

240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Shaw T. Chen, Center for Drug Evaluation and Research (HFD-105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2601.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of August 11, 2000 (65 FR 49247), FDA published a notice announcing the availability of a draft guidance for industry entitled "Botanical Drug Products." In a notice published in the **Federal Register** of December 15, 2000 (65 FR 78496), FDA reopened the comment period on the draft guidance until March 15, 2001.

FDA received a number of comments on the botanical drugs draft guidance. FDA has made a few substantive changes along with several editorial revisions to the draft guidance. For example, FDA has revised the guidance to emphasize the importance of maintaining batch-to-batch consistency in the drug substance and drug product used throughout the clinical development process. FDA also is adding to the final guidance a section that provides answers to what the agency expects may be frequently asked questions concerning the guidance.

**II. Description of the Guidance**

The guidance is intended to encourage the clinical study and submission for marketing approval of botanical drug products. The guidance explains the circumstances under which FDA regulations require approval of an NDA submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) before marketing a botanical drug and when such a drug may be marketed under an OTC drug monograph. The guidance also provides scientific and regulatory guidance to sponsors about conducting initial and expanded clinical investigations of botanical drugs, including those botanical products currently lawfully

marketed as foods and dietary supplements in the United States.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the development of botanical drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**III. Comments**

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

**IV. The Paperwork Reduction Act of 1995**

This guidance contains no new 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 guidance explains the circumstances under which FDA regulations require approval of an NDA for marketing a botanical drug product and when such a product may be marketed under an OTC drug monograph. The regulations governing the preparation and submission of an NDA are in part 314 (21 CFR part 314), and the guidance does not contain any recommendations that exceed the requirements of these regulations. FDA estimated the information collection requirements resulting from the preparation and submission of an NDA, and OMB approved the reporting and recordkeeping burden until March 31, 2005, under OMB control number 0910-0001. FDA anticipates that any NDAs submitted for botanical drug products would be included under the burden estimates approved by OMB for part 314.

The regulations on the procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing OTC drug monographs, are set forth in § 330.10 (21 CFR 330.10). FDA believes that any botanical drug products that may be eligible for inclusion in an OTC

drug monograph under current § 330.10 have already been or presently are being considered for such inclusion.

The guidance also provides scientific and regulatory guidance to sponsors on conducting clinical investigations of botanical drugs. The regulations governing the preparation and submission of INDs are in part 312 (21 CFR part 312). The guidance does not contain any recommendations that exceed the requirements in those regulations. FDA estimated the information collection requirements resulting from the preparation and submission of an IND under part 312, and OMB approved the reporting and recordkeeping burden until January 31, 2006, under OMB control number 0910-0014.

**V. Electronic Access**

Persons with access to the Internet may obtain this guidance at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: June 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-13031 Filed 6-8-04; 8:45 am]

**BILLING CODE 4160-01-S**

---

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[USCG 2003-16298]

**Information Collection Under Review by the Office of Management and Budget (OMB): 1625-0080, Customer Satisfaction Surveys**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the Coast Guard has forwarded one Information Collection Report (ICR), Customer Satisfaction Surveys, to the Office of Information and Regulatory Affairs (OIRA) of the OMB for review and comment. Our ICR describes the information we seek to collect from the public. Review and comment by OIRA ensures that we impose only paperwork burdens commensurate with our performance of duties.

**DATES:** Please submit comments on or before July 9, 2004.

**ADDRESSES:** To make sure that your comments and related material do not enter the docket [USCG 2003-16298]

more than once, please submit them by only one of the following means:

(1)(a) By mail to the Docket Management Facility, U.S. Department of Transportation, room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001. (b) By mail to OIRA, 725 17th Street, NW., Washington, DC 20503, to the attention of the Desk Officer for the Coast Guard. Caution: Because of recent delays in the delivery of mail, your comments may reach the Facility more quickly if you choose one of the means described below.

(2)(a) By delivery to room PL-401 at the address given in paragraph (1)(a) above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329. (b) By delivery to OIRA, at the address given in paragraph (1)(b) above, to the attention of the Desk Officer for the Coast Guard.

(3) By fax to (a) the Facility at 202-493-2298 and (b) OIRA at 202-395-5806, or e-mail to OIRA at [oiradocket@omb.eop.gov](mailto:oiradocket@omb.eop.gov) attention: Desk Officer for the Coast Guard.

(4)(a) Electronically through the Web Site for the Docket Management System at <http://dms.dot.gov>. (b) OIRA does not have a website on which you can post your comments.

The Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401 (Plaza level), 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

Copies of the complete ICR are available for inspection and copying in public dockets. They are available in docket USCG 2003-16298 Docket Management Facility between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays; for inspection and printing on the internet at <http://dms.dot.gov>; and for inspection from the Commandant (CG-611), U.S. Coast Guard, room 6106, 2100 Second Street, SW., Washington, DC, between 10 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. Arthur Requina, Office of Information Management, 202-267-2326, for questions on this document; Ms. Andrea M. Jenkins, Program Manager, U.S. Department of Transportation, 202-366-0271, for questions on the docket.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

We encourage you to participate in this request for comment by submitting comments and related materials. We will post all comments received, without change, to <http://dms.dot.gov>, and they will include any personal information you have provided. We have an agreement with DOT to use the Docket Management Facility. Please see the paragraph on DOT's "Privacy Act" below.

**Submitting comments:** If you submit a comment, please include your name and address, identify the docket number for this request for comment [USCG 2003-16298], indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

**Viewing comments and documents:** To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://dms.dot.gov> at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**Privacy Act:** Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://dms.dot.gov>.

