FDA Center Director. Except when initiated by an FDA Center Director, a request for an exception or alternative must be in writing and must:

- Identify the specified lots, batches, or other units of the affected product;
- Identify the specific labeling provisions under this rule that are the subject of the request;
- Explain why compliance with the specified labeling provisions could adversely affect the safety, effectiveness, or availability of the product subject to the request;
- Describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product given the anticipated circumstances of use of the product;
- Provide copies of the proposed labeling of the specified lots, batches, or other units of the affected product that will be subject to the exception or alternative; and
- Provide any other information requested by the FDA Center Director in support of the request.

If the request is granted, the manufacturer may need to report to FDA any resulting changes to the New Drug Application, Biologics License Application, Premarket Approval Application or Premarket Notification (510(k)) in effect, if any. The submission and grant of an exception or an alternative to the labeling requirements specified in the interim final rule (72 FR 73589) may be used to satisfy certain reporting obligations relating to changes to product applications under § 314.70 (21 CFR 314.70) (human drugs), § 601.12 (21 CFR 601.12) (biological products), § 814.39 (21 CFR 814.39) (medical devices subject to premarket approval), or § 807.81 (21 CFR 807.81) (medical devices subject to 510(k) clearance requirements). The information collection provisions in §§ 314.70, 601.12, 807.81, and 814.39 have been approved under OMB control numbers 0910–0001, 0910–0338, 0910–0120, and 0910–0231, respectively. On a case-by-case basis, the appropriate FDA Center Director may also determine when an exception or alternative is granted that certain safeguards and conditions are appropriate, such as additional labeling on the SNS products, so that the labeling of such products would include information needed for safe and effective use under the anticipated circumstances of use.

Respondents to this collection of information are entities that manufacture (including labeling, packing, relabeling, or repackaging), distribute or store affected SNS products. Based on the number of requests for an exception or alternative received by FDA since issuance of the interim final rule, FDA estimates an average of two requests annually. FDA is estimating that each respondent will spend an average of 24 hours preparing each request. The hours per response for each submission are based on the estimated time that it takes to prepare a supplement to an application, which may be considered similar to a request for an exception or alternative. To the extent that labeling changes not already required by FDA regulations are made in connection with an exception or alternative granted under the interim final rule, FDA is estimating one occurrence annually in the event FDA would require any additional labeling changes not already covered by FDA regulations, and that it would take 8 hours to develop and revise the labeling to make such changes.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	2	1	2	24	48
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	8	8
Total					56

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

Dated: November 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30036 Filed 11–29–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0576]

Supplemental Funding Under the Food and Drug Administration's Convener of Active Medical Product Surveillance Discussions (U13) RFA–FD–09–012; Request for Supplemental Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is announcing a program expansion of its Conference Cooperative Agreement Program (U13), awarded to the Engelberg Center for Health Care Reform at the Brookings Institution (Brookings). The goal of this expansion is to plan and hold meetings and conferences that will ensure broad stakeholder input on FDA programs and initiatives related to disseminating information from active medical product surveillance activities and other sources of product information.

DATES: Important dates are as follows:

1. The supplemental application due date is December 13, 2010.

2. The award anticipated start date is January 1, 2011.

3. The opening date is November 30, 2010.

4. The expiration date is December 14, 2010.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Melissa Robb, Office of Medical Policy, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, rm. 6360, Silver Spring, MD 20993–0002, 301–796–2500, e-mail: *Melissa.Robb@fda.hhs.gov;* or

Camille R. Peake, Division of Acquisition Support and Grants, Food and Drug Administration, 5630 Fishers Lane (HFA–500), Rockville, MD 20857, 301–827–7175, FAX: 301–827–7101, e-mail: *Camille.Peake@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

For more information on the original full funding opportunity announcement (FOA) RFA–FD–09–012, go to *http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm168759.htm.*

A. Background

This FOA, issued by FDA, announces a proposed program expansion of FDA's Conference Cooperative Agreement Grant U13 FD003802 awarded to Brookings. The goal of this program is to plan and hold meetings and conferences that will ensure broad stakeholder input on FDA programs and initiatives related to disseminating information from active medical product surveillance activities and other sources of product information. The information obtained through these meetings and workshops is being used to develop, implement, and evaluate medical product surveillance methods and systems, which support the gathering, analysis, and communication of medical product safety information.

Supplementing the parent grant to incorporate expansion of the scope of work would support activities including convening discussions, leveraging the information learned from medical product surveillance, and engaging stakeholders, namely the health care community, consumers and industry, on topics related to patient counseling and dissemination of product information on the risks, benefits, and safe use of prescription drugs. Discussions would cover issues related to developing a quality systems approach to make sure that user-friendly, easily accessible, up-to-date information is available to the public and health care practitioners who are interacting with patients to prescribe and dispense medications. It is important that practitioners and pharmacists are able to adequately inform patients about the proper use of medications being prescribed or dispensed. This supplement would include convening meetings and synthesizing, summarizing, and communicating the findings on topics such as those listed in the Research Objectives. (*See* section B of this document.)

During Year 1, a supplement was awarded that allowed for the convening of discussions on topics related to the development and appropriate dissemination of Patient Medication Information (PMI). With this FOA, FDA proposes to further expand the scope of work of the 2009 supplement and increase the amount of supplemental funding for each budget year to $501,534 total cost (direct costs only), beginning in 2010, and future years 2011, 2012, and 2013. (Funding for this supplement will be subject to availability of funds and satisfactory progress of the project).

B. Research Objectives

This supplement will expand the existing program to convene meetings and synthesize, summarize, and communicate relevant findings on topics such as those discussed in the following paragraphs.

• Patient Medication Information (PMI)

To be able to use prescription medications safely, consumers need to receive clear, actionable medication information that is accurate, balanced, and delivered in a consistent and easily understood format. In February 2009, FDA's Risk Communication Advisory Committee recommended FDA adopt a single, standard document for communicating essential information about prescription drugs, which would replace Consumer Medical Information, Patient Package Insert (PPI), and Medication Guides. Such changes to the delivery of PMI may require changes to the Federal Food, Drug, and Cosmetics Act law and/or regulations to implement. Following a series of public workshops convened by FDA, the Agency developed three draft patient information prototypes as well as a strategy for evaluating the prototypes. Upon approval from the Office of Management and Budget, FDA plans to evaluate the three prototypes using an experimental consumer testing study. As part of its evaluation process, FDA intends to hold a series of workshops to ensure continued, broad public input on the prototypes. In addition, Brookings also convened three workshops in cooperation with FDA (Year 1) to discuss optimizing, implementing, and evaluating adoption of a single, standard medication information document. As a followup to the outcomes and recommendations received from the meetings described previously, FDA is interested in obtaining additional feedback, guidance, and expert opinion from a broad range of stakeholders during the supplemented years needed to move the PMI initiative forward, including, for example, through pilot projects for PMI distribution using modern media and exploration of additional issues related to PMI monitoring, compliance, and enforcement, as well as by developing processes for follow-up assessments.

• Professional Labeling

In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule that amended the requirements for the content and format of the package insert for human prescription drug and biologic products. The purpose of the new requirements was to improve the management of the risks of medical product use and reduce medical errors by health care professionals, as well as enable health care practitioners to better communicate risk information to their patients. The new regulation (21 CFR 201.57) was designed to make information in the prescription package insert easier for health care practitioners to access, read, and use, thereby facilitating use of the package insert to make prescribing decisions. The final rule has a phased-in implementation schedule that initially targets new and recently approved drugs. These new requirements have been in effect for 4 years, and many drugs on the market have package inserts in the new format.

Because complying with these new requirements is essential for meeting the objective of better risk communication, FDA is interested in obtaining feedback from health care practitioners on whether the new package insert format is being implemented in a manner that meets the needs of the practicing physician and other health care practitioners or whether there are areas in which FDA could improve implementation.

• Risk Evaluation and Mitigation Strategies (REMS)

With the additional regulatory authority granted to FDA in the FDA Amendments Act of 2007, FDA has begun requiring REMS, with the components of each individual strategy varying by the risks involved and patient populations eligible.

Based on existing FDA guidance, REMS components have included medication guides ("MedGuides"); patient package inserts; communication plan(s) for health care practitioners (*e.g.* "Dear Provider" letters); and elements to assure safe use (ETASU), including requirements for those who prescribe, dispense, or use the drug. In some cases, MedGuides have been the only component required; in other cases, FDA has required ETASU of varying designs, such as those requiring that a drug be dispensed to patients with evidence (*e.g.,* restricted distribution) or other documentation of safe-use conditions (*e.g.,* certain laboratory test result outcomes required before a drug may be dispensed).

The current REMS requirement process has led to the implementation of more than 100 new strategies, with varying elements based on the severity

of risk projected and different approaches taken by manufacturers seeking to meet those requirements. FDA would like to convene sessions of experts and hold focused meetings over the next 3 years to discuss REMS implementation to date, and explore practical policy approaches relevant to restricted distribution processes and quality care counseling.

C. Eligibility Information

This supplement is available only to the existing grant recipient, Brookings.

D. Requirements of the Supplemental Application

1. The application clearly demonstrates an understanding of the purpose and objectives of the program expansion as described in section B of this document.

2. The application clearly describes the steps involved in a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the program expansion.

3. The application establishes Brookings ability to perform the responsibilities under the program expansion including the availability of appropriate staff and sufficient funding.

4. The application describes Brookings ability to act as a neutral, independent third party to convene a wide group of diverse stakeholders with relevant expertise related to selected topics.

5. The application specifies the manner in which interaction with FDA will be maintained throughout the lifetime of the project.

6. The application specifies how Brookings will monitor progress of the work under the program expansion and how progress will be reported to FDA.

7. The application shall include a detailed budget that shows: (1) Anticipated costs for personnel, travel, communications and postage, and supplies and (2) the sources of funds to meet those needs, if other than FDA.

II. Award Information/Funds Available

A. Award Amount

FDA anticipates supplementing this program expansion by providing approximate total cost of $501,534 (direct costs only) in each budget period beginning in 2010, and the remaining budget periods (years: 2011, 2012, and 2013).

B. Length of Support

The initial supplemental award will be awarded to correspond with the 2010 budget period, and the remaining budget periods (2011, 2012, and 2013) will be dependant on the grantee's successful performance, and financial management.

III. Paper Application and Submission Information

To submit a paper application in response to this supplemental notice, applicants should download the PHS–398 form at *http://grants.nih.gov/grants/funding/phs398/phs398.html.* (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

For all paper application submissions, the following steps are required:

Submit paper via Express mail to (*see* the *For Further Information and Additional Requirements Contact* section of this document).

Dated: November 23, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–30054 Filed 11–29–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB), under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Ryan White HIV/AIDS Program Core Medical Services Waiver Application Requirements (OMB No. 0915–0307)—Extension

HRSA utilizes standards for granting waivers of the core medical services requirement for the Ryan White HIV/AIDS Program. These standards meet the intent of the Ryan White HIV/AIDS Program to increase access to core medical services, including antiretroviral drugs, for persons with HIV/AIDS and to ensure that grantees receiving waivers demonstrate the availability of such services for individuals with HIV/AIDS who are identified and eligible under Title XXVI of the Public Health Service (PHS) Act. The core medical services waiver uniform standard and waiver request process will apply to Ryan White HIV/AIDS Program Grant awards under Parts A, B, and C of Title XXVI of the PHS Act. Core medical services waivers will be effective for a 1-year period that is consistent with the grant award period.

Title XXVI, Section 2671 of the PHS Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, Public Law 111–87, (Ryan White HIV/AIDS Program), requires that grantees expend 75 percent of Parts A, B, and C funds on core medical services, including antiretroviral drugs, for individuals with HIV/AIDS who are identified and eligible under the legislation. In order for grantees under Parts A, B, and C to be exempt from the 75 percent core medical services requirement, they must request and receive a waiver from HRSA.

Grantees must submit the waiver request with the annual grant application that includes the certifications and documentation which will be utilized by HRSA in making determinations regarding waiver requests. Grantees must provide evidence that all of the core medical services listed in the statute, regardless of whether such services are funded by the Ryan White HIV/AIDS Program, are available to all individuals with HIV/AIDS who are identified and eligible under Title XXVI of the PHS Act in the service area within 30 days.

The annual estimate of burden is as follows: