

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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices."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 statutes 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet.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 "Use of Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1500012 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and guidance. 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 have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E (premarket approval) have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H (humanitarian device exemption) have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 812 (investigational device exemption) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 822 (postmarket surveillance) have been approved under OMB control number 0910–0449; the collections of information in 21 CFR part 50.23 (exception from general requirements

for informed consent) have been approved under OMB control number 0910–0586; the collections of information in 21 CFR part 54 (financial disclosure by clinical investigators) have been approved under OMB control number 0910–0396; the collections of information in 21 CFR part 56.115 (IRB records) have been approved under OMB control number 0910–0130; and the collections of information in 21 CFR parts 50 (informed consent) and 56 (IRBs) have been approved under OMB control number 0910–0755. The collections of information in the guidance "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910–0756.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17750 Filed 7–26–16; 8:45 am]

BILLING CODE 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; Guidance for Industry and Food and Drug Administration Staff; 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 the guidance entitled "Adaptive Designs for Medical Device Clinical Studies." 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.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome 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–2015–D–1439 for "Adaptive Designs for Medical Device Clinical Studies." 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.

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 guidance document entitled "Adaptive Designs for Medical Device Clinical Studies" 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; or the Office of Communication, Outreach, and Development, 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 request.

FOR FURTHER INFORMATION CONTACT:
Gerry Gray, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2112, Silver Spring, MD 20993-0002, 301-796-6012; or the Division of Biostatistics, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993-0002, 301-796-5750; 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, 240-402-7911.

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 (PMA), premarket notification (510(k)) submissions, de novo submissions (evaluation of automatic class III designation), humanitarian device exemption (HDE) applications, and investigational device exemption (IDE) 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. The draft guidance was available from May 18, 2015, to August 17, 2015. FDA received 151 comments from seven entities and has incorporated most of them in this final guidance.

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[DeviceRegulationandGuidance/GuidanceDocuments/default.htm](http://www.fda.gov/DeviceRegulationandGuidance/GuidanceDocuments/default.htm). Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of "Adaptive Designs for Medical Device Clinical Studies" 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 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 have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812, have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910-0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910-0332; and the collections of information in the guidance document "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910-0756.

Dated: July 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-17651 Filed 7-26-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting: