

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. FDA-2011-N-0017]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Voluntary National Retail Food Regulatory Program Standards**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Voluntary National Retail Food Regulatory Program Standards" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 28, 2011 (76 FR 17132), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0621. The approval expires on May 31, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 3, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-14064 Filed 6-7-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. FDA-2010-N-0381]

**Generic Drug User Fee; Notice of Public Meeting; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the comment period for the notice of public meeting, that appeared in the **Federal Register** of August 9, 2010 (75 FR 47820). In the notice, FDA requested comments to gather stakeholder input on the development of a generic drug user fee program. The Agency is taking this action to allow interested persons additional time to submit comments.

**DATES:** Submit either electronic or written comments by August 1, 2011.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2010-N-0381, by any of the following methods:

**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

**Written Submissions**

Submit written submissions in the following ways:

- *Fax:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993, 301-796-4830, *Fax:* 301-847-3541, *e-mail:* [peter.beckerman@fda.hhs.gov](mailto:peter.beckerman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

*I. Background*

In the **Federal Register** of August 9, 2010, 75 FR 47820, FDA published a notice soliciting comment on development of a generic drug user fee program, and indicated an intent to keep the docket open for the duration of its negotiations.

FDA and the industry trade organizations with which it is negotiating have extended the negotiations until the end of July 2011. Consequently, FDA is extending the comment period for the notice until August 1, 2011. The Agency believes this extension allows adequate time for interested persons to submit comments and reflects the Agency's previously-articulated commitment to receiving input from all interested parties.

*II. Request for Comments*

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 3, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-14120 Filed 6-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. FDA-2011-N-0012]

**Strengthen and Promote the Role of Local Health Departments in Retail Food Safety Regulation (U-50)**

**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 a cooperative agreement between the Center for Food Safety and Applied Nutrition (CFSAN) and the National Association of County and City Health Officials (NACCHO). The goal of the cooperative agreement for CFSAN is to have NACCHO conduct work that will strengthen the role of local health departments and help FDA/CFSAN

promote effective city and county regulatory programs responsible for retail food protection in the United States.

**DATES:** 1. The application due date is June 15, 2011.

2. The anticipated start date is August 2011.

3. The opening date is June 8, 2011.

4. The expiration date is June 16, 2011.

*For Further Information and Additional Requirements Contact:*

*Scientific/Programmatic Contact:*

Peter A. Salisbury, Center for Food Safety and Applied Nutrition (HFS-320), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 301-436-1655.

*Grants Management Contact:* Gladys Melendez-Bohler, Office of Acquisition and Grant Services (OAGS) (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301-827-7175.

*gladys.bohler@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://www.fda.gov/Food/NewsEvents/default.htm>.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Funding Opportunity Description**

*Funding Opportunity Number:* RFA-FY-FD-020.

*Catalog of Federal Domestic Assistance Number:* 93.103.

#### **A. Background**

The FDA is responsible for protecting and promoting public health. The public health focus of the FDA Foods Program integrates a comprehensive, preventative, and risk-based approach to safeguard the American food supply. The goal is to identify potential threats to the food supply and to counteract them before they harm American consumers. CFSAN administers the FDA Foods Program with the assistance of the Office of Regulatory Affairs' (ORA) field offices nationwide.

CFSAN regulates \$417 billion worth of domestic food, \$49 billion worth of imported foods, and over \$60 billion worth of cosmetics sold across state lines. This regulation takes place from the products' point of the United States (U.S.) entry or processing to their point of sale. There are over 377,000 registered food facilities (including approximately 154,000 domestic facilities and 223,000 foreign facilities) that manufacture, process, pack, or hold food consumed by humans or animals in the United States and several

thousand cosmetic firms. These figures do not include restaurants, institutional food service establishments, or supermarkets, grocery stores, and other food outlets regulated by almost 3,000 States, and local and tribal agencies that have primary responsibility to regulate the retail food and food service industries in the United States. These state and local agencies are responsible for the inspection and oversight of over 1 million food establishments, restaurants and grocery stores, as well as vending machines, cafeterias, and other outlets in health-care facilities, schools, and correctional facilities. FDA strives to promote the application of science-based food safety principles in retail and food service settings to minimize the incidence of foodborne illness. FDA assists regulatory agencies and the industries they regulate by providing a model Food Code, scientifically-based guidance, training, program evaluation, and technical assistance.

