

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–2016–N–3362 for “Intent to Review a Study Data Standardization Plan Template.” 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.

#### FOR FURTHER INFORMATION CONTACT:

Crystal Allard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 1518, Silver Spring, MD 20993–0002, 301–796–8856, [crystal.allard@fda.hhs.gov](mailto:crystal.allard@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is a participating member of PhUSE, an independent, non-profit consortium of academic, regulatory, non-profit, and private sector entities. PhUSE provides a global platform for the discussion of topics encompassing the work of biostatisticians, data managers, statistical programmers, and e-clinical information technology professionals, with the mission of providing an open, transparent, and collaborative forum to address computational science issues. As part of this collaboration, PhUSE working groups develop and periodically publish proposals for enhancing the review and analysis of human and animal study data submitted to regulatory agencies. You can learn more about PhUSE working groups at <http://www.phuse.eu/cs-working-groups.aspx>. (FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

In December 2014, FDA published the Study Data Technical Conformance Guide (the “Guide,” available at <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>), which contains technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format. In section 2.1 of the Guide, FDA recommends that sponsors should include a plan (e.g., in the IND) describing the submission of standardized study data to FDA. FDA’s Study Data Standards Resources Web page provides recommendations for preparing an SDSP (<http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM447119.pdf>).

FDA now intends to review the PhUSE SDSP template, a deliverable of the working group effort described previously in this document, with the potential result that FDA could recommend the use of the template in its current form, or in a modified form, for use in the regulatory submission of study data in conformance with the Guide. FDA invites public comment on

all matters regarding the use of the PhUSE SDSP template.

##### II. Electronic Access

The PhUSE SDSP template is available at: [http://www.phusewiki.org/wiki/images/e/ea/SDSP\\_Template.pdf](http://www.phusewiki.org/wiki/images/e/ea/SDSP_Template.pdf).

Dated: November 2, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–26913 Filed 11–7–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–D–0743]

#### Medical Device Reporting for Manufacturers; 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) is announcing the availability of the guidance entitled “Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff.” This guidance document is intended to assist medical device manufacturers meet applicable reporting and recordkeeping requirements for certain device-related adverse events and malfunctions.

**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-2013-D-0743 for “Medical Device Reporting for Manufacturers”. 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>.

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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 “Medical Device Reporting for Manufacturers” 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.

#### **FOR FURTHER INFORMATION CONTACT:**

Isaac Chang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3114, Silver Spring, MD 20993-0002, 301-796-2789.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Medical device reporting under section 519(a) of the Federal Food Drug, and Cosmetic Act (21 U.S.C. 360i(a)) provides a mechanism that allows FDA and device manufacturers, user facilities, and importer of medical devices to identify and monitor adverse events (deaths and serious injuries) and certain malfunctions involving your medical devices. The goal is to detect and correct problems in a timely manner. This guidance updates FDA’s policy and clarifies FDA’s interpretations of the regulatory requirements under part 803 (21 CFR part 803) and includes a section on common reporting errors.

The draft of this guidance was made available in the **Federal Register** on July 9, 2013 (78 FR 41069), and the comment period closed October 7, 2013. FDA reviewed and considered all public

comments received and revised the guidance as appropriate.

This document supersedes the draft entitled, “Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff,” dated July 9, 2013, and the previous guidance on this topic, “Medical Device Reporting for Manufacturers,” issued March 1997.

##### **II. Significance of Guidance**

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 medical device reporting. 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 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 “Medical Device Reporting for Manufacturers; Guidance for Industry and Food and Drug Administration Staff” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1828 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 parts 801 and 809, regarding labeling, have been approved under OMB control number 0910-0485; the collections of information in part 803, regarding medical device reporting, have been approved under OMB control number 0910-0437; the collections of information in 21 CFR part 806, regarding corrections and removals, have been approved under OMB control number 0910-0359; the collections of information in 21 CFR part 807, subpart E, regarding premarket notification,

have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812, regarding investigational device exemptions, have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820, regarding quality system regulations, have been approved under OMB control number 0910–0073; the collections of information regarding MedWatch: The Food and Drug Administration Medical Products Reporting Program have been approved under OMB control number 0910–0291; and the collections of information regarding the Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun)) have been approved under OMB control number 0910–0471.

Dated: November 3, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–26933 Filed 11–7–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–D–0075]

#### Non-Inferiority Clinical Trials To Establish Effectiveness; 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 “Non-Inferiority Clinical Trials to Establish Effectiveness.” This document provides guidance to sponsors and applicants submitting investigational new drug applications (INDs), new drug applications (NDAs), biologics licensing applications (BLAs), or supplemental applications on the appropriate use of non-inferiority (NI) study designs to provide evidence of the effectiveness of a drug or biologic. The guidance gives advice on when NI studies demonstrating effectiveness of an investigational drug can provide interpretable results, how to choose the NI margin, and how to test the NI hypothesis.

**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–2010–D–0075 for “Non-Inferiority Clinical Trials to Establish Effectiveness; Guidance for Industry.” 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>.

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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 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Scott Goldie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire