to revoke, suspend, or modify their tolerances, will remain in the channels of trade after the applicable tolerance is revoked, suspended, or modified. If FDA encounters food bearing a residue of a pesticide chemical for which the tolerance has been revoked, suspended, or modified, it intends to address the situation in accordance with provisions of the guidance. In general, FDA anticipates that the party responsible for food found to contain pesticide chemical residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, suspended, or modified will be able to demonstrate that such food was handled, *e.g.,* packed or processed, during the acceptable timeframes cited in the guidance by providing appropriate documentation to the Agency as discussed in the guidance document. FDA is not suggesting that firms maintain an inflexible set of documents where anything less or different would likely be considered unacceptable. Rather, the Agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so handled during the acceptable timeframes.

Examples of documentation which FDA anticipates will serve this purpose consist of documentation associated with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

FDA is requesting the extension of OMB approval for the information collection provisions in the guidance.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food-processing industries that handle food products that may contain residues of pesticide chemicals after the tolerances for the pesticide chemicals have been revoked, suspended, or modified.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Documentation Submission	1	1	1	3	3

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

FDA expects the total number of pesticide tolerances that are revoked, suspended, or modified by EPA pursuant to dietary risk considerations in the next 3 years to remain at a low level, as there have been no changes to the safety standard for pesticide residues in food since 1996. Thus, FDA expects the number of submissions it will receive pursuant to the guidance document will also remain at a low level. However, to avoid counting this burden as zero, FDA has estimated the burden at one respondent making one submission a year for a total of one annual submission.

FDA based its estimate of the hours per response on the assumption that the information requested in the guidance is readily available to the submitter. We expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for submission to FDA. The submitter will almost always merely need to copy existing documentation. We believe that this effort should take no longer than 3 hours per submission.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
Documentation Recordkeeping	1	1	1	16	16

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

In determining the estimated annual recordkeeping burden, FDA estimated that at least 90 percent of firms maintain documentation, such as packing codes, batch records, and inventory records, as part of their basic food production or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not be currently maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. In previous information collection requests, this recordkeeping burden was estimated to be 16 hours per record. FDA has retained its prior estimate of 16 hours per record for the recordkeeping burden. As shown in table 1 of this document, FDA estimates that one respondent will make one submission per year. Although FDA estimates that only 1 out of 10 firms will not be currently maintaining the necessary documentation, to avoid counting the recordkeeping burden for the 1 submission per year as 1/10 of a recordkeeper, FDA estimates that 1 recordkeeper will take 16 hours to develop and maintain documentation recommended by the guidance.

Dated: March 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0012]

Campaign To Improve Poor Medication Adherence (U18)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Drug Evaluation and Research. A goal of the Center for Drug Evaluation and Research is to raise consumers' awareness of the

importance of good medication adherence, a vital first step toward improved adherence behavior and better public health outcomes.

DATES: Important dates are as follows:

1. The application due date is April 15, 2011.
2. The anticipated start date is April 16, 2011.
3. The opening date is March 15, 2011.
4. The expiration date is April 15, 2011.

For Further Information and Additional Requirements Contact: Programmatic Contact: Tamara Ford, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Executive Programs, 10903 New Hampshire Ave., rm. 6114, Silver Spring, MD 20993, 301–796–5226, FAX: 301–847–8737, e-mail: *Tamara.Ford@fda.hhs.gov;* Grants Management Contact: Oluyemisi Akinneye, Division of Acquisition Support and Grants (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2129, Rockville, MD 20857, 301–827–0079, FAX: 301–827–7101, e-mail: *Oluyemisi.Akinneye@fda.hhs.gov.*

For more information on the 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/Drugs/DrugSafety/ucm187806.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

A. Background

This funding opportunity is a single source application for the award of a cooperative agreement to the National Consumers League (NCL) to develop and lead a groundbreaking national campaign to raise consumers' awareness of the importance of good medication adherence and provide tools to prescribers to help their patients use their medications in the most safe and efficacious manner. This campaign is a vital first step toward improved adherence behavior and better health outcomes.

Relevance

Inadequate medication adherence is a $290 billion dollar problem that touches everyone. Nearly three out of four Americans report that they do not take their medications as directed. One in three people never fill their prescriptions. Americans with chronic conditions account for nearly 45 percent of the population, and they are at greater risk for health complications and negative health outcomes because of medication adherence problems. Understanding the root causes for inadequate medication adherence, and effecting changes in knowledge and behaviors to increase appropriate medication adherence and thus enhance health outcomes is an important goal for all Americans.

B. Research Objectives

The goal of this broad campaign is to increase consumer awareness of the importance of medication adherence; targeting both consumers with chronic conditions and health care practitioners as well as to provide tools and support for both health care practitioners and consumers in managing and adhering to their medications and medication regimens. To plan and facilitate the campaign the NCL has brought together a public-private coalition of more than 110 stakeholder organizations from within and outside the health care arena, including businesses, chain drug stores, health care professionals, insurance companies, labor, researchers, pharmaceutical companies, health information technology companies, and government agencies. The NCL has the expertise, background, and motivation necessary to successfully lead this campaign. In addition, the campaign complements FDA's mission, protecting the public health by assuring the safety, efficacy, and security of human drugs and helping the public obtain accurate, science-based information that they need to use medicines and foods to maintain and improve their health.

C. Eligibility Information

Competition is limited to the NCL because it has unique expertise and capacity found nowhere else. As part of the implementation of their campaign, the NCL is building on extensive research and lessons learned from earlier adherence promotion efforts, and with the active involvement of more than 110 leading nonprofit organizations, professional associations, businesses, and Federal Agencies, including FDA, the NCL will: (1) Leverage partnerships with public and private stakeholders to raise awareness and disseminate campaign messages through their networks, (2) reach out to people suffering from common chronic conditions and their caregivers, and (3) conduct more intensive targeted outreach in six strategic markets.

II. Award Information/Funds Available

A. Award Amount

The estimated amount of support in fiscal year (FY) 2011 will be up to ($40,000) total costs (direct plus indirect cost) with a possibility of 2 additional years at $40,000 each for FY 2012 and FY 2013.

B. Length of Support

The award will provide 1 year of support, with the possibility of 2 additional years of support, contingent upon satisfactory performance in the achievement of project and program report objectives during the preceding year and the availability of 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/Drugs/DrugSafety/ucm187806.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 from the PHS 398 application instructions available at *http://grants.nih.gov/grants/forms.htm,* or *http://www.fda.gov/Drugs/DrugSafety/ucm187806.htm.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number.
- Step 2: Register With Central Contractor Registration.
- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit paper applications to: *http://www.fda.gov/Drugs/DrugSafety/ucm187806.htm;* Tamara Ford, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Executive Programs, 10903 New Hampshire Ave., rm. 6114, Silver Spring, MD 20993; Oluyemisi Akinneye, Division of Acquisition Support and Grants (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2129, Rockville, MD 20857.

Dated: March 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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