Dated: September 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0787]

Investigational Device Exemptions for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human Studies; Guidance for Industry 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 guidance entitled ''Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies.'' Through the approaches announced in this guidance, FDA intends to facilitate early feasibility studies of medical devices, using appropriate risk mitigation strategies, under the IDE regulations. Early feasibility studies allow for limited early clinical evaluations of devices to provide proof of principle and initial clinical safety data, often before the device design is finalized. This 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 study protocol during the early feasibility study.

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: Submit written requests for single copies of the guidance document entitled ''Investigational Device Exemptions (IDEs) 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 (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, 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 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; 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.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is intended to provide assistance to FDA staff, clinicians, medical device 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 clinical experience is necessary because nonclinical testing methods are not available or adequate to provide the information needed to advance the developmental process. As with all clinical studies, initiation of an early feasibility study must be justified by an appropriate benefit/risk analysis and adequate human subject protection measures.

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

Concurrent with the publication of this guidance in draft, November 10, 2011 (76 FR 70150), FDA initiated a pilot program for early feasibility study IDE applications (November 10, 2011, 76 FR 70152) to solicit nominations from sponsors of innovative device technologies. In addition to making clarifications within the final guidance in response to comments from the public on the draft guidance, FDA has incorporated changes based on information learned and experiences gained from the pilot program.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the Agency's current thinking on IDEs for Early Feasibility Medical Device Clinical 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.

III. Electronic Access

Persons interested in obtaining a copy of the 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 CBER at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*. To receive ''Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies,'' 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 1782 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;

and the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910–0130.

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: September 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1120]

Draft Guidance for Industry on Abbreviated New Drug Application Submissions—Refuse-to-Receive Standards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDA Submissions—Refuse-to-Receive Standards.'' This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs) and related submissions (i.e., prior approval supplements (PASs) for new strengths). The guidance contains details on what should be included in these submissions and highlights serious deficiencies that may cause FDA to *refuse to receive* the submission.

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 October 31, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, 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 draft guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Johnny Young, Center for Drug Evaluation and Research (HFD–613), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8677.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDA Submissions—Refuse-to-Receive Standards.'' This guidance is intended to assist applicants preparing to submit to FDA ANDAs and PASs to ANDAs for which the applicant is seeking approval of a new strength of the drug product. The guidance contains details on what should be included in an ANDA and highlights serious deficiencies that may cause FDA to refuse to receive an ANDA. A refuse-to-receive decision indicates that FDA has determined that an ANDA is incomplete on its face, usually because of omissions.

With the enactment of the Generic Drug User Fee Act on July 9, 2012 (Pub. L. 112–144, Title III), FDA's Office of Generic Drugs (OGD) was tasked with a number of activities, including developing enhanced refusal to receive standards for ANDAs and related submissions. Recent data underscore the need for improvement in the quality of original ANDA submissions. Between 2009 and 2012, OGD refused to receive 497 ANDAs, primarily because the submissions contained serious deficiencies. FDA evaluates each incoming ANDA individually to determine whether its format and content meet threshold criteria to permit a substantive review and can thus be received by FDA. The Agency cannot receive an ANDA unless it contains the information required under section 505(j) of the Federal Food, Drug, and Cosmetic Act and related regulations (e.g., 21 CFR 314.101(b)(1)). This guidance explains in some detail the kind of omissions that can lead to a refuse-to-receive determination. The guidance is intended to assist applicants preparing ANDAs and related submissions to help improve the quality of those submissions and ensure that their format and content meet the threshold criteria for FDA receipt and review.

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 refusing to receive ANDAs and related submissions. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 collection of information in 21 CFR part 314 for ANDA and related submissions has been approved under OMB control number 0910–0001.

III. 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*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: September 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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