Resettlement Act of 2010 (Pub. L. 111–291).

SUMMARY: The Administration for Children and Families (ACF), Office of Family Assistance (OFA), Division of State and Territory TANF Management (DSTTM) announces the award of a single-source cooperative agreement of $1,500,000 to Rubicon Programs, Inc., in Richmond, CA.

The cooperative agreement will support a demonstration pilot project for responsible fatherhood activities authorized by the Claims Resolution Act of 2010 (Pub. L. 111–291). The Community-Centered Responsible Fatherhood Ex-Prisoner Reentry Pilot Project supports programs that are designed to offer community-centered, pre- and post-release responsible fatherhood and supportive services to formerly incarcerated fathers. The primary purpose of the program is to eliminate barriers to social and economic self-sufficiency for individuals preparing to reenter their communities, or those who have recently returned to their communities following incarceration. The project will implement three legislatively specified activities: Healthy marriage, responsible parenting, and economic stability.

The project will implement a program that includes comprehensive case management to strengthen father, couple, and family relationships and that connect formerly incarcerated fathers to employment, housing (when necessary), and other needed support services to help reduce the likelihood of recidivism. It is expected that the full project period will be 24 months so that, based on performance; the recipient may receive an additional noncompetitive award in Fiscal Year 2013.

DATES: September 30, 2012–September 29, 2013.

FOR FURTHER INFORMATION CONTACT: Robin Y. McDonald, Division Director, Office of Family Assistance, 370 L'Enfant Promenade SW., 5th Floor East, Washington, DC 20047. Telephone: (202) 401–5587 Email: *robin.mcdonald@acf.hhs.gov.*

Earl S. Johnson,

Director, Office of Family Assistance, Administration for Children and Families.

[FR Doc. 2012–15783 Filed 6–27–12; 8:45 am]

BILLING CODE 4184–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0021]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe; Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 30, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0342. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR 170.36 and 570.36 (OMB Control Number 0910–0342)—Revision

I. Background

Section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives;'' section 201(s) of the FD&C Act (21 U.S.C. 321) provides an exemption from the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. In the **Federal Register** of April 17, 1997 (62 FR 18938) (the 1997 proposed rule), FDA published a proposed rule that would establish a voluntary procedure whereby manufacturers would notify FDA about a view that a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS. The proposed regulations (proposed 21 CFR 170.36 and 21 CFR 570.36) provide a standard format for the voluntary submission of a notice. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the subject of the GRAS notice, and the Agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes. In the **Federal Register** of December 28, 2010 (75 FR 81536) (the GRAS reopener), FDA announced the reopening of the comment period for the 1997 proposed rule. The Agency requested that comments be submitted by March 28, 2011.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has recently developed a form that prompts a notifier to include certain elements of a GRAS notice in a standard format. New Form FDA 3667 is entitled ''Generally Recognized as Safe (GRAS) Notice.'' The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the Electronic Submissions Gateway (ESG), or may be submitted in paper format, or as electronic files on physical media with paper signature page. CFSAN expects that most if not all businesses filing GRAS notices in the next 3 years will choose to take advantage of the option of electronically submitting their GRAS notice. Thus, the burden estimate in Table 1, line 1 is based on the expectation of 100 percent participation in the electronic submission process.

FDA's Center for Veterinary Medicine (CVM) continues to comply with the GRAS Pilot Program procedures announced on June 4, 2010 (75 FR 31800).

II. GRAS Information on Form FDA 3667

The GRAS notice submitted to CFSAN includes the following information on Form FDA 3667 and in attachments to the form:

A. Introductory Information About the Submission

- Whether the GRAS notice submission is a new GRAS notice, or an amendment or supplement to a previously transmitted GRAS notice;
- Whether the notifier has determined that all files provided in an electronic transmission are free of computer viruses;
- The date of the notifier's most recent meeting with FDA before transmitting a new GRAS notice; and
- The date of any correspondence, sent to the notifier by FDA, relevant to an amendment or supplement the notifier is transmitting.

B. Information About the Notifier

- The name of and contact information for the notifier, including the identity of the contact person and the company name (if applicable); and
- The name of and contact information for any agent or attorney who is authorized to act on behalf of the notifier.

C. General Administrative Information

- The name of the substance that is the subject of the GRAS notice submission;
- The format of the submission (i.e., paper, electronic, or electronic with a paper signature page);
- The mode of transmission of any electronic submission (i.e., ESG or transmission on physical media such as CD–ROM or DVD);
- Whether the notifier is referring us to information already in our files;
- The statutory basis for the notifier's determination of GRAS status;
- Whether the notifier has designated in its submission any information as trade secret or as confidential commercial or financial information; and
- Whether the notifier has attached a redacted copy of some or all of the submission.

D. Intended Use

- The intended conditions of use of the notified substance.

E. Identity

- Information that identifies the notified substance. For example, there may be a chemical name and formula and a standardized registry number.

F. Checklist of Other Elements Not Completed Directly on Form FDA 3667

- Any additional information about identity not previously covered;
- Method of manufacture;
- Specifications for food-grade material;
- Dietary exposure;
- Self-limiting levels of use;
- Common use in food before 1958 (if applicable);
- Comprehensive discussion of the basis for the determination of GRAS status; and
- Bibliography.

Form FDA 3667 also requires the signature of a responsible official (or agent or attorney) and a list of attachments.

The information is used by FDA to evaluate whether the notice provides a sufficient basis for a conclusion of GRAS status and whether information in the notice or otherwise available to FDA raises issues of public health significance that lead the Agency to question whether use of the substance is GRAS.

III. Description of Respondents

The respondents to this collection of information are manufacturers of substances used in food and feed.

In the **Federal Register** of January 18, 2012 (77 FR 2552), 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 REPORTING BURDEN [1]

21 CFR Section	FDA Form No. [2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
170.36 (CFSAN)	FDA 3667 [3]	40	1	40	150	6,000
570.36 (CVM)	N/A	20	1	20	150	3,000
Total						9,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Only CFSAN uses Form FDA 3667. CVM continues to comply with the GRAS Pilot Program procedures announced on June 4, 2010 (75 FR 31800).
[3] Form FDA 3667 may be submitted electronically via the ESG.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
170.36(c)(v) (CFSAN)	40	1	40	15	600
570.36(c)(v) (CVM)	20	1	20	15	300
Total					900

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

As noted, CFSAN estimates that all of the future Form FDA 3667 submissions will be made electronically via the ESG. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20–$30.

Both CFSAN and CVM receive submissions that are intended by the submitter to be GRAS notices. Not all of the submissions received contain sufficient information to be filed by the Agency as GRAS notices. In the December 28, 2010, GRAS reopener, FDA requested comment on its GRAS submission filing decision process and

described its current preliminary review process of GRAS submissions (75 FR 81536 at 81543). Therefore, the Agency is basing the following estimates on the number of GRAS notices that have been filed by the relevant Center.

In the 1997 proposed rule, FDA estimated that CFSAN would file approximately 50 GRAS notices per year and that CVM would file approximately 10 GRAS notices per year. Approval for the GRAS notification program was granted by OMB on June 16, 1997, under OMB control number 0910–0342. In 2009, FDA's estimate of the annual number of GRAS notices that will be filed by CFSAN and CVM was revised downward from the original PRA approval, based on the actual number of GRAS notices filed by CFSAN from 1998 to 2008. In 2009, FDA sought and OMB approved an estimate that CFSAN would file 25 GRAS notices and CVM would file 5 GRAS notices. On June 4, 2010, CVM announced the beginning of a GRAS Pilot Program (75 FR 31800). This notice stated that the revised estimate in the 2009 PRA approval reflected FDA's best judgment at the time as to the number of notices CVM will file annually through this pilot program.

