4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1439]

Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff." This guidance provides sponsors and FDA staff with guidance on how to plan and implement adaptive designs for clinical studies when used in medical device development programs. An adaptive design for a medical device clinical study is defined as a clinical trial design that allows for prospectively planned modifications based on accumulating study data without undermining the trial's integrity and validity. Adaptive designs, when properly implemented, can reduce resource requirements and/or increase the chance of study success. This draft guidance is not final nor is it in effect at this time.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Greg Campbell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2110, Silver Spring, MD 20993-0002, 301-796-5750.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides sponsors and FDA staff with guidance on how to plan and implement adaptive designs for clinical studies when used in medical device development programs. This document addresses adaptive designs for medical device clinical trials and is applicable to premarket medical device submissions including premarket approval applications,

premarket notification (510(k)) submissions, de novo submissions (evaluation of automatic class III designation), humanitarian device exemption applications, and investigational device exemption submissions. This guidance can be applied throughout the clinical development program of a medical device, from feasibility studies to pivotal clinical trials. This guidance does not apply to clinical studies of combination products or codevelopment of a pharmaceutical product with an unapproved diagnostic test.

II. Significance of Guidance

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 the adaptive design of clinical studies for medical devices. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Adaptive Designs for Medical Device Clinical Studies; Draft Guidance for Industry and Food and Drug Administration Staff" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUD1500005 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 part 807, subpart E, which have been approved under 0910-0120; 21 CFR part 812, which have been approved under 0910-0078; 21 CFR part 814, subparts A, B, and C, which have been approved under OMB control number 0910-0231; and 21 CFR part 814, subpart H, which have been approved under OMB control number 0910-0332.

V. 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.

Dated: May 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-11820 Filed: 5/15/2015 08:45 am; Publication Date: 5/18/2015]