**Regulatory History**

This request constitutes the 30-day notice required by OIRA. The Coast Guard has already published the 60-day notice required by OIRA (68 FR 60110,

October 21, 2003). That notice elicited no comments.

**Request for Comments**

The Coast Guard invites comments on the proposed collection of information to determine whether the collection is necessary for the proper performance of the functions of the Department. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the collection; (2) the accuracy of the Department's estimated burden of the collection; (3) ways to enhance the quality, utility, and clarity of the information that is the subject of the collection; and (4) ways to minimize the burden of collection on respondents, including the use of automated collection techniques or other forms of information technology.

Comments, to DMS or OIRA, must contain the OMB Control Number of the ICR addressed. Comments to DMS must contain the docket number of this request, USCG 2003-16298 comments to OIRA are best assured of having their full effect if OIRA receives them 30 or fewer days after the publication of this request.

**Information Collection Request**

*Title:* Customer Satisfaction Surveys.

*OMB Control Number:* 1625-0080.

*Type of Request:* Reinstatement, with change, of a previously approved collection for which approval has expired.

*Affected Public:* Recreational boaters, commercial mariners, industry groups, and State and local governments.

*Form:* This collection of information does not require the public to fill out forms, but does require submitting information to the Coast Guard in written or electronic format.

*Abstract:* Putting people first means ensuring that the Federal Government provides the highest quality of service possible to the American people. Executive Order 12862, requires that all executive departments and agencies providing significant services directly to the public seek to meet established standards of customer service and (1) identify the customers who are, or should be, served by the agency and (2) survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.

*Burden:* The estimated burden is 5,847 hours a year. This estimate represents an increase of 847 hours from the estimate in our 60-day notice.

Dated: May 27, 2004.

**Clifford I. Pearson,**

*Assistant Commandant for C4 and Information Technology.*

[FR Doc. 04-12966 Filed 6-8-04; 8:45 am]

BILLING CODE 4910-15-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2004-17971]

#### Collection of Information Under Review by Office of Management and Budget (OMB): OMB Control Numbers: 1625-0019, 1625-0041, 1625-0062, 1625-0088, and 1625-0092

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of five Information Collection Requests (ICRs). The ICRs comprise (1) 1625-0019, Alternative Compliance for International and Inland Navigation Rules—33 CFR Parts 81 and 89; (2) 1625-0041, Various International Agreement Pollution Prevention Certificates and Documents, and Equivalency Certificates; (3) 1625-0062, Approval of Alterations to Marine Portable Tanks; Approval of Non-Specification Portable Tanks; (4) 1625-0088, Voyage Planning for Tank Barge Transits in the Northeast United States; and (5) 1625-0092, Sewage and Graywater Discharge Records for Certain Cruise Vessels Operating on Alaskan Waters. Before submitting the ICRs to OMB, the Coast Guard is inviting comments on them as described below.

**DATES:** Comments must reach the Coast Guard on or before August 9, 2004.

**ADDRESSES:** To make sure that your comments and related material do not enter the docket [USCG-2004-17971] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001. Caution: Because of recent delays in the delivery of mail, your comments may reach the Facility more quickly if you choose one of the other means described below.

(2) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

Copies of the complete ICR are available through this docket on the Internet at <http://dms.dot.gov>, and also from Commandant (CG-611), U.S. Coast Guard Headquarters, room 6106 (Attn: Mr. Arthur Requina), 2100 Second Street, SW., Washington, DC 20593-0001. The telephone number is 202-267-2326.

**FOR FURTHER INFORMATION CONTACT:** Mr. Arthur Requina, Office of Information Management, 202-267-2326, for questions on these documents; or Ms. Andrea M. Jenkins, Program Manager, U.S. DOT, 202-366-0271, for questions on the docket.

#### SUPPLEMENTARY INFORMATION:

#### Public Participation and Request for Comments

We encourage you to participate in this request for comment by submitting comments and related materials. We will post all comments received, without change, to <http://dms.dot.gov>, and they will include any personal information you have provided. We have an agreement with DOT to use the Docket Management Facility. Please see the paragraph on DOT's "Privacy Act" below.

**Submitting comments:** If you submit a comment, please include your name and address, identify the docket number for this request for comment [USCG-2004-17971], indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for

copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

**Viewing comments and documents:** To view comments, as well as documents mentioned in this notice as being available in the docket, go to <http://dms.dot.gov> at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**Privacy Act:** Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://dms.dot.gov>.

#### Information Collection Requests

1. **Title:** Alternative Compliance for International and Inland Navigation Rules—33 CFR Parts 81 and 89.

**OMB Control Number:** 1625-0019.

**Summary:** The information collected provides an opportunity for an owner, operator, builder, or agent of a unique vessel to present their reasons why the vessel cannot comply with existing International/Inland Navigation Rules and how alternative compliance can be achieved. If appropriate, a Certificate of Alternative Compliance is issued.

**Need:** Certain vessels cannot comply with the International Navigation Rules (33 U.S.C. 1601-1608) and Inland Navigation Rules (33 U.S.C. 2001-2073). The Coast Guard thus provides an opportunity for alternative compliance. However, it is not possible to determine whether alternative compliance is appropriate, or what kind of alternative procedures might be necessary, without this collection.

**Respondents:** Vessel owners, operators, builders and agents.

**Frequency:** One-time application.

**Burden Estimate:** The estimated burden is 180 hours a year.

2. **Title:** Various International Agreement Pollution Prevention