

Submit reply comments by February 23, 2004.

**ADDRESSES:** Submit written and reply comments 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>.

**FOR FURTHER INFORMATION CONTACT:** Robert L. Sherman, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of May 29, 2003 (68 FR 32232), FDA published an ANPR based on the recommendations of the Dental Plaque Subcommittee (the Subcommittee) of the Nonprescription Drugs Advisory Committee (NDAC). FDA issued this notice to establish conditions under which OTC drug products for the reduction or prevention of dental plaque and gingivitis are generally recognized as safe and effective and not misbranded.

##### **II. Request for Extension of Time**

On July 15, 2003, the Consumer Healthcare Products Association (CHPA), a trade association of manufacturers of nonprescription drugs and dietary supplements, and the Cosmetic, Toiletry, and Fragrance Association (CTFA), a trade association of manufacturers of personal care products, requested a 90-day extension in which to file comments and new information (Ref. 1). CHPA/CTFA also requested that FDA accept reply comments up to 180 days after the closing date for the comment period. The request stated that the closing date for the original comment period would not allow CHPA/CTFA time to adequately assess the implications of the Subcommittee's proposed rulemaking. The request noted that, because this is the first time FDA published the Subcommittee's recommendations, industry needs sufficient time to provide additional data and perspectives on inclusion of several of the Subcommittee's proposed Category III (insufficient data) active ingredients in a tentative final monograph, and to support a Category I (safe and effective) status for these ingredients. In addition, CHPA/CTFA stated that because FDA specifically requested information on testing protocols, statistical methods, and effectiveness criteria, industry needs sufficient time to develop a set of

common elements and basic criteria for performance testing.

CHPA/CTFA stated that individual companies are likely to submit relevant data on antigingivitis/antiplaque active ingredients and on drug products in which antigingivitis/antiplaque active ingredients are combined with other oral health care active ingredients. Further, these companies are considering additional clinical studies that would involve time for FDA's review of submitted protocols and likely require 12 to 18 months to complete.

##### **III. FDA's Decision**

FDA has carefully considered the request and acknowledges its request for information on effectiveness criteria for antigingivitis/antiplaque active ingredients, performance testing, and the statistical approaches used to evaluate these tests. Manufacturers and CTFA/CTFA may require additional time to develop and review information to fully respond to the agency's request. However, FDA believes that extension of the reply comment period from 60 to 90 days should be sufficient time for manufacturers to respond to comments submitted during the comment period. The reply comment period is not intended to remain open for new study results to be submitted. Accordingly, the comment period is extended to November 25, 2003, and the reply comment period is extended to February 23, 2004. FDA considers an extension of time for comments in this case to be in the public interest.

##### **IV. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the ANPR. Submit a single paper 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

##### **V. Reference**

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. EXT7.

Dated: August 19, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-21669 Filed 8-22-03; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HOMELAND SECURITY**

### **Coast Guard**

#### **46 CFR Part 4**

**[USCG-2001-8773]**

**RIN 1625-AA27 (formerly 2115-AG07)**

### **Marine Casualties and Investigations; Chemical Testing Following Serious Marine Incidents**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking; notice of public meeting; reopening of comment period.

**SUMMARY:** The Coast Guard is reopening the comment period on the notice of proposed rulemaking for Marine Casualties and Investigations; Chemical Testing Following Serious Marine Incidents published in the **Federal Register** on February 28, 2003. In response to requests for a public meeting that were submitted to the public docket, the Coast Guard will hold a public meeting in Washington, DC. The purpose of the meeting is to obtain information from the public in addition to the comments already submitted to the docket.

**DATES:** The meeting will be held Friday, September 19, 2003, from 9 a.m. to 5 p.m. in Washington, DC. This meeting may close early if all business is finished. Comments must reach the docket on or before September 30, 2003.

**ADDRESSES:** The meeting location is: United States Coast Guard Headquarters, Transpoint Building, 2100 Second Street, SW., Room 2415, Washington, DC 20593. You may submit comments identified by Coast Guard docket number USCG-2001-8773 to the Docket Management Facility at the U.S. Department of Transportation (DOT). To avoid duplication, please use only one of the following methods:

- (1) Web Site: <http://dms.dot.gov>.
- (2) Federal eRulemaking Portal: <http://www.regulations.gov>.
- (3) Mail: Docket Management Facility, DOT, 400 Seventh Street SW., Washington, DC 20590-0001.
- (4) Fax: 202-493-2251.
- (5) Delivery: 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.

**FOR FURTHER INFORMATION CONTACT:** For questions on this proposed rule, contact Mr. Robert C. Schoening, Drug and Alcohol Program Manager, telephone 202-267-0684; e-mail address: [rschoening@comdt.uscg.mil](mailto:rschoening@comdt.uscg.mil). For questions on viewing material in the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, DOT, telephone 202-366-0271.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to <http://dms.dot.gov> and will include any personal information you have provided. We have an agreement with the DOT to use the Docket Management Facility even though the Coast Guard has recently transferred to DHS. Please see the DOT's statement on the Privacy Act under the section titled Viewing comments and documents.

**Submitting comments:** If you submit a comment, please include your name and address, identify the docket number for this rulemaking [USCG-2001-8773], indicate the specific section of the proposed rule 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 in developing the final rule.

**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 into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, or the like). You may review the DOT's statement on the Privacy Act in the **Federal Register** published on April 11, 2000 [65 FR 19477], or you may visit <http://dms.dot.gov>.

**Background Information**

The 1998 Coast Guard Authorization Act requires the Coast Guard to establish procedures ensuring alcohol testing is conducted within two hours of a serious marine casualty. The Coast Guard proposes to establish requirements for testing within the statutory time limits, to expand the existing requirements for commercial vessels to have alcohol testing devices on board, and to authorize use of a wider variety of testing devices (Notice of Proposed Rulemaking, [68 FR 9722], February 28, 2003). This rulemaking would also make additional minor procedural changes to Part 4, including a time limit for conducting drug testing following a serious marine incident. The Coast Guard reopened the comment period and scheduled this public meeting in response to comments previously submitted to the docket.

**Public Meeting**

The public meeting will be held September 19, 2003, from 9 a.m. to 5 p.m., at the United States Coast Guard Headquarters, Transpoint Building, 2100 Second Street, SW., Washington, DC. The building is located adjacent to Army Fort Leslie J. McNair at Buzzard Point. Entry to the Transpoint Building is controlled. All attendees must have a picture identification issued by a U.S. Federal Agency or a State or Territory issued drivers license. Valid Passports and Merchant Mariner Documents are also acceptable. Everyone is subject to a weapons search.

Members of the public may provide oral statements at the meeting. Oral statements may be time limited if there are numerous speakers. Persons wishing to make oral statements should notify Mr. Robert C. Schoening listed under **FOR FURTHER INFORMATION CONTACT** no later than two days before the meeting.

On street public parking in the vicinity of Coast Guard Headquarters is very limited. James Creek Marina, National Park Service, is adjacent to Coast Guard Headquarters and has some parking available for a nominal fee. The closest Metro Station is SEU-Waterfront

on the Green Line, about nine blocks from Coast Guard Headquarters. Attendees are encouraged to utilize taxi or public buses serving the Buzzard Point area. (For Bus Schedules, please see the Washington Area Metro Transit Authority-WMATA Web site at <http://www.wmata.com/>. Bus Route 71 serves Coast Guard Headquarters).

**Information on Services for Individuals With Disabilities**

For information on facilities or services for individuals with disabilities, or to request assistance at the meeting, Contact Mr. Robert C. Schoening listed under **FOR FURTHER INFORMATION CONTACT** as soon as possible.

Dated: August 18, 2003.

**L.L. Hereth,**

*Acting Assistant Commandant for Marine Safety, Security and Environmental Protection.*

[FR Doc. 03-21643 Filed 8-22-03; 8:45 am]

**BILLING CODE 4910-15-P**

---

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 64**

**[CG Docket No. 03-123; FCC 03-112]**

**Telecommunication Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities**

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This document seeks comment on technological advancements that may further the statutory goal of functionally equivalent Telecommunications Relay Services (TRS) for persons with hearing and speech disabilities, including comment on whether TRS facilities should have the same National Security Emergency Preparedness (NS/EP) designation as local exchange carriers under the Telecommunications Service Priority (TSP) System to ensure that persons with hearing and speech disabilities have access to telecommunications services during time of local, national, or international crisis.

**DATES:** Comments are due on or before September 24, 2003 and reply comments are due on or before October 9, 2003. Written comments by the public on the proposed information collection are due September 24, 2003. Written comments must be submitted by the Office of Management and Budget