



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0096]

Determining the Extent of Safety Data Collection Needed in Late-Stage Premarket and Postapproval Clinical Investigations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Determining the Extent of Safety Data Collection Needed in Late-Stage Premarket and Postapproval Clinical Investigations." The guidance is intended to help sponsors determine the amounts and types of safety data to collect in late-stage premarket and postapproval clinical investigations based on what is already known about a drug's safety profile. Sponsors collect extensive safety data in clinical investigations of drug and biological products conducted to support marketing approval (premarket) and after approval (postapproval). FDA believes that selective safety data collection may be possible for some late-stage premarket and postapproval clinical investigations because certain aspects of a drug's safety profile will be sufficiently well-established and comprehensive data collection is not needed. This guidance finalizes the draft guidance issued in February 2012.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-0096 for "Determining the Extent of Safety Data Collection Needed in Late-Stage Premarket and Postapproval Clinical Investigations; Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this 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 to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ebla Ali Ibrahim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6302, Silver Spring, MD 20993-0002, 301-796-3691; 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 guidance for industry entitled "Determining the Extent of Safety Data Collection Needed in Late-Stage Premarket and Postapproval Clinical Investigations." The guidance is intended to help sponsors determine the amounts and types of

safety data to collect during late-stage premarket and postapproval clinical investigations (e.g., phase 3 clinical trials, studies of new uses, long-term outcomes) based on what is already known about a drug's safety profile.

If the drug's safety profile is well-established before completion of clinical development or for marketed drugs used in postmarketing clinical trials, it may no longer be necessary in some cases to collect certain types of safety data. In some cases, collection of data that do not contribute to better characterizing the safety profile of a drug may have negative consequences. Additionally, excessive safety data collection practices may discourage the conduct of certain types of trials by increasing the resources needed to perform the trials and may also be a disincentive to investigator and patient participation in clinical trials. FDA believes that selective safety data collection may: (1) Facilitate the conduct of larger trials without compromising the integrity and the validity of trial results or losing important information, (2) facilitate investigators' and patients' participation in clinical trials, and (3) help contain costs by making more-efficient use of clinical trial resources.

The guidance outlines the circumstances where selective data collection may be appropriate and the types of safety data that may be eligible for selective collection. The guidance provides recommendations on maintaining a balance between eliminating the collection of data that will not be useful and collecting sufficient data to allow adequate characterization of the safety profile of a drug in scenarios where selective safety data collection is appropriate. The guidance also strongly encourages sponsors to work closely with the relevant FDA review division or divisions to establish and implement selective safety data collection.

In the Federal Register of February 10, 2012 (77 FR 7166), FDA announced the availability of a draft guidance for industry of the same title. The public comment period closed

on April 10, 2012. FDA carefully considered all comments received in developing the guidance. In response to public comments requesting more detail and examples, the guidance was revised and reorganized to clarify what types of safety data and what circumstances may be appropriate for selective collection, add detail regarding the draft guidance topics, and provide additional information on safety data reporting issues. This guidance finalizes the draft guidance issued in February 2012.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on determining the extent of safety data collection needed in late-stage premarket and postapproval clinical investigations. 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. Paperwork Reduction Act of 1995

This guidance refers 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 21 CFR 312.32 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR 312.47 have been approved under OMB control numbers 0910-0014 and 0910-0429; the collections of information in 21 CFR 314.80 have been approved under OMB control number 0910-0230; and the collections of information in 21 CFR 600.80 have been approved under OMB control number 0910-0308.

III. 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/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: February 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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