



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1777]

Factors to Consider When Making Benefit-Risk Determinations for Medical Device

Investigational Device Exemptions; Guidance for Investigational Device Exemption Sponsors,

Sponsor-Investigators, 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 "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions." The purpose of this guidance is to provide greater clarity for FDA staff and Investigational Device Exemptions (IDE) application sponsors and sponsor-investigators regarding the principal factors that the Agency considers when assessing the benefits and risks of IDE applications for human clinical study. The guidance also characterizes benefits in the context of investigational research, which includes direct benefits to the subjects and benefits to others.

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-1777 for "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions." 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 "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions" 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: Karen Ulisney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1545, Silver Spring, MD 20993-0002, 301-796-5513; 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

A primary goal of this guidance is to clarify the factors that FDA considers when assessing risks and anticipated benefits for IDE studies, and how uncertainty may be offset by a variety of risk mitigation measures that can ensure appropriate patient and participant protections

in investigational research settings. At earlier stages of device development, FDA considers appropriate mitigation measures for anticipated possible risks and unanticipated risks, whereas in later stages, risk mitigation focuses increasingly on the most probable risks. Another important goal of this guidance is to characterize benefits in the context of investigational research, which includes direct benefits to the subjects and benefits to others (to the extent there are indirect benefits to subjects or reflect the importance of knowledge to be gained).

As with the benefit-risk framework for evaluating marketing applications, FDA assessment of benefits and risks for an IDE application takes into account the contextual setting in which the study is being proposed, including, but not limited to, the characterization of the disease or condition being treated or diagnosed, the availability of alternative treatments or diagnostics, and the risks associated with them. When available, information characterizing subject tolerance for risk and perspective on benefit may provide useful context during this assessment.

In the Federal Register on June 18, 2015 (80 FR 34909), FDA announced the availability of the draft guidance and interested parties were requested to comment by September 16, 2015. FDA has considered all of the public comments received prior to finalizing this guidance.

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 "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions." 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.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryinformation/Guidances/default.htm> or <http://www.regulations.gov>. Persons unable to download an electronic copy of "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1783 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 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR 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 56.115 (Institutional Review Board records) have been approved under OMB control number 0910-0130; and the collections of information in 21 CFR part 50, subpart B (Informed Consent of Human Subjects) and part 56 (Institutional Review Boards) have been approved under OMB control number 0910-0755.

Dated: January 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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