

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* The Office of Community Services (OCS) Evaluation Initiative.  
*OMB No.:* New Collection.

*Description:* This questionnaire is part of a contract that addresses evaluation strategies for three programs administered by OCS: Community Economic Development (CED), Rural Community Facilities (RF), and Job Opportunities for Low-Income Individuals (JOLI). The legislative requirement for two of these programs, *i.e.*, the RF and CED programs, is in Title IV of the Community Opportunities, Accountability, and Training and Educational Services Act (COATS Human Services Reauthorization Act) of Oct. 27, 1998, Pub. L. 105–285, sec. 680(b) as amended. This legislative directive states that “The Secretary shall require all activities receiving assistance under this section to be evaluated for their

effectiveness. Funding for such evaluations shall be provided as a stated percentage of the assistance or through a separate grant awarded by the Secretary specifically for the purposes of evaluation of a particular activity or group of activities.”

Under Title V, Section 505, of the Family Support Act of 1988, Public Law 100–485, sec. 505(f), JOLI was initially a demonstration program that required local evaluations of each project. When JOLI was reauthorized in 1996 (Pub. L. 104–193—Aug. 22, 1996), it no longer had demonstration status and evaluation requirements. As a result, a formal evaluation for the JOLI program has not been conducted since the 1996 Public Law reauthorization. At this time, OCS is interested in a formal evaluation to assess the JOLI program.

OCS has chosen to evaluate all three of these programs through a separate contract awarded by the Secretary using the Office of Management and Budget’s (OMB) Performance Assessment Rating Tool (PART) in order to critically review the overall design and effectiveness of each program in its totality. The evaluation initiative contract provides the central office with the mechanism to

ensure that all programs evaluated will have consistent data that is in agreement with the direction of OMB and provides the Secretary with information on program efficiency and effectiveness.

The evaluation survey’s primary purpose is to document and systematically evaluate the program performance of these OCS discretionary grants programs in qualitative and quantitative terms. Thus it will assess each of the three OCS discretionary grants programs—CED, RF and JOLI—using qualitative and quantitative evaluation methods that capture key information about program and grantee-level performance in four general areas: (1) Program purpose and design; (2) strategic planning; (3) program management; and (4) program results. The evaluation activities will build on the initial year’s findings and methods, with the goal of expanding data collection and analysis to improve the validity and generalizability of findings.

The questions will be administered online.

*Respondents:* Active CED and JOLI grantees with grants awarded from 2001 through 2004.

**ANNUAL BURDEN ESTIMATES**

Instruments	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Questionnaire from OCS–CED and JOLI Grantees in the U.S. ....	172	1	1.5	258
Estimated Total Annual Burden Hours .....	.....	.....	.....	258

*Additional Information:* Copies of the proposed collection may be obtained from writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L’Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

OMB is required to make a decision concerning the collection of information between 30 and 760 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30-days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, *E-mail address:* [Katherine\\_T.\\_Astrich@omb.eop.gov](mailto:Katherine_T._Astrich@omb.eop.gov).

Dated: May 12, 2006.  
**Robert Sargis,**  
*Reports Clearance Officer.*  
[FR Doc. 06–4636 Filed 5–17–06; 8:45 am]  
BILLING CODE 4184–01–M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003D–0379] (formerly Docket No. 03D–0379)

**Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of a guidance document entitled “Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition” (the guidance). This guidance provides information to industry on how to prepare a claim of categorical exclusion or an environmental assessment (EA) for submission to the Center for Food Safety and Applied Nutrition (CFSA) in notifications for food contact substances, food additive petitions, color additive petitions, requests for exemption from regulation as a food additive, generally recognized as safe (GRAS) petitions, and petitions for certain food labeling regulations.

**DATES:** This guidance document is final upon the date of publication. Submit written or electronic comments concerning this guidance document at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document to the Office of Food Additive Safety (HFS-265), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. To ensure a timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Layla I. Batarseh, Center for Food Safety and Applied Nutrition (HFS-246), 5100 Paint Branch Pkwy., College Park, MD, 20740-3835, 301-436-1296, FAX 301-436-2973, or e-mail: [layla.batarseh@fda.hhs.gov](mailto:layla.batarseh@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

As an integral part of its decision-making process, FDA is obligated under the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of its actions, including allowing notifications for food contact substances to become effective and approving food additive petitions, color additive petitions, GRAS affirmation petitions, requests for exemption from regulation as a food additive, and actions on certain food labeling citizen petitions, nutrient content claims petitions, and health claims petitions. In 1997, FDA amended its regulations in 21 CFR part 25 to provide for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant effect on the human environment (62 FR 40570, July 29, 1997). As a result of that rulemaking, FDA no longer routinely requires submission of information about the manufacturing and production of FDA-regulated articles. FDA also has eliminated the previously required EA and abbreviated EA formats from the amended regulations. Instead, FDA is providing this guidance that contains sample formats to help industry submit a claim of categorical exclusion or an EA to CFSAN. This guidance document identifies, interprets, and clarifies existing requirements imposed by statute and regulation, consistent with

the Council on Environmental Quality regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA's own procedures in order to ensure full compliance with the purposes and provisions of NEPA.

This guidance provides information to assist in the preparation of claims of categorical exclusion and EAs for submission to CFSAN. The following topics are covered in this guidance: (1) What types of industry-initiated actions are subject to a claim of categorical exclusion, (2) What must a claim of categorical exclusion include by regulation, (3) What is an EA, (4) When is an EA required by regulation and what format should be used, (5) What are extraordinary circumstances, and (6) What suggestions does CFSAN have for preparing an EA? Although CFSAN encourages industry to use the EA formats described in this guidance because standardized documentation submitted by industry increases the efficiency of the review process, alternative approaches may be used if these approaches satisfy the requirements of the applicable statutes and regulations.

In the **Federal Register** of September 17, 2003 (68 FR 54462), FDA announced the availability of a draft guidance document entitled "Guidance for Industry: Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition." The agency solicited public comments on the draft guidance document. FDA did not receive any comments and is finalizing the draft guidance without revision, except for those revisions necessary to update certain contact information.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents FDA's current thinking on the preparation of a claim of categorical exclusion or an EA for submission to CFSAN. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

**II. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in this guidance was approved under OMB control number 0910-0541.

**III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**IV. Electronic Access**

Persons with access to the Internet may obtain the guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: May 10, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[USCG-2006-24700]

**Chemical Transportation Advisory Committee; Vacancies**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for applications.

**SUMMARY:** The Coast Guard is seeking applications for appointment to membership on the Chemical Transportation Advisory Committee (CTAC). CTAC provides advice and makes recommendations to the Coast Guard on matters relating to the safe and secure transportation and handling of hazardous materials in bulk on U.S.-flag vessels in U.S. ports and waterways.

**DATES:** Application forms should reach the Coast Guard on or before September 29, 2006.

**ADDRESSES:** You may request an application form by writing to