

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Submit electronic comments on the draft guidance to 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](mailto: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]

**BILLING CODE 4160-01-P**

**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

of IDE applications for an early feasibility study, including a first in human study, is expected to be based on less nonclinical data than would be expected for a traditional feasibility or a pivotal study. The pilot will also involve new approaches to IDE review to facilitate timely device and clinical protocol modifications during an early feasibility study.

**DATES:** FDA will begin accepting nominations for participation in the voluntary pilot program on December 12, 2011.

**FOR FURTHER INFORMATION CONTACT:** Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, rm. 1676, Silver Spring, MD 20993-0002, (301) 796-5640.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Early feasibility studies allow for early clinical evaluation of significant risk devices to provide proof of principle and initial clinical safety data. During these studies, iterative device modifications are likely to be made based on clinical experience. Early feasibility studies may be appropriate early in the device development process in a limited number of subjects when nonclinical testing methods are not available or adequate to provide the information needed to advance the development process, making clinical experience necessary. As with all clinical studies, the initiation of an early feasibility study must be justified by an appropriate risk-benefit analysis and adequate human subject protection measures. Because these studies are performed early in the device development process before the device design is finalized and are only appropriate where additional nonclinical testing is not available or adequate to provide the information needed to advance device development, the information included in the IDE application may vary from the information typically included in IDE applications for traditional feasibility or pivotal studies. To address the unique challenge of early feasibility studies, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the early feasibility study draft guidance.

The anticipated benefits of this pilot program include facilitating development of innovative products in the United States and evaluating the new approaches for modifications made during early feasibility studies, which are outlined in the early feasibility study draft guidance. The information

learned and experiences gained from the pilot program will help inform the final guidance document.

### II. Early Feasibility Study IDE Pilot Program

FDA has developed a pilot program that presents a streamlined process to interested sponsors/requesters. This notice outlines: (1) The guiding principles underlying the pilot program, (2) appropriate candidates for the pilot program, and (3) the procedures FDA intends to follow in the pilot program for early feasibility IDEs.

#### A. Guiding Principles

The following basic principles underline the early feasibility study IDE pilot program described in this notice. FDA intends that these principles create a common understanding between the sponsor and FDA about the goals and parameters of the early feasibility study IDE application pilot program:

1. FDA will not publicly disclose participation of a sponsor in the early feasibility IDE pilot program, unless the sponsor consents or has already made this information public, or disclosure is required by law.
2. Participating in this pilot program does not guarantee approval of an IDE application, nor is a sponsor precluded from withdrawing from the pilot program and pursuing traditional IDE review.
3. Due to FDA resource issues, FDA intends to limit the pilot program to nine candidates.

#### B. Appropriate Candidates

Appropriate candidates for the pilot program are medical devices for which:

1. The sponsor has not already submitted an IDE application.
2. An application for premarket review or approval would require the submission of clinical data.
3. Limited clinical study of the device (e.g., generally fewer than 10 initial subjects) is necessary because additional nonclinical testing is unlikely to provide the insights necessary to further the development of the device, or appropriate nonclinical tests are unavailable.

FDA encourages any interested sponsors who believe their device and/or study are appropriate candidates to contact FDA through the Center for Devices and Radiological Health (CDRH), Investigational Device Exemption Section at (301) 796-5640, before initiating the procedures referenced in this document in section *C. Procedures*.

#### C. Procedures

FDA has developed the following procedures to ensure adequate information to assess a candidate's suitability for the pilot program is provided to FDA without creating a burdensome new application process:

##### 1. Nomination

The sponsor/requester of an innovative therapeutic or diagnostic device may nominate their study for participation in the pilot program by submitting a nomination to the CDRH Document Mail Center (Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center, Bldg. 66, rm. G609, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002), with a duplicate copy sent to the Investigational Device Exemption Section (see **FOR FURTHER INFORMATION CONTACT**). FDA intends to acknowledge receipt of nominations via email. The following information will assist FDA in processing and responding to nominations:

- Name of the sponsor/requester and relevant contact information,
- Name of the product,
- Succinct description of the technology and disease or condition the device is intended to diagnose or treat, and
- A brief statement explaining why the device is an appropriate candidate for the pilot program as described in this document in section *B. Appropriate Candidates*.

##### 2. FDA Consideration

FDA intends to consider each nomination within 30 days of receiving the complete information described in this document in section *C. Procedures*. FDA may contact the sponsor/requester to request supplemental information during the 30-day review period.

##### 3. Sponsor/Requester Notification

FDA intends to notify the sponsor/requester whether or not the product is an appropriate candidate for the early feasibility study IDE pilot program within 30 days from receiving the complete information described in this document in section *C. Procedures*.

##### 4. Acceptance Meeting

If the nominee is deemed an appropriate candidate, FDA intends to meet with the product sponsor/requester, either in person or by telephone, within 30 days of notifying the sponsor/requester that its nominee was accepted.

## 5. FDA Review

Under the pilot program, early feasibility study IDE applications will be reviewed according to the approaches outlined in the early feasibility study draft guidance. The essential elements announced in the early feasibility study draft guidance are:

- FDA may approve an IDE application for an early feasibility study, including certain first in human studies, based on less nonclinical data than would be expected for a traditional feasibility or a pivotal study. This is because early feasibility studies are only appropriate where additional nonclinical testing is not available or adequate to provide the information needed to advance the developmental process. Identification of the data necessary to support an early feasibility study should be based on a thorough device evaluation strategy that describes the device and procedure-related attributes and addresses the potential failure modes. Appropriate human subject protection measures and risk mitigation strategies must also be identified. This policy is intended to facilitate initiation of clinical studies in the United States earlier in the device development process than has historically occurred, when appropriate.

- New approaches that facilitate timely device and clinical protocol modifications during an early feasibility study while still requiring compliance with the IDE regulations in 21 CFR part 812.

FDA has provided additional information regarding its expectations for early feasibility study IDE applications in the early feasibility study draft guidance.

*D. Duration of the Pilot*

FDA intends to accept requests for participation in the pilot program for 180 days from the date of publication of this notice. FDA may decide to terminate the pilot program before the close of the 180-day period or extend the pilot program beyond the 180-day period. The decision to terminate or extend the pilot will be announced in the **Federal Register**. FDA may also decide to modify the pilot program while it is in effect. Any modifications will also be announced in the **Federal Register**. FDA intends to terminate the pilot program when the early feasibility study draft guidance is finalized.

*E. Evaluation*

FDA intends to use the experience gained from the pilot program to inform the final version of the early feasibility study draft guidance.

Dated: November 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-29116 Filed 11-9-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel, Life after Linkage: The Future of Family Studies.

*Date:* December 1-2, 2011.

*Time:* 8:30 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 20814.

*Contact Person:* YingYing Li-Smerin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892-7924. (301) 435-0277. [lismerein@nhlbi.nih.gov](mailto:lismerein@nhlbi.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel, COPD Case Finding Methodology.

*Date:* December 1, 2011.

*Time:* 9 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW., Washington, DC 20008.

*Contact Person:* Stephanie J Webb, Ph.D., Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892. (301) 435-0291. [stephanie.webb@nih.gov](mailto:stephanie.webb@nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel, PPG Review: Endothelium and cardiovascular function.

*Date:* December 2, 2011.

*Time:* 8:30 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

*Contact Person:* Tony L Creazzo, Ph.D., Scientific Review Officer.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 4, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011-29142 Filed 11-9-11; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel, Small Grants Program for Cancer Epidemiology.

*Date:* November 17-18, 2011.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8059, Bethesda, MD 20892-8329. (301) 496-7904. [decluej@mail.nih.gov](mailto:decluej@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/sep/sep.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction;