# Guidance for Industry and Investigators

## Enforcement of Safety Reporting Requirements for INDs and BA/BE Studies

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**
**Center for Biologics Evaluation and Research (CBER)**

**April 2011**
**Drug Safety**

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*Contains Nonbinding Recommendations*

# Guidance for Industry and Investigators[1] Enforcement of Safety Reporting Requirements for INDs and BA/BE Studies

This guidance represents the Food and Drug Administration's (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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

## I. INTRODUCTION

This document provides guidance to sponsors and investigators on enforcement of FDA's final rule, "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans" (75 FR 59935, September 29, 2010). This guidance contains information regarding the Agency's intent to exercise enforcement discretion regarding the reporting requirements in the final rule until September 28, 2011.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## II. DISCUSSION

On September 29, 2010, FDA published a final rule "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans" (75 FR 59935) and issued related draft guidance "Safety Reporting Requirements for INDs and BA/BE Studies" (75 FR 60129, Docket No. FDA-2010-D-0482). The final rule amended the investigational new drug (IND) safety reporting requirements under 21 CFR part 312 and added safety reporting requirements for persons conducting bioavailability (BA) and bioequivalence (BE) studies under 21 CFR part 320. The draft guidance contains definitions used for 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.

[1] This guidance has been prepared by the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) in conjunction with the Center for Biologics Evaluation and Research (CBER) at FDA.

The effective date for the final rule was March 28, 2011. In comments to the docket and in other communications to the agency placed in the docket, sponsors have requested an extension to the effective date of the final rule because of the need for significant internal process changes to meet the new requirements.

The agency acknowledges these concerns and intends to exercise enforcement discretion regarding the reporting requirements in the final rule until September 28, 2011. During this period of time, FDA does not intend to take enforcement action if sponsors report in compliance with the reporting requirements under 21 CFR 312.32, 312.64 and 320.31 that were in effect prior to March 28, 2011.

FDA strongly encourages compliance with the new regulations as soon as possible, and we expect all sponsors and investigators to be in compliance with the new regulations no later than September 28, 2011.