



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0012]

"Script Your Future" Medication Adherence Campaign

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the continuing support of a national effort to promote the importance of medication adherence to enhance the health of Americans. Medication adherence is taking medicine as directed to treat an illness or disease in order to get the best health outcome possible for each patient. Nearly three out of four Americans report that they do not take their medication as directed. One in three people never fill their prescriptions. The annual price tag for medication adherence failure is estimated to be \$290 billion, and the impact on the medical system and patients from this lack of adherence may result in relapses or recurrences of medical symptoms, increases in hospital visits, or even death. FDA is committed to addressing this issue, which has enormous implications for public health and the U.S. economy, by, in part, continuing its financial and other contributions to a carefully planned, well-executed effective national campaign begun in 2010 by the National Consumers League (NCL) called "Script Your Future".

To continue and enhance this important public health initiative, the Division of Health Communications (DHC)/Office of Communications (OCOMM)/Center for Drug Evaluation and Research (CDER) in FDA seeks to assist the National Consumers League in the development of new online resources and tools for patients, engagement of public and private partners to build

on and complement existing medication adherence programs, education of health care professionals with strategies to share with patients, continuous evaluation of the campaign to enhance and improve it, expansion of public-private partnerships, strengthening of this national forum focused on informing consumers about medication adherence, and tailoring messaging to subpopulations of consumers who may need adaptations or special efforts to inform and educate them.

DATES: Important dates are as follows:

1. The application due date is July 1, 2013.
2. The anticipated start date is August 2013.
3. The opening date is the date this announcement is published in the Federal Register.
4. The expiration date is July 2, 2013.

ADDRESSES: Submit the paper application to: Gladys Melendez, Grants Management (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 2032, Rockville, MD 20857; and a copy to Elaine Frost, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., rm. 1140, Silver Spring, MD 20903. For more information, see section III of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Paula Rausch, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., rm. 4110, Silver Spring, MD 20903, 301-796-3121; or Gladys Melendez, Grants Management Branch (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 2032, Rockville, MD 20857, 301-827-7175. For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please obtain the full FOA from gladys.bohler@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Request for Application: FDA-RFA-13-027

Catalog of Federal Domestic Assistance: 93.103

A. Background

In order to fulfill FDA's mission to protect public health by assuring the safety, efficacy, and security of human drugs; and helping the public to obtain the accurate, science-based information they need to use medications in ways that maintain and improve their health, FDA seeks to continue its participation in a national campaign aimed at promoting the importance of medication adherence to enhance the health of Americans.

FDA recognizes medication adherence as a formidable health problem that results in health system and human costs that adversely impact our nation. FDA has a responsibility as a public health agency to educate and inform the public and health professionals about the importance of medication adherence. Since 2010, FDA has been a key government stakeholder in the NCL's initiative, along with other major government agencies and private and nonprofit organizations, to address the issue of poor medication adherence. FDA is committed to educating and informing the public about this issue, including key subpopulations such as those with low literacy and health literacy, or that faces health disparities or is economically disadvantaged.

The NCL is the nation's oldest consumer organization. With FDA and its other government partners, NCL launched its nationwide "Script Your Future" campaign in 2010 to address the issue of poor medication adherence. NCL possesses an extensive research and evaluation framework from past medication outreach efforts that helped ensure the campaign's medication adherence messages and materials are based on sound communication science. In

addition, NCL assembled a coalition of more than 130 public-private partners to mobilize resources that can increase awareness and outreach to the public far beyond what FDA would be able to do alone to promote increased understanding and positive actions among the general public and health professionals related to this critical issue. Future NCL plans are in sync with FDA goals for a national medication adherence campaign and FDA seeks to enhance this carefully designed communications intervention. FDA has been and remains a key partner with NCL on issues pertaining to the safe use of medicines.

B. Research Objectives

The following are the primary objectives that FDA/CDER/OCOMM/DHC seeks to achieve through further support of this national outreach campaign: (1) To collaborate with a large group of public-private partners that can significantly increase awareness and outreach far beyond what FDA would be able to do on its own to promote increased understanding and positive actions among the general public and health professionals related to this critical issue; (2) to develop new online resources and tools for patients; (3) to educate health care professionals with strategies to share with patients; (4) to continually evaluate the campaign to improve and enhance it; (5) to tailor campaign messaging to subpopulations of consumers who may need adaptations to best inform and educate them; (6) to further targeted market outreach through community events and activities; (7) to develop new campaign materials for patients and health care providers; (8) to further widespread dissemination of campaign materials to consumers and health care professionals across the country, including at pharmacies, community centers, workplaces, clinic offices, health fairs, and local events; (9) to provide counseling and education directly to consumers about adherence in their communities, including through the involvement of students studying pharmacy, medicine, nursing, and other health professions;

(10) to explore new media opportunities for dissemination of the program at the local, State and national levels, in trade press, online journals, radio, television, and more; and (11) to extend outreach through social media, such as Twitter chats, free text message reminders, online pledges through Facebook and Twitter and other channels.

The following are some specific objectives that FDA believes can further enhance the "Script Your Future" campaign: (1) Addition of patient and family caregiver testimonials to the campaign Web site; (2) creation of a custom "I Will" tab on the "Script Your Future" Facebook page; (3) translation of the radio public service announcement from English to Spanish; (4) development of "Script Your Future-in-A-Box," a turnkey package incorporating press background materials and other elements; and (5) organization of a public event in fall 2013 and a study to measure the reach of events, media, and partner engagement.

C. Eligibility Information

Competition is limited to the NCL because it has unique expertise and capacity found nowhere else. Specifically, the FDA/CDER/OCOMM, DHC, seeks to continue and enhance its public health mission to educate and inform the public and health professions about the importance of medication adherence by awarding a grant to the NCL to advance its national campaign, "Script Your Future." This campaign represents a comprehensive, integrated approach to raise awareness about the problem of poor medication adherence, and FDA has served as a key government stakeholder since 2010. Because FDA has been a partner in the formative stages of this campaign and has seen evidence indicating that it has already had an impact in helping to resolve the problem of medication adherence, FDA seeks to continue funding new dimensions of the campaign, especially to serve U.S. subpopulations of people having low literacy/health literacy, or who face health disparities and social and economic disadvantages.

II. Award Information/Funds Available

A. Award Amount

The total amount of funding for this grant is \$200,000 over 2 years. Applications budgets will be limited to \$100,000 in the first year and \$100,000 in the second year depending on the availability of funds. The number of awards anticipated is one individual award.

B. Length of Support

The term for this grant will begin in August 2013 for a period of 2 years through August 15, 2015.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement. 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 (SAM)
- 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: Gladys Melendez, Grants Management Branch (HFA-500), Food and Drug Administration, rm. 2031, 5630 Fishers Lane, Rockville, MD 20857.

Dated: June 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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