available. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year and (2) the availability of Federal fiscal year funds.

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

Year 01: $7,500,000
Year 02: $7,500,000
Year 03: $7,500,000
Year 04: $7,500,000
Year 05: $7,500,000

B. Length of Support

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

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://www.grants.gov.* Search by Funding Opportunity Number: RFA–FD–14–017. (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)
- Step 3: Obtain Username & Password
- 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: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11924 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0835]

Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another Institutional Review Board; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB.'' The guidance announced in this document discusses regulatory responsibilities of institutional review boards (IRBs), clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. The guidance also addresses questions that have been previously raised concerning procedures and processes that are required and/or recommended by FDA when such oversight is transferred.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 (1–888–463–6332 or 301–796–3400); or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or 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. 4622, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Managements (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bridget Foltz, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5174, Silver Spring, MD 20993, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled, ''Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB.'' The guidance discusses the regulatory responsibilities of IRBs, clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. In particular, the guidance discusses eight steps to be considered when transferring oversight of a previously approved clinical investigation from one IRB to another IRB. These include identifying those studies for which IRB oversight is being transferred; ensuring availability and retention of pertinent records; establishing an effective date for the transfer of oversight; conducting a review of the study(ies) by the receiving IRB, where appropriate; confirming or establishing the date for the next continuing review; determining whether the consent form needs to be revised; notifying the key parties; and updating IRB registration information. The IRB transfer process is expected to vary depending on the reasons for the transfer, the parties involved, and the number and risk of the studies being transferred.

To enhance human subject protections and reduce regulatory burden, FDA and the Office for Human Research Protections (OHRP) have been actively working to harmonize the agencies' regulatory requirements and guidance for human subjects research. This guidance document was developed as a part of these efforts and in consultation with OHRP.

In the **Federal Register** of June 12, 2012 (77 FR 34958), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and considered them in preparing the final guidance. In response to the comments, FDA added a recommendation that the receiving IRB notify the sponsor if it decides to suspend or terminate study

approval. FDA also clarified both drug and device sponsor's reporting requirements related to such suspensions and terminations. Section III(6) was modified to recommend the use of a letter to provide currently enrolled subjects with any changes in contact information regarding subject rights or research-related injuries from a resulting IRB transfer. In addition, numerous editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 2012.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. The 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 312 have been approved under OMB control number 0910–0014; 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 part 56 have been approved under OMB control number 0910–0130.

III. Comments

Interested persons may submit either electronic comments regarding this document *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.regulations.gov* or *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm.*

Dated: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11923 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0469]

Determination of Regulatory Review Period for Purposes of Patent Extension; LINZESS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for LINZESS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product LINZESS (linaclotide). LINZESS is indicated for treatment of irritable bowel syndrome with constipation and chronic idiopathic constipation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LINZESS (U.S. Patent No. 7,304,036) from Ironwood Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 10, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LINZESS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LINZESS is 2,863 days. Of this time, 2,475 days occurred during the testing phase of the regulatory review period, while 388 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* October 30, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 30, 2004.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* August 9, 2011. FDA has verified the applicant's claim