For purposes of this extension request, CFSAN and CVM are re-evaluating their estimates of the annual number of GRAS notices that will be received by CFSAN and CVM in the next 3 years, 2012 through 2015. CFSAN filed 365 GRAS notices during the 13-year period from 1998 through 2010, for an average of approximately 28 GRAS notices per year. However, recent years have seen an increase in the number of GRAS notices filed, with 36 notices filed in both 2008 and 2009 and 55 notices in 2010. Based on an approximate average from the last 3 years, FDA is revising its estimate of the annual number of GRAS notices filed by CFSAN to be 40 or less. CFSAN expects that most if not all businesses filing GRAS notices in the next 3 years will choose to take advantage of the option of electronically submitting their GRAS notice. We expect participation to be 100 percent; thus the estimate in Table 1 is based on the burden of that experience. FDA also is revising its estimate of the annual number of GRAS notices submitted to CVM. As noted, on June 4, 2010, CVM announced the beginning of a GRAS Pilot Program. From June 2010 to October 2011, CVM filed 13 GRAS notices. Based on this experience, FDA is revising its estimate of the annual number of GRAS notices filed by CVM to be 20 or less.

In the 1997 proposed rule, FDA estimated that the notification procedures would require 150 hours per response for the reporting burdens and 15 hours per response for the recordkeeping burdens for both proposed sections (§§ 170.36 and 570.36). FDA is retaining these estimates for this request. The availability of the form, and the opportunity to provide the information in electronic format, could reduce this estimate. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of the form and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a GRAS notification.

Dated: June 22, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–15811 Filed 6–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Cooperative Agreements for the Office of Direct Service and Contracting Tribes Under the National Indian Health Outreach and Education Program

Announcement Type: New.

Funding Announcement Number: HHS–2012–IHS–NIHOE–0002.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: August 2, 2012.

Review Date: August 15, 2012.

Earliest Anticipated Start Date: September 16, 2012.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for two limited competition cooperative agreements for the Office of Direct Service and Contracting Tribes under the National Indian Health Outreach and Education (NIHOE) program: the Behavioral Health—Methamphetamine and Suicide Prevention Intervention (MSPI) outreach and education award and the Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) outreach and education award. The Behavioral Health—MSPI outreach and education award is funded by IHS and is authorized under the Snyder Act, codified at 25 U.S.C. 13; the Transfer Act, codified at 42 U.S.C. 2001; the Department of the Interior, Environment, and Related Agencies Appropriations Act, 2010, Public Law 111–88; and the Consolidated Appropriations Act, 2012, Public Law 112–74. The HIV/AIDS outreach and education award is funded by the Office of the Secretary (OS), Department of Health and Human Services (HHS). Funding for the HIV/AIDS award will be provided by OS via an Intra-Departmental Delegation of Authority dated March 30, 2012 to IHS to permit obligation of funding appropriated by the Consolidated Appropriations Act, 2012, Public Law 112–74. Each award is funded through a separate funding stream by each respective agency's appropriations. The awardee is responsible for accounting for each of the two awards separately and must provide two separate financial reports (one for each award), as indicated below. This program is described in the Catalog of Federal Domestic Assistance under 93.933.

Limited Competition Announcement

This is a Limited Competition announcement. The funding levels noted include both direct and indirect costs (IDC). *See Section VI. Award Administration Information, 3. Indirect Costs.* Applicant must address both projects. Applicants must provide a separate budget for each application. Limited competition refers to a competitive funding opportunity that limits the eligibility to compete to more than one entity but less than all entities.

Limited Competition Justification

Competition for both of the awards included in this announcement is limited to national Indian health care organizations with at least ten years of experience providing education and outreach on a national scale. This limitation ensures that the awardee will have: (1) A national information-sharing infrastructure which will facilitate the timely exchange of information between HHS and Tribes and Tribal organizations on a broad scale; (2) a national perspective on the needs of American Indian/Alaska Native (AI/AN) communities that will ensure that the information developed and disseminated through the projects is appropriate, useful and addresses the most pressing needs of AI/AN communities; and (3) established relationships with Tribes and Tribal organizations that will foster open and honest participation by AI/AN communities. Regional or local organizations will not have the mechanisms in place to conduct communication on a national level, nor