

**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.*

[FR Doc. E6-7528 Filed 5-17-06; 8:45 am]

**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

Commandant (G-PSO-3), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593-0001; by calling (202) 372-1425/1422; or by faxing (202) 372-1926. Submit application forms to the same address. This notice and the application form are available on the Internet at <http://dms.dot.gov>. The application form is also available at <http://www.uscg.mil/hq/g-m/advisory/ctac/ctac.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Commander Robert J. Hennessy, Executive Director of CTAC, or Ms. Sara S. Ju, Assistant to the Executive Director, telephone (202) 372-1425/1422, fax (202) 372-1926.

**SUPPLEMENTARY INFORMATION:** The Chemical Transportation Advisory Committee (CTAC) is an advisory committee constituted under the Federal Advisory Committee Act, 5 U.S.C. App. 2. It provides advice and makes recommendations to the Commandant through the Assistant Commandant for Prevention 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. The advice and recommendations of CTAC also assist the U.S. Coast Guard in formulating the position of the United States on hazardous material transportation issues prior to meetings of the International Maritime Organization.

CTAC meets at least once a year, usually twice a year, at Coast Guard Headquarters in Washington, DC, or in another location. CTAC's subcommittees and working groups may meet to perform specific assignments as required.

The Coast Guard will consider applications for seven positions that expire on December 31, 2006. To be eligible, applicants should have the following experience associated with marine chemical transportation: Chemical manufacturing, vessel design and construction, safety and security, marine environmental protection, or marine handling or transportation of chemicals. Each member serves for a term of 3 years. Some members may serve consecutive terms. All members serve at their own expense, and receive no salary, reimbursement of travel expenses, or other compensation from the Federal Government.

In support of the policy of the Department of Homeland Security on gender and ethnic diversity, the Coast Guard encourages applications from qualified women and members of minority groups.

Dated: May 4, 2006.

**Howard L. Hime,**

*Acting Director of Standards, Assistant Commandant for Prevention.*

[FR Doc. E6-7518 Filed 5-17-06; 8:45 am]

**BILLING CODE 4910-15-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Bureau of Customs and Border Protection**

**Agency Information Collection Activities: Lien Notice**

**AGENCY:** Bureau of Customs and Border Protection, Department of Homeland Security.

**ACTION:** Proposed collection; comments requested.

**SUMMARY:** The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Lien Notice. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (71 FR 12388) on March 10, 2006, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

**DATES:** Written comments should be received on or before June 19, 2006.

**ADDRESSES:** Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget Desk Officer at [Nathan.Lesser@omb.eop.gov](mailto:Nathan.Lesser@omb.eop.gov).

**SUPPLEMENTARY INFORMATION:** The Bureau of Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary

for the Proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Title:* Lien Notice.

*OMB Number:* 1651-0012.

*Form Number:* Form 3485.

*Abstract:* The Lien Notice, CBP Form-3485, enable the carriers, cartmen, and similar businesses to notify CBP that a lien exists against an individual/business for non-payment of freight charges, etc., so that CBP will not permit delivery of the merchandise from public stores or a bonded warehouse until the lien is satisfied or discharged.

*Current Actions:* This submission is being submitted to extend the expiration date.

*Type of Review:* Extension (without change).

*Affected Public:* Businesses, Institutions.

*Estimated Number of Respondents:* 112,000.

*Estimated Time Per Respondent:* 5 minutes.

*Estimated Total Annual Burden Hours:* 9,296.

*Estimated Total Annualized Cost on the Public:* N/A.

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202-344-1429.

Dated: May 11, 2006.

**Tracey Denning,**

*Agency Clearance Officer, Information Services Branch.*

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