insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and ''other appropriate actions as the Secretary deems necessary'' (section 513(a)(1)(B) of the FD&C Act). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on February 3, 2006, establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification was codified in 21 CFR 866.3332, a regulation that describes the new classification for reagents for detection of specific novel influenza A viruses and sets forth the special controls that help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation refers to the special controls guidance document entitled ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,'' which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents. The guidance document recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses become available from the World Health Organization, National Institutes of Health, and other public health entities, sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g), to determine if any design changes may be necessary.

FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year; each response is estimated to take 15 hours. This results in a total data collection burden of 300 hours. The guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

In the **Federal Register** of September 25, 2012 (77 FR 58997), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

FD&C Act section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
513(g)	10	2	20	15	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–05722 Filed 3–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Cooperative Agreement To Support Regulatory Research Related to Food and Drug Administration Commitments Under the 2012 Prescription Drug User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for award of a cooperative agreement to the Brookings Institution's Engelberg Center for Health Care Reform (ECHCR) in support of efforts to inform major initiatives for process improvement and regulatory science related to FDA commitments under the 2012 reauthorization of the Prescription Drug User Fee Act (PDUFA V).

DATES: Important dates are as follows:

1. The application due date is April 15, 2013.

2. The anticipated start date is June 1, 2013.

3. The expiration date is April 16, 2013.

For Further Information and Additional Requirements Contact:

Adam Kroetsch, Office of Planning and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993, 301–796–3842, *Adam.Kroetsch@fda.hhs.gov;*

or

Yemisi Akinneye, Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane, HFA 500, Rm. 2037, Rockville, MD 20857, 301–827–0079, *Oluyemisi.Akinneye@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://grants2.nih.gov/grants/guide/and/or http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093567.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–005; 93.103.

A. Background

The FDA Center for Drug Evaluation and Research (CDER) seeks to support efforts to research, identify key issues, and convene appropriate subject matter experts to help inform major initiatives for process improvement and regulatory

science related to FDA commitments under PDUFA V. PDUFA, first enacted in 1992, has provided FDA with the resources and process enhancements to enable a transformation of the human drug review process, increasing the quality, number, and timely access to new drugs for U.S. patients.

The 2012 reauthorization of PDUFA initiated a set of performance goals and procedures for FDA through fiscal year 2017. These performance goals represent a series of commitments which were established in consultation with drug industry representatives, patient and consumer advocates, and health care professionals. Specific PDUFA commitments include public meetings, staff training procedures, and efficiency standards on a variety of issues. More information about FDA's commitments under PDUFA V can be found at the following Web site: *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

B. Research Objectives

In the most recent reauthorization of PDUFA, FDA has committed to build on a record of continuing improvement through a wide range of new innovative initiatives related to virtually every aspect of the new drug life cycle, each of which represent specific areas of research interest. These initiatives may include, but not be limited to, the following:

- Enhancing regulatory science and expediting drug development;
- Advancing metaanalysis methods;
- Advancing the use of biomarkers and pharmacogenomics;
- Developing and enhancing patient-reported outcomes to support patient-focused drug development;
- Facilitating rare disease drug development;
- Structured approaches to enhancing FDA's assessment of benefits and risks in human drugs;
- Improving evaluation, standardization, and integration of Risk Evaluation and Mitigation Strategies (REMS);
- Exploring the use of Sentinel as a tool for evaluating drug safety issues; and
- Requiring electronic submissions and standardization of electronic application data.

Several key areas of research interest are described in greater detail below:

1. Developing and Enhancing Patient-Reported Outcomes To Support Patient-Focused Drug Development

The advancement of patient-reported outcome measures (PROs) is designed to promote patient engagement throughout the drug development process. FDA has dedicated steps toward the development of these tools by expanding clinical and statistical staff capacity, providing qualification consultations, and promoting best practices for the use of outcome assessment tools. FDA seeks to identify the challenges and opportunities within the current review and qualification of PROs, to address key issues with PRO evidentiary standards, develop new methods for communication between the multiple stakeholders involved in PROs, and identify best practices for evaluation and statistical analysis and design of PROs.

2. Structured Approaches to Enhancing FDA's Assessment of Benefits and Risks in Human Drugs

FDA recognizes that the Agency's efforts to develop a more structured approach to benefit-risk assessment could be complemented by further engagement of stakeholders and other parties. This engagement seeks to focus on the current efforts and methods that have been applied to structure and communicate regulatory decisions, including the relevance to the work of a regulator and how well such approaches integrate with how regulators think about their decisions. FDA expects that these discussions would focus on the results of implementing frameworks at regulatory agencies both in premarket application review as well as post-market safety review, providing an opportunity to share challenges and lessons learned in applying a more structured approach to regulatory decision-making.

3. Improving Evaluation, Standardization, and Integration of REMS

FDA seeks stakeholder and expert feedback on approaches to standardizing of REMS and integrating them into the health care delivery system. Areas for research include the following:

- A standardized methodology for selecting appropriate risk management interventions when a REMS is deemed necessary. Such a methodology should allow FDA and sponsors to proactively identify and address the underlying causes of patient harm, and evaluate and prioritize risk management interventions based on evidence of their effectiveness and burden on the health care delivery system.
- Standard approaches and best practices for implementing REMS and integrating them into the existing health care delivery system. These approaches may include the use of improved methods for communicating with and training REMS stakeholders and the use of information technology to facilitate REMS implementation.
- Standard methods to evaluate REMS, including methods to assess REMS effectiveness, impact on patient access, and burden on the health care delivery system.

C. Approach

In order to achieve these research objectives as part of its PDUFA V commitments, FDA has committed to seek input from relevant external subject matter experts and other interested public stakeholders. In addition, this input process should be conducted so as to be timely, well-informed, candid, thoughtful, thorough, and well-documented.

FDA has a limited capacity to conduct the needed research to fully inform and undertake these external expert engagements to ensure the successful accomplishment of these PDUFA V commitments. FDA is therefore seeking to establish a cooperative agreement with the Brookings Institution's ECHCR for its unique qualifications and experience in the conduct of the needed research, workshops and other meetings, and related work.

The goal of this collaboration is to support the implementation of PDUFA V performance goals by convening stakeholders with diverse expertise. Through a series of meetings, workshops, webinars, and/or workgroups, ECHCR would provide effective opportunities for engagement of these stakeholders to inform implementation of the PDUFA V goals. In addition to gathering input from selected stakeholder groups, ECHCR may conduct background research prior to expert engagement, and to communicate updates on the progress of PDUFA implementation to broader audiences. Specific objectives of this collaboration would include:

- Working collaboratively with FDA to identify and prioritize pressing issues related to the implementation of PDUFA reauthorization performance goals and procedures;
- Conducting research and reviews of relevant literature to plan the focus of sessions in which experts are convened to provide critical input to FDA regulatory enhancement discussions;
- Convening expert stakeholders in focused, substantive discussions of these issues, and identify and explore potential strategies for resolving them; and
- Developing reports that summarize the background research and discussion

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]

BILLING CODE 4160–01–P

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