4164-01-P

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Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions; Draft Guidance for Investigational Device Exemption Sponsors, Sponsor-Investigators, and Food and Drug Administration Staff; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)." The purpose of this draft guidance is to provide greater clarity for FDA staff and IDE sponsors and sponsor-investigators regarding the principa factors that FDA considers when assessing the benefits and risks of IDE applications for human clinical study. The draft guidance also characterizes benefits in the context of investigational research, which includes direct benefits to the subjects and benefits to others (to the extent they are indirect benefits to subjects or reflect the importance of knowledge to be gained). This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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 Submit written requests for a single hard copy of the draft guidance entitled "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)" to the Office of the Center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: Sugato De, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5435, Silver Spring, MD 20993-0002, 301-796-6270; 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 assure 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 they 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 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.

FDA believes use of this benefit-risk framework in an IDE application will facilitate the incorporation of evidence and knowledge from different domains--clinical, nonclinical, and patient--to support a comprehensive, balanced decision-making approach. FDA envisions this will facilitate a common understanding between FDA and sponsors/sponsor-investigators by highlighting which factors are critical in the benefit-risk assessment for a specific application, and clearly explaining how these factors influence a regulatory decision. FDA also believes

implementation of this guidance document will improve the predictability, consistency, and transparency of the review process for IDE applications.

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 Agency's current thinking on "Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions (IDEs)." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach 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 or from CBER at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. 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 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 812 have been approved under OMB control number 0910-0078; 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 56.115 (IRB 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 56 (Institutional Review Boards) have been approved under OMB control number 0910-0755.

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: June 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-14982 Filed: 6/17/2015 08:45 am; Publication Date: 6/18/2015]