at each meeting and post these reports for public access.

D. Eligibility Information

The following organization is eligible to apply: ECHCR. Within the Brookings Institution, the mission of the ECHCR is to provide practical solutions to achieve high-quality, innovative, affordable health care with particular emphasis on identifying opportunities on the national, State, and local levels. Leveraging its status as a neutral, nonprofit, research-focused institution with deep health care policy and technical expertise, ECHCR frequently serves as a convener of discussions, workshops, and symposia on complex policy and science topics. The Center has developed a reputation as an ''honest broker'' with the ability to identify practical solutions that reflect the best available science and input from all stakeholders. The performance goals and procedures outlined within PDUFA V will require a high degree of leadership, research, outreach, and involvement from a broad range of stakeholders across the health care system. ECHCR is uniquely qualified to conduct the background research and act as a convener for engaging critical stakeholders, raising awareness, and identifying practical solutions that identify and overcome potential challenges and help determine a clear path forward.

II. Award Information/Funds Available

A. Award Amount

FDA intends to fund one award, corresponding to a total of $700,000, for fiscal year (FY) 2013. Future year amounts will depend on annual appropriations. CDER anticipates providing in FY2013 up to $700,000 (total costs include direct and indirect costs) for one award subject to availability of funds in support of this project. The possibility of four additional years of support is contingent upon successful performance and the availability of funds, and would provide funds up to following amounts:

FY 2014: $721,000
FY 2015: $743,000
FY 2016: $765,000
FY 2017: $788,000

B. Length of Support

The support will be 1 year with the possibility of an additional 4 years of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a noncompeting continuation application and available Federal FY appropriations.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *http://grants2.nih.gov/grants/guide* and/or *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093567.htm.* (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**.) Persons interested in applying for a grant may obtain an application at *http://grants.nih.gov/grants/forms.htm.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* After you have followed these steps, submit paper applications to: Yemisi Akinneye, Grants Management, 5630 Fishers Lane, HFA–500, rm. 2037, Rockville, MD.

Dated: March 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05726 Filed 3–12–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0221]

Draft Guidance for Industry and Review Staff on Formal Dispute Resolution: Appeals Above the Division Level; 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 and review staff entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' This guidance is intended to provide recommendations for industry on the procedures in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for resolving scientific and procedural disputes that cannot be resolved at the division level. This guidance describes procedures for formally appealing such disputes to the office or center level and providing information to assist FDA officials in resolving the issue(s) presented. This guidance revises the guidance of the same name issued in February 2000.

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 June 11, 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, 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. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. 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: Amy Bertha, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6469, Silver Spring, MD 20993–0002, 301–796–0700; or, Sheryl Lard-Whiteford, Center for Biologics Evaluation and Research (HFM–4), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Formal Dispute Resolution: Appeals Above the Division Level.'' In the course of drug review, CDER and CBER make a wide variety of scientific and procedural decisions that are critical to a sponsor's drug development program. Sometimes, a

sponsor may disagree with one of these decisions, and a dispute arises. Because these disputes often involve complex scientific or procedural matters and also may be precedent setting, it is critical that there be procedures in place to encourage open, prompt discussion of such disputes. The procedures and policies described in this guidance are intended to promote rapid resolution of scientific and procedural disputes between sponsors and FDA. This draft guidance is a revision of the guidance of the same name that published in February 2000. The procedures and policies have been updated to reflect the current practices.

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 formal dispute resolution regarding appeals above the division level. 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 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 this draft guidance have been approved under OMB control number 0910–0430. This draft guidance is a revision of an earlier version of the guidance. The revised version contains no additional information collections; therefore, it continues to be covered under OMB control number 0910–0430.

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 *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: March 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05721 Filed 3–12–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0595]

Guidance for Industry on Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation.'' This guidance provides recommendations to sponsors of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) regarding what criteria should be met when evaluating and labeling tablets that have been scored. (A scoring feature facilitates tablet splitting, which is the practice of breaking or cutting a higher-strength tablet into smaller portions.) Specifically, this guidance recommends guidelines to follow, data to provide, and criteria to meet and detail in an application to support approval of a scored tablet; and nomenclature and labeling for approved scored tablets.

This guidance does not address specific finished-product release testing, where additional requirements may apply to scored tablets. This guidance does not describe the medical practice conditions under which tablet splitting is considered or recommended.

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. Send one self-addressed adhesive label to assist that 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 Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Russell Wesdyk, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4182, Silver Spring, MD 20993–0002, 301–796–2400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation.'' This guidance provides recommendations to sponsors of NDAs and ANDAs regarding what criteria should be met when evaluating and labeling tablets that have been scored. (A scoring feature facilitates tablet splitting, which is the practice of breaking or cutting a higher-strength tablet into smaller portions.) Specifically, this guidance recommends:

- Guidelines to follow, data to provide, and criteria to meet and detail in an application to support approval of a scored tablet; and
- Nomenclature and labeling for approved scored tablets.

On August 30, 2011 (76 FR 53909), FDA announced the availability of the draft version of this guidance. The public comment period closed on November 28, 2011. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes. The Agency also held an Advisory Committee for Pharmaceutical Science and Clinical Pharmacology meeting on August 9, 2012, to discuss the draft guidance. Any changes to the guidance were minor and made to clarify statements in the draft guidance.

The Agency has previously considered tablet scoring as an issue when determining whether a generic drug product is the same as the reference listed drug (RLD). One characteristic of a tablet dosage form is that it may be manufactured with a score or scores. This characteristic is useful because the score can be used to facilitate the splitting of the tablet into fractions when less than a full tablet is desired for a dose. Although there are