written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft recommendations for preparing the Standardization Plan.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–002, 301–796–5333, email: *ronald.fitzmartin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft recommendations for preparing the Standardization Plan. The Standardization Plan is referenced in the Guide. The Guide supplements the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' and provides specifications, recommendations, and general considerations on submitting standardized study data using FDA-supported data standards; it is posted on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.*

The Guide recommends that, for clinical and nonclinical studies, sponsors include a plan that describes the submission of standardized study data to FDA. The Standardization Plan will assist FDA in identifying potential data standardization issues early in the development program (*e.g.,* pre-investigational new drug application stage). The draft recommendations describe the information that should be included in the Standardization Plan. The recommendations include, but are not limited to, the following: (1) General sponsor information, (2) product information, (3) list of completed studies and standards, and (4) list of planned studies and standards.

II. 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.*

III. Electronic Access

Persons with access to the Internet may obtain the proposed recommendations at either *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm* or *http://www.regulations.gov.*

Dated: May 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11846 Filed 5–15–15; 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; 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 August 17, 2015.

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 5–15–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1580]

Patient Preference Information—Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Device Labeling; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; 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 ''Patient Preference Information—Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Device Labeling.'' This document provides guidance on collecting and submitting patient preference information that may be used by FDA staff in decisionmaking relating to premarket approval applications (PMAs), Humanitarian Device Exemption (HDE) applications, and *de novo* requests. This draft guidance also outlines considerations for including patient preference information in labeling for patients and health care professionals. 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 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 August 17, 2015.

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 ''Patient Preference Information—Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Device Labeling'' 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.

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: Anindita Saha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5414, Silver Spring, MD 20993–0002, 301–796–2537, *Anindita.Saha@fda.hhs.gov;* 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

FDA is announcing the availability of a draft guidance for industry entitled ''Patient Preference Information—Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Device Labeling.'' FDA believes that patients can and should bring their own experiences to bear in helping the Agency to evaluate the risk-benefit profile of certain devices. This document provides guidance on collecting and submitting patient preference information that may be used by FDA staff in decision-making relating to PMAs, HDE applications, and *de novo* requests. The objectives of this draft guidance are: (1) To encourage voluntary submission of patient preference information by sponsors or other stakeholders in certain circumstances; (2) to outline recommended qualities of patient preference studies, which may result in valid scientific evidence; (3) to provide recommendations for collecting and submitting patient preference information to FDA; and (4) to outline