4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry on Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations." This guidance is intended to assist sponsors of clinical investigations in determining the amounts and types of safety data to collect in trials conducted late in the development of a drug for marketing approval or after approval based on what is already known about a drug's safety profile. Extensive safety data are collected in clinical trials of investigational drugs to support marketing approval (premarket) and trials conducted after approval (postmarket). FDA believes that more selective or targeted safety data collection may be possible for some late stage premarket trials and postmarket trials because certain aspects of a drug's safety profile will be sufficiently well-established that comprehensive data collection is not needed. FDA believes more selective or targeted safety data collection in appropriate circumstances may improve the quality of the safety assessment without compromising the integrity of the trial results.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on

the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), 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 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:

Lori Bickel,

Center for Drug Evaluation and Research,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 51, rm. 6353,

Silver Spring, MD 20993

301-796-0210;

or

Stephen Ripley,

Center for Biologics Evaluation and Research (HFM-17),

Food and Drug Administration,

1401 Rockville Pike, suite 200N,

Rockville, MD 20852-1448,

301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Determining the Extent of Safety Data Collection Needed in Late Stage Premarket and Postapproval Clinical Investigations." This guidance is intended to assist clinical trial sponsors in determining the amounts and types of safety data that should be collected during late-stage premarket and postmarket clinical investigations of a drug product based on what is already known about the safety profile of the drug.

To meaningfully weigh the risks and benefits of a drug, it is important to collect a broad range of safety-related data and develop a comprehensive safety profile of a drug. In some cases, however, certain aspects of the safety profile may be well-established prior to the completion of clinical trials to support marketing approval of an investigational drug. Similarly, for a marketed drug being studied for a new use, much of the existing safety profile for the approved use may be relevant to the new use. If certain aspects of a safety profile are well-established, it may not be necessary to collect certain types of safety data in clinical trials because the data would not contribute anything additional to the safety profile and may even have negative consequences (e.g., serve as a disincentive to clinical investigators). In those settings, more targeted or

selective data collection can be used to focus on collecting data that will further contribute to the safety profile.

The draft guidance identifies the types of safety data collected and recommends more selective or targeted safety data collection in a variety of circumstances, offers suggestions on methods that may be used to conduct selective or targeted data collection where appropriate, and highlights circumstances in which comprehensive data collection is generally needed.

This draft guidance is being developed consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on determining the extent of safety data collection needed in late stage premarket and postapproval clinical investigations. It does not create or 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 submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document 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: February 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy

[FR Doc. 2012-3096 Filed 02/09/2012 at 8:45 am; Publication Date: 02/10/2012]