of the same title dated April 2005. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized.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 The guidance announced in this notice finalizes the draft guidance dated April 2005.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 any rights, 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.


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