

“Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention.” This guidance is intended to assist sponsors in developing clinical trials for drug products that treat or prevent gingivitis.

Gingivitis, an inflammation of the soft tissues that surround the teeth, is a part of the wider classification of periodontal diseases, which include gingivitis at the milder end and periodontitis at the more severe end. In 1986, FDA approved Peridex (0.12% chlorhexidine gluconate rinse), the first prescription product for gingivitis. In 1997, Colgate’s Total toothpaste (0.30% triclosan, 0.24% sodium fluoride) was approved through the new drug application (NDA) process as an over-the-counter (OTC) dentifrice that also has a gingivitis indication. During the past several decades, many products have also entered the marketplace as OTC products that were purported to treat or prevent gingivitis. As a result of the proliferation and promotion of those products, the agency convened a subcommittee of the Dental Products Panel (the Subcommittee) in 1993 to evaluate OTC products that make gingivitis and related claims and that were in the marketplace without an NDA. The Subcommittee’s charge was to review the submitted data and to report its findings on the safety and effectiveness of OTC ingredients for the reduction or prevention of gingivitis. On May 29, 2003, a final subcommittee report was published in the **Federal Register** (68 FR 32232) as an advance notice of proposed rulemaking, the first step in establishing an OTC monograph for these drug products.

Unlike the NDA process that consists of a review of the entire drug product, the monograph process reviews only active ingredients in the class of drug products for safety and efficacy. Until the monograph is finalized, only gingivitis products containing active ingredients that were marketed in the United States before 1975 can continue to be marketed. Any manufacturer attempting to enter the marketplace with a gingivitis product containing an active ingredient that has no prior marketing history in the United States should either petition the developing monograph to consider its inclusion or submit a new NDA for approval before marketing. Sponsors of OTC antingivitis drugs with active ingredients that the Subcommittee classified as needing further information to make a decision are encouraged to submit further data for review. As a result of these actions, FDA is publishing this guidance document on the development of antingivitis drugs.

The guidance is intended to aid drug sponsors in developing clinical trials either for submitting additional information to the antingivitis rulemaking, or for gaining approval for a new antingivitis drug through the NDA process.

This guidance document provides assistance in several ways. It addresses specific design elements such as choosing inclusionary and exclusionary criteria, selecting relevant endpoints, assessing gingivitis, determining the clinical significance of the effect, and collecting meaningful safety data. It also provides comments on general concerns (e.g., prevention versus treatment claims, OTC versus prescription status, special population enrollment, and nonclinical development issues related to products that are intended for administration within the oral cavity for the treatment or prevention of gingivitis).

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 the development and evaluation of drugs for treatment or prevention of gingivitis. 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. The draft guidance and 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: June 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Office of the Under Secretary for Management; Notice of Availability of Alternative Fuel Vehicle Report for Fiscal Year 2004

AGENCY: Office of the Under Secretary for Management, Department of Homeland Security.

ACTION: Notice.

SUMMARY: The Department of Homeland Security, Office of the Under Secretary for Management, is issuing this notice in order to comply with the Energy Policy Act of 1992 and 42 U.S.C. 13218(b). The purpose of this notice is to announce the public availability of the Department of Homeland Security’s Alternative Fuel Vehicle (AFV) Report for Fiscal Year 2004 at the following Web site: http://www.dhs.gov/dhspublic/interapp/editorial/editorial_0620.xml.

FOR FURTHER INFORMATION CONTACT:

Questions regarding AFV reports on the Department of Homeland Security Web site should be addressed to the Department of Homeland Security, Fleet and Transportation Program Manager (Attn: Steven Sosson), Washington, DC 20528, telephone 202–692–4226.

Janet Hale,

*Under Secretary for Management,
Department of Homeland Security.*

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD17–05–009]

Application for Recertification of Cook Inlet Regional Citizens’ Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Coast Guard announces the availability of and seeks comments on the application for recertification submitted by the Cook Inlet Regional Citizen’s Advisory Council (CIRCAC) for September 1, 2005, through August 31, 2006. 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. The current certification for CIRCAC will expire August 31, 2005.

DATES: Public comments on CIRCAC's recertification application must reach the Seventeenth Coast Guard District on or before August 12, 2005.

ADDRESSES: Comments should be mailed to the Seventeenth Coast Guard District (mor), P.O. Box 25517, Juneau, AK 99802-5517. Or, hand carried documents may be delivered to the Juneau Federal Building, 709 West 9th Street, Room 753, Juneau, AK between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

The Seventeenth Coast Guard District maintains the public docket for this recertification process. The application and comments regarding recertification will become part of this docket and will be available for inspection or copying at the Juneau Federal Building, 709 West 9th Street, Room 753, Juneau, AK.

A copy of the application will also be available for inspection at the CIRCAC offices at 910 Highland Avenue, Kenai, AK between the hours of 8 a.m. and 5 p.m., Monday through Friday, except federal holidays. CIRCAC's telephone number is (907) 283-7222.

FOR FURTHER INFORMATION CONTACT: For questions on viewing or submitting material to the docket, contact CDR Chris Myskowski, Seventeenth Coast Guard District (mor), (907) 463-2804.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to submit written data, views, or arguments. We solicit comments from interested groups including oil terminal facility owners and operators, owners and operators of crude oil tankers calling at terminal facilities, and fishing, aqua cultural, recreational and environmental citizens groups, concerning the recertification application of CIRCAC. Persons submitting comments should include their names and addresses, identify this notice (CGD17-05-009), the specific section of the document to which each comment applies, and give the reason for each comment. Please submit all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgement of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to Commander (m), Seventeenth Coast Guard District, P.O. 25517, Juneau, AK 99802-5517. The request should include reasons why a hearing would be beneficial. If there is sufficient evidence to determine that

oral presentations will aid this recertification process, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard published guidelines on December 31, 1992 (57 FR 62600) to assist groups seeking recertification under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (33 U.S.C. 2732) (the Act). The Coast Guard issued a policy statement on July 7, 1993 (58 FR 36504) to clarify the factors that the Coast Guard would be considering in making its determination as to whether advisory groups should be certified in accordance with the Act; and the procedures which the Coast Guard would follow in meeting its certification responsibilities under the Act. Most recently, on September 16, 2002 (67 FR 58440) the Coast Guard changed its policy on recertification procedures for regional citizen's advisory council by requiring applicants to provide comprehensive information every 3 years. For the 2 years in between, applicants only submit information describing substantive changes to the information provided at the last triennial recertification. This is the year in this triennial cycle that CIRCAC must provide comprehensive information.

At the conclusion of the comment period, August 12, 2005, the Coast Guard will review all application materials and comments received and will take one of the following actions:

(a) Recertify the advisory group under 33 U.S.C. 2732(o).

(b) Issue a conditional recertification for a period of 90 days, with a statement of any discrepancies, which must be corrected to qualify for recertification for the remainder of the year.

(c) Deny recertification of the advisory group if the Coast Guard finds that the group is not broadly representative of the interests and communities in the area or is not adequately fostering the goals and purposes of 33 U.S.C. 2732.

The Coast Guard will notify CIRCAC by letter of the action taken on their respