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

AGENCIES: 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 The pilot program will conform to the approaches outlined in the draft guidance entitled "Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies."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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Sheila Brown,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 1676,

Sliver 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.

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