4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0787]

Draft Guidance for Industry and Food and Drug Administration Staff; Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies." Through the approaches announced in this draft guidance, FDA intends to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE requirements. Early feasibility studies allow for limited early clinical evaluations of devices to provide proof of principle and initial clinical safety data before the device design is finalized. This draft guidance addresses the information that should be provided to FDA in support of an early feasibility study IDE application and explains the requirements applicable to modifications to the device design or clinical protocol during the early feasibility study. This draft guidance is not final nor is it in effect at this time.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft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 [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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:

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SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to provide assistance to FDA staff, clinicians, clinical innovators, and industry on the development and review of IDE applications (21 CFR 812.20) for early feasibility studies of significant risk devices. Early feasibility studies allow for early clinical evaluation of devices to provide proof of principle and initial clinical safety data in a limited number of subjects. During these studies, iterative device modifications are likely to be made based on clinical experience. Early feasibility studies may be appropriate early in device development when nonclinical testing methods are not available or adequate to provide the information needed to advance the developmental process, and clinical experience is thus necessary. As with all clinical studies, initiation of an early feasibility study must be justified by an appropriate risk-benefit analysis and adequate human subject protection measures.

This draft guidance discusses the key principles unique to the justification for, and design of, early feasibility studies, as well as outlines the general principles for preparing and reviewing early feasibility study IDE applications. This draft guidance is not intended to address all required elements of an IDE application generally or to provide a comprehensive tutorial on best clinical practices for investigational medical device studies.

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 IDE for early feasibility studies. 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. Elsewhere in this issue of the Federal Register, FDA is announcing the solicitation of nominations from sponsors of innovative device technologies to participate in a pilot program for

early feasibility study IDE applications, which implements the approaches announced in this draft guidance. The experience gained from the pilot program will be used to inform the final version this draft guidance.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov.

You may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of this draft guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1782 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.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: November 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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