

approximately \$4.1 million will fund 5 to 10 new awards, subject to availability of funds. It is anticipated that funding for the number of noncompeting continuation awards and new awards in FY 2017, FY 2018, and FY 2019 will be similar to FY 2016. Phase 1 studies are eligible for grants of up to \$250,000 per year for up to 3 years. Phase 2 and 3 studies are eligible for grants of up to \$500,000 per year for up to 4 years. Please note that the dollar limitation will apply to total costs (direct plus indirect). Budgets for each year of requested support may not exceed the \$250,000 or \$500,000 total cost limit, whichever is applicable.

B. Length of Support

The length of support will depend on the nature of the study. For those studies with an expected duration of more than 1 year, a second, third, or fourth year of noncompetitive continuation of support will depend on the following factors: (1) Performance during the preceding year, (2) compliance with regulatory requirements of investigational new drug/investigational device exemption, and (3) availability of Federal funds.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at <http://grants.nih.gov/grants/guide>. (FDA has verified the Web site addresses throughout this document but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

- *Step 1:* Obtain a Dun and Bradstreet (DUNS) Number
- *Step 2:* Register With System for Award Management (SAM) (formerly Central Contractor Registration (CCR))
- *Step 3:* Obtain Username & Password on Grants.gov
- *Step 4:* Authorized Organization Representative (AOR) Authorization
- *Step 5:* Track AOR Status
- *Step 6:* Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you

have followed these steps, submit electronic applications to: <http://www.grants.gov>.

Dated: August 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0790]

Food and Drug Administration Decisions for Investigational Device Exemption Clinical Investigations: Guidance for Sponsors, Clinical Investigators, Institutional Review Boards, 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 “FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations.” This guidance document was developed to promote the initiation of clinical investigations to evaluate medical devices under FDA’s IDE regulations. The 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 reasons for those decisions.

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: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “FDA Decisions for Investigational Device Exemption Clinical Investigations” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

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:

Owen Faris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1522, Silver Spring, MD 20993-0002, 301-796-6210; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA seeks to encourage medical device research and innovation to address important clinical needs and improve patient care. In many cases, device development and evaluation include clinical investigation. This guidance document has been developed to facilitate the initiation of clinical investigations to evaluate medical devices under FDA’s IDE regulations, part 812 (21 CFR part 812).

FDA approval of an IDE submission allows the initiation of subject enrollment in a significant risk clinical investigation of a medical 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 reasons for those decisions.

In an effort to promote timely initiation of subject enrollment in clinical investigations in a manner that protects study subjects, FDA has developed methods to allow a clinical investigation of a device to begin under certain circumstances, even when outstanding issues regarding the IDE submission remain. These mechanisms, including Approval with Conditions, Staged Approval, and communication of outstanding issues related to the IDE through Study Design Considerations and Future Considerations, are described in this guidance.

FDA’s decision-making process for IDEs was modified with passage of the

Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144). Section 601 of FDASIA amended section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) to specify certain situations in which FDA cannot disapprove an IDE. Section 520(g)(4)(C) of the FD&C Act states that, consistent with section 520(g)(1), FDA shall not disapprove an IDE because: (1) The investigation may not support a substantial equivalence or de novo classification determination or approval of the device; (2) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or (3) an additional or different investigation may be necessary to support clearance or approval of the device. However, the Agency recognizes that some IDE sponsors may wish to ensure that a pivotal study's design may support a marketing application if it is successfully executed, meets its stated endpoints, and does not raise unforeseen safety concerns. FDA is interested in working interactively with sponsors to assist in addressing important limitations with such a study that might impair its ability to support a future marketing application.

In the draft guidance, issued on June 14, 2013 (78 FR 35937), FDA specifically sought public comment on three questions. Based on its consideration of that feedback, the Agency has revised the guidance as discussed further in this document.

