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Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Dorothy Abel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1204, Silver Spring, MD 20993–0002, (301) 796–6366.

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This draft guidance is intended to provide assistance to FDA staff, clinicians, clinical innovators, and industry on the development and review of IDE applications (21 CFR 812.20)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This draft guidance discusses the key principles unique to the justification for, and design of, early feasibility studies, as well as outlines the general principles for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 This draft guidance is not intended to address all required elements of an IDE application generally or to provide a comprehensive tutorial on best clinical practices for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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).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.

[FR Doc. 2011–29117 Filed 11–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0790]

Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff; Food and Drug Administration Decisions for Investigational Device Exemption Clinical Investigations; 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 ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.'' This guidance document has been developed to promote the initiation of clinical investigations to evaluate medical devices under FDA's IDE regulations. In an effort to promote timely clinical investigations in a manner that protects study subjects, FDA has developed methods to allow a clinical investigation to begin under certain circumstances, even when there are outstanding issues regarding the IDE submission. These mechanisms, including approval with conditions, staged approval or staged approval with conditions, and communication of outstanding issues related to the IDE through future considerations, are described in this guidance.

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 February 8, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations'' 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; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. 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:

Owen Faris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1108, Silver Spring, MD 20993–0002, (301) 796–6356; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, (301) 827–6210.

I. Background

FDA approval of an IDE submission allows the initiation of a clinical investigation of a significant risk device. This guidance is intended to provide clarification regarding the regulatory implications of the decisions that FDA may render based on review of an IDE and to provide a general explanation of the reasoning and implications of those decisions. FDA has traditionally referred to IDE approvals that have conditions as ''Conditional Approvals.'' FDA believes that the term ''Approval with Conditions'' is more appropriate because the term conveys that the IDE has been approved and may begin without awaiting further FDA review. An IDE may be approved with conditions if FDA has determined, despite outstanding issues, that the information provided is sufficient to justify human clinical evaluation of the device, and that the proposed study design is generally acceptable. FDA may now also include ''future considerations'' in an approval or approval with conditions letter, which are issues and recommendations that FDA believes the sponsor should consider in preparation for a marketing application or a future clinical investigation. Future considerations are intended to provide helpful advice to sponsors regarding important elements of the future application that the IDE may not specifically address.

In this guidance new mechanisms are introduced, termed ''stage approval'' and ''staged approval with conditions,'' by which FDA may grant IDE approval or approval with conditions, while certain outstanding questions are being answered in parallel with enrollment in the clinical investigation. Staged approval and staged approval with conditions permit the clinical investigation to begin in a timely manner while maintaining appropriate subject protections. Staged approval or staged approval with conditions is most common for pivotal studies in which many subjects will be enrolled over an extended period of time, but may be applicable to other clinical investigations as well.

As a result of this draft guidance, FDA, where appropriate, seeks to offer flexibility in how outstanding issues can be addressed to allow clinical investigations to commence without unnecessary delay, while ensuring that human subjects are adequately protected.

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 ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.'' 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 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* or from the CBER Internet site at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm.* To receive ''FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to (301) 847–8149 to receive a hard copy. 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.

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.

[FR Doc. 2011–29118 Filed 11–9–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0788]

Pilot Program for Early Feasibility Study Investigational Device Exemption Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is soliciting nominations from sponsors of innovative device technologies to participate in a pilot program for early feasibility study investigational device exemption (IDE) applications. The pilot program will conform to the approaches outlined in the draft guidance entitled ''Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.'' Under the pilot program, FDA's review