



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1484]

Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators.” The purpose of this guidance is to assist sponsor-investigators in preparing and submitting complete investigational new drug applications (INDs) to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at FDA. Although not an exhaustive step-by-step instruction manual, this guidance highlights certain elements of this process to facilitate a sponsor-investigator’s successful submission of an IND. This guidance also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical

investigations. Details of the informational content of an IND as well as information needed to complete required forms also are provided throughout this guidance.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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:** Amalia Himaya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6439, Silver Spring, MD 20993-0002, 301-796-0700; or Stephen Ripley, Center for Biologics

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

## SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Investigational New Drug Applications Prepared and Submitted by Sponsor-Investigators.” The purpose of this guidance is to assist investigators in preparing and submitting complete INDs to CDER and CBER at FDA. Sponsor-investigators seeking to do clinical research often do not have the regulatory knowledge or the resources to hire experts to help them with the IND submission process. Although not an exhaustive step-by-step instruction manual, this guidance highlights certain elements of this process to facilitate a sponsor-investigator’s successful submission of an IND. This guidance also discusses the IND review process and general responsibilities of sponsor-investigators related to clinical investigations. The guidance does not include discussions of all of the requirements that apply to the IND submission and review process or to conducting clinical research.

This guidance is directed primarily at those sponsor-investigators who are seeking to evaluate a drug that is either currently approved or is being investigated under an existing IND for a different indication. This guidance is not intended for sponsor-investigators who are developing a drug for commercial purposes (i.e., seeking market approval or licensure). This guidance does not apply to clinical trials that do not need to be conducted under an IND (i.e., that qualify for an IND exemption). The guidance also is not intended to address expanded access INDs or biologic devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on INDs prepared and submitted by sponsor-investigators. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 21 CFR part 312 have been approved under OMB control number 0910-0014.

## III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). 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>.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: May 11, 2015.

Leslie Kux,

Associate Commissioner for Policy,

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