

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

[Docket No. 2005D-0312]

**Draft Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Products; Chemistry, Manufacturing, and Controls Information; Availability****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "ANDAs: Impurities in Drug Products; Chemistry, Manufacturing, and Controls Information." This draft guidance provides recommendations on what chemistry, manufacturing, and controls information sponsors should include regarding reporting, identification, qualification, and setting acceptance criteria for impurities that are classified as degradation products in drug products when submitting an abbreviated new drug application (ANDA) or supplement to support changes in drug substance synthesis or process, formulation of the drug product, the manufacturing process, or components of the container/closure system.

**DATES:** Submit written or electronic comments on the draft guidance by November 28, 2005. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Devinder Gill, Center for Drug Evaluation and Research (HFD-630), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5845.

**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of January 5, 1999 (64 FR 516), FDA published the draft guidance for industry on "ANDAs: Impurities in Drug Products." The draft guidance provided recommendations for including information in ANDAs and ANDA supplements about the reporting, identification, qualification of, and setting acceptance criteria for degradation products in drug products that are manufactured from drug substances produced by chemical synthesis.

FDA is announcing the availability of a revised draft guidance for industry entitled "ANDAs: Impurities in Drug Products," which revises the January 5, 1999, draft guidance. The draft guidance is being revised to update information on listing of degradation products, setting acceptance criteria, and qualifying degradation products in conformance with our current thinking and the revision of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidance for industry on "Q3B(R) Impurities in New Drug Products," published in November 2003. The draft guidance is also being revised to remove sections of the guidance containing recommendations that are no longer needed because they are addressed in the more recent Q3B(R).

This draft 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 draft guidance was approved under OMB Control No. 0910-0001.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on these topics. 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.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

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

Dated: August 16, 2005.

**Jeffrey Shuren,***Assistant Commissioner for Policy.*

[FR Doc. 05-17150 Filed 8-26-05; 8:45 am]

**BILLING CODE 4160-01-S****DEPARTMENT OF HOMELAND SECURITY****Coast Guard**

[CGD17-05-0010]

**Annual Certification of Cook Inlet Regional Citizen's Advisory Council (CIRCAC)****AGENCY:** Coast Guard, DHS.**ACTION:** Notice of recertification.

**SUMMARY:** Under the Oil Terminal and Tanker Environmental Oversight Act of 1990, the Coast Guard may certify on an annual basis an alternative voluntary advisory group in lieu of a regional citizens' advisory council for Cook Inlet, Alaska. This certification allows the advisory group to monitor the activities of terminal facilities and crude oil tankers under the Cook Inlet Program established by the statute. The purpose of this notice is to inform the public that the Coast Guard has recertified the alternative voluntary advisory group for Cook Inlet, Alaska.

**DATES:** This recertification is effective for the period from September 1, 2005 through August 31, 2006.

**FOR FURTHER INFORMATION CONTACT:** For general information regarding the CIRCAC or viewing material submitted to the docket, contact Rick Janelle, Seventeenth Coast Guard District, Marine Safety Division, (907) 463-2808.

**SUPPLEMENTARY INFORMATION:** In section 5002 of the Oil Pollution Act of 1990, cited as the Oil Terminal and Tanker Environmental Oversight and Monitoring Act of 1990 (the Act), Congress sought to foster the long-term partnership among industry, government, and local communities in overseeing compliance with the environmental concerns in the operation of terminal facilities and

crude-oil tankers. Subsection 5002(o) permits an alternative voluntary advisory group to represent to communities and interests in the vicinity of the terminal facilities in Cook Inlet (CI), in lieu of a council of the type specified in subsection 5002(d), if certain conditions are met.

The Act requires that the group enter into a contract to ensure annual funding, and that it receive annual certification by the President to the effect that it fosters the general goals and purposes of the Act, and is broadly representative of the communities and interests in the vicinity of the terminal facilities and Cook Inlet. Accordingly, in 1991, the President granted certification to the Cook Inlet Regional Citizen's Advisory Council (CIRCAC). The authority to certify alternative advisory groups was subsequently delegated to the Commandant of the Coast Guard and redelegated to the Commander, Seventeenth Coast Guard District.

On June 28, 2005, the Coast Guard published a notice of availability of an application for recertification submitted by the Cook Inlet Regional Citizens' Advisory Council in the **Federal Register** (70 FR 37103) and we requested comments. Eight comments were received.

#### Discussion of Comments

Of the comments received, all were supportive of recertification and noted the positive efforts, good communication, and broad representation of Cook Inlet communities by CIRCAC as it carries out its responsibilities as intended by the Act.

The Coast Guard received one letter of public comment from the Cook Inlet Keeper, a citizen-based, non-profit group dedicated to protecting Alaska's Cook Inlet watershed. This comment supported the recertification of the CIRCAC and also encouraged the Coast Guard to investigate ways to ensure the CIRCAC has a more reliable, long-term funding stream. Although the Coast Guard understands the Cook Inlet Keeper's concern, the Coast Guard is limited to determining whether the CIRCAC has entered into a contract for funding in accordance with the requirements of 33 U.S.C. 2732(o), and reviewing the expenditure of those funds.

Upon review of the comments received regarding the CIRCAC's performance during the past year and the information provided by the RCAC in their annual report and recertification package, the Coast Guard finds the CIRCAC meets the criteria established under the Oil Pollution Act, and that

recertification in accordance with the Act is appropriate.

#### Recertification

By letter dated 12 August, 2005 the Commander, Seventeenth Coast Guard, certified that the CIRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification lasts through August 31, 2006.

Dated: August 15, 2005.

**James C. Olson,**

*Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.*

[FR Doc. 05-17093 Filed 8-26-05; 8:45 am]

**BILLING CODE 4910-15-P**

### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

[USCG-2005-22235]

#### Towing Safety Advisory Committee

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Licensing Implementation Working Group of the Towing Safety Advisory Committee (TSAC) will meet to discuss matters relating to specific issues of towing safety. The meeting will be open to the public.

**DATES:** The Licensing Implementation Working Group will meet via teleconference on Friday, September 2, 2005 from 10 a.m. to approximately 12 noon EDT. Written material and requests to make oral presentations should reach the TSAC working group Chairperson on or before August 30, 2005.

**ADDRESSES:** The Working Group will meet via conference call only. Contact Ms. Jennifer Carpenter, working group Chairperson, or her assistant, Ms. Amy Hewett at 703-841-9300 for the conference call telephone number and access code. Send written material and requests to make oral presentations to Ms. Jennifer Carpenter; American Waterways Operators; 801 North Quincy Street, Suite 200; Arlington, VA 22209. This notice and related documents are available on the Internet at <http://dms.dot.gov> under the docket number USCG-2005-22235.

**FOR FURTHER INFORMATION CONTACT:** For general TSAC information you may also contact Mr. Gerald Miente, Assistant Executive Director of TSAC, telephone 202-267-0214, fax 202-267-4570, or e-mail [gmiente@comdt.uscg.mil](mailto:gmiente@comdt.uscg.mil). If you plan to participate in this meeting,

please notify both Mr. Miente and either Ms. Carpenter or Ms. Hewett by August 30, 2005.

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2 (Pub. L. 92-463, 86 Stat.770, as amended).

#### Agenda of Working Group Meeting

The agenda for the Licensing Working Group tentatively includes the following items:

- (1) Time frame flexibility—
    - Credit apprentice mate/steersman time at higher rate if individual is carried as an extra person;
    - Model course;
  - (2) Combine inland and Western Rivers routes;
  - (3) Ability to upgrade from tonnage-limited Master of Towing Vessels to Master of Towing Vessels without tonnage Limitation;
  - (4) Require towing endorsement for Master of Steam or Motor Vessels of Not More Than 500 Gross Tons. (Current regs allow Master 500 to operate towing vessels if he/she has either a towing endorsement or a completed Towing Officer's Assessment Record (TOAR).);
  - (5) Clarify how Master of Towing Vessels can obtain a Standards of Training, Certification and Watchkeeping (STCW) certificate if needed;
  - (6) Reconcile apparent discrepancies between licensing regulations and Navigation and Vessel Inspection Circular (NVIC) 4-01 *Licensing and Manning for Officers of Towing Vessels* re. TOAR format;
  - (7) Clarify TOAR requirements for harbor tug operators. Can certain items be marked "Not Applicable" (N/A)?;
  - (8) Reconsider elements that may prolong time needed to complete a TOAR (e.g., operate in high water, high wind.);
  - (9) Work with the Coast Guard to develop a communications plan aimed at mariners; and
  - (10) Proposed changes to NVIC 4-01.
- A letter proposing changes is attached; the NVIC can be found on-line at: <http://www.uscg.mil/hq/g-m/nvic/index00.htm#2001>.

#### Procedural

The meeting is open to the public. Please note that the meeting may close early if all business is finished. At the Chair's discretion, members of the public may make oral presentations during the meeting. If you would like to make an oral presentation at the meeting, please notify the working group Chairperson (as provided above in **ADDRESSES** no later than August 30,