4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0482]

# Guidances for Industry and Investigators on Safety Reporting Requirements for Investigational New Drug Applications and Bioavailability/Bioequivalence Studies, and a Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidances for industry and investigators entitled "Safety Reporting Requirements for INDs and BA/BE Studies" and "Safety Reporting Requirements for INDs and BA/BE Studies--Small Entity Compliance Guide." These guidances are intended to help sponsors and investigators comply with the requirements in the final rule entitled "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans," published in the Federal Register on September 29, 2010 (75 FR 59935). FDA has prepared the Small Entity Compliance Guide in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses understand and comply with the regulations issued by FDA concerning safety reporting requirements for investigational new drug applications (IND) and bioavailability (BA) and bioequivalence (BE) studies.

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

ADDRESSES: Submit written requests for single copies of the guidances to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance documents.

Submit electronic comments on the guidances to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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Rockville, MD 20852-1448,

301-827-6210.

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of two guidances for industry and investigators entitled "Safety Reporting Requirements for INDs and BA/BE Studies" and "Safety Reporting Requirements for INDs and BA/BE Studies--Small Entity Compliance Guide." These guidances are intended to help sponsors and investigators comply with the requirements for IND safety reporting and safety reporting for BA and BE studies. In addition, the Small Entity Compliance Guide is intended to help small businesses understand and comply with the regulations issued by FDA concerning the safety reporting requirements for INDs and BA/BE studies. FDA has prepared the Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act.

On September 29, 2010, FDA published a final rule amending the IND safety reporting requirements under 21 CFR part 312 and adding safety reporting requirements for persons conducting BA and BE studies under 21 CFR part 320. The requirements in the final rule are intended to improve the utility and quality of safety reports, expedite and strengthen FDA's ability to review critical safety information, and better protect human subjects enrolled in clinical trials. FDA also published a draft guidance entitled "Safety Reporting Requirements for INDs and BA/BE Studies" on September 29, 2010 (75 FR 60129), and the public was provided with an opportunity to comment on it until December 28, 2010. FDA carefully considered all of the

comments received in developing the final guidance. The final guidance includes clarifications and additional detail regarding the draft guidance topics as well additional information on safety reporting issues raised in the comments.

The final guidance entitled "Safety Reporting Requirements for INDs and BA/BE Studies" contains the definitions used for IND safety reporting, makes recommendations on when and how to submit a safety report, and provides advice on other safety reporting issues that have generated questions from sponsors and investigators.

The Small Entity Compliance Guide provides answers to many frequently asked questions FDA has received from investigators and sponsors regarding the safety reporting requirements that are applicable to small entities.

In addition, on June 7, 2011, the Agency published a guidance describing enforcement discretion with the reporting requirements until September 28, 2011, to allow sponsors additional time to make process changes to implement the final rule (76 FR 32863; June 7, 2011). At this time, the Agency is withdrawing this guidance.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the Agency's current thinking on safety reporting requirements for IND and BA/BE studies. They do not create or confer any rights for or on any person and do 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 submit either written comments regarding these documents to the Division of Dockets Management (see ADDRESSES) or electronic comments to

http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at http://www.regulations.gov.

## III. Paperwork Reduction Act of 1995

These guidances refer to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in these guidances have been approved under OMB control number 0910-0672.

## IV. Electronic Access

Persons with access to the Internet may obtain the documents at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: December 13, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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