#### **B. Research/Cooperative Investigations and Assessments Objectives**

CFSAN's Office of Food Safety (OFS)/Retail Food and Cooperative Programs Coordination Staff (RFCPCS) as part of FDA's National Retail Food Team, works to promote the sharing of best practices, including those regulatory and industry interventions that are targeted at improving the management of food safety practices in the retail setting. CFSAN/OFS desires to work cooperatively with NACCHO to increase partnerships and collaboration with our regulatory partners at local and state health and agriculture departments that represent city and county health departments, to identify best practices and innovative approaches used to implement the FDA Food Code and Voluntary National Retail Food Regulatory Program Standards (Retail Program Standards) and begin to examine the impact they have on the reduction of foodborne illness risk factors. NACCHO has the expertise needed to provide expert advice and recommendations to FDA that can be shared and used by multiple local and state health and agriculture departments to help improve public health in retail and food service settings.

The Cooperative Agreement with NACCHO will also help FDA examine how the Retail Program Standards can most effectively be integrated with broadening efforts to establish accreditation for health departments as guided by the Public Health Accreditation Board.

Other possible areas for collaboration with NACCHO include working to identify how to improve prevention,

performance, and response at the local government level; establishing peer mentoring opportunities that pair up experienced local health department officials who have experience implementing the Retail Program Standards with those who have struggled or are just beginning the process; and doing a comprehensive study to assess the effectiveness of food inspection grading and scoring systems used by local health departments.

#### **C. Eligibility Information**

NACCHO is the only national organization representing local health departments, to include county, city, district, metro, and tribal agencies. Membership in NACCHO is limited to the executive officer of the department of health of any local health department. NACCHO supports efforts that protect and improve the health of all people and all communities by promoting national policy, developing resources and programs, seeking health equity, and supporting effective local public health practice and systems.

In performing an internet search for national organizations whose members are local governmental health officials, and whose mission includes efforts to support and work with local health departments to improve food safety and prevent foodborne illness, no other organizations were discovered. There are organizations that represent local boards of health, but no other organization whose membership is comprised of local governmental health officials. NACCHO has been in existence since 1994 and has always been exclusively associated with local health officials.

NACCHO values guide staff and leadership in work to achieve optimal health for all through an effective local governmental presence for public health. NACCHO believes that by incorporating these values with a focus on and commitment to their mission and vision, NACCHO will effectively influence improvements in health status around the country. Another unique aspect of NACCHO is its membership. As governmental health officials, NACCHO is able to join forces with other governmental health officials to improve the effectiveness of public health at the local and state level.

### **II. Award Information/Funds Available**

#### **A. Award Amount**

The estimated amount of this cooperative agreement award with NACCHO in fiscal year 2011 will be for up to \$400,000 (direct plus indirect costs).

### B. Length of Support

This Cooperative Agreement established with NACCHO has the possibility of 4 additional years of support for up to \$400,000 per year, subject to the availability of funds. Future year amounts will depend on annual appropriations and successful performance.

### 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://www.fda.gov/Food/NewsEvents/default.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 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](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 the following. Please note that the application should not be submitted through Grants.gov or eRA Commons: Gladys Melendez-Bohler, Office of Acquisition and Grant Services (OAGS) (HFA-500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301-827-7175, [gladys.bohler@fda.hhs.gov](mailto:gladys.bohler@fda.hhs.gov).

Dated: June 2, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-14059 Filed 6-7-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0008]

#### Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." The Food and Drug Administration Amendments Act (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) addressing the Agency's treatment of certain citizen petitions and petitions for stay of agency action (collectively, petitions), as well as related applications. The guidance describes how FDA will determine if the new provisions apply to a particular petition and how FDA will determine if a petition would delay approval of a pending abbreviated new drug application (ANDA) or 505(b)(2) application. The guidance also describes how FDA will interpret the requirements that such petitions include a certification and that supplemental information or comments to such petitions include a verification. The guidance also addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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:** Kimberly K. Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6223, Silver Spring, MD 20993-0002, 301-796-3601.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act." In the **Federal Register** of January 21, 2009 (74 FR 3611), FDA announced the availability of a draft version of this guidance and provided interested parties an opportunity to submit comments. As described in the January 21, 2009, **Federal Register** notice, the guidance provides information regarding FDA's current thinking on interpreting section 914 of Title IX of FDAAA (Pub. L. 110-85). Section 914 of FDAAA added new section 505(q) to the FD&C Act (21 U.S.C. 355(q)) and governs certain citizen petitions and petitions for stay of Agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) of the FD&C Act. The guidance describes FDA's interpretation of section 505(q) of the FD&C Act regarding how the Agency will determine if: (1) The provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending ANDA or a 505(b)(2) application. The guidance also describes how FDA will interpret the provisions of section 505(q) requiring that: (1) A petition includes a certification and (2) supplemental information or comments to a petition include a verification. Finally, the guidance addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

The Agency has carefully reviewed and considered the comments it received in response to the draft guidance in developing this final version of the guidance. The Agency has added information in sections III.C and III.D of the guidance to further explain how FDA will apply the certification