A. Inclusion of Study Design Considerations in FDA's Decision Letters

If FDA believes that modifications to the study design unrelated to the safety, rights, or welfare of study subject are needed to enable a sponsor to rely on the study as primary clinical support for a future marketing approval or clearance, those modifications will be noted as “study design considerations” (SDCs). Sponsors are not required to modify the investigational plan to address SDCs. However, if these considerations are not addressed, the study design may not support the study goals (e.g., a future marketing application). The draft guidance proposed that SDCs be included in a section of the IDE decision letter.

FDA received comments from several stakeholders proposing that FDA provide SDCs and its assessment of the study design in a communication separate from the decision letter. Other stakeholders expressed support for inclusion of SDCs in the letter. Still others focused on ensuring that the

decision letter clearly conveys whether FDA believes the study design is adequate to support its goals, even if the actual SDCs are conveyed separately from the letter.

Based on the comments received, FDA believes that sponsors and other stakeholders may misinterpret SDCs included in the body of a decision letter as issues that are required to be addressed. Therefore, FDA intends to convey SDCs in a separate attachment included with the decision letter, rather than in the body of the letter. The decision letter itself will state whether FDA believes that the study design is adequate to support the study goals or whether FDA recommends study design considerations to enable it to do so. If FDA recommends SDCs, FDA's letter will note the following: “These recommendations do not relate to the safety, rights or welfare of study subjects, and they do not need to be addressed in order for you to conduct your study.” FDA will continue to engage with stakeholders on this issue and may make modifications to this approach in the future.

B. Inclusion of Future Considerations in FDA's Decision Letters

Future considerations are issues and recommendations that FDA believes the sponsor should consider in preparing for a marketing application or a future clinical investigation. Future considerations are intended to provide helpful, non-binding advice to sponsors regarding important elements of the future application that the IDE may not specifically address. FDA sought comment on whether future considerations should be communicated in its IDE decision letters or whether they should be sent to the sponsor in a separate communication. FDA received comments proposing that the Agency provide future considerations as a separate communication and not in the decision letter. Based on the comments received, FDA intends to convey future considerations in a separate attachment included with the decision letter rather than in the body of the letter.

C. Utility of the Proposed Pre-Decisional IDE Process

The draft guidance proposed a new mechanism for review and interaction for pivotal IDEs called the Pre-Decisional IDE. The process included a comprehensive FDA review of a draft IDE prior to formal IDE submission, followed by written feedback from FDA and an interactive discussion between FDA and the sponsor. The goal of the Pre-Decisional IDE was to facilitate the development of an improved IDE

submission more likely to be approved as well as a study design adequate to support a future marketing application.

FDA specifically sought comment on the expected utility of the Pre-Decisional IDE process. Some commenters expressed support for the proposal and felt that it might shorten the time to full approval of pivotal IDE studies. Other commenters expressed concern that the Pre-Decisional IDE process itself might be too time-consuming or require extensive FDA resources that could be better allocated elsewhere. Based on the comments received and FDA's consideration of the points raised, FDA will not pursue the Pre-Decisional IDE at the present time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on decisions for 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 guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health 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 <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. Persons unable to download an electronic copy of “Decisions for Investigational Device Exemption Clinical Investigations,” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1783 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 part 812 have been approved under OMB control number 0910–0078.

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: August 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-19577 Filed 8-18-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Food Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Food Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 16-17, 2014, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Karen Strambler, Center for Food Safety and Applied Nutrition (HFS-024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-

402-2589 or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

If you are unable to attend in person, FDA encourages you to watch the free Web cast. Visit the Food Advisory Committee Web site at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/default.htm>. The link will become active shortly before the open session begins on December 16, 2014, at 8:30 a.m.

Agenda: The committee will discuss science issues surrounding susceptible life stages or populations and the circumstances under which FDA might decide to conduct a separate risk assessment for these populations. Also, FDA is requesting advice from the Food Advisory Committee on how to integrate concern for susceptible populations into its risk assessment procedures and methodologies including under what conditions a separate risk assessment should be conducted.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 8, 2014. Oral presentations from the public will be scheduled for December 17, 2014, between approximately 11 a.m. to 12 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of

the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 25, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 1, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Strambler at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1130]

Brain-Computer Interface Devices for Patients With Paralysis and Amputation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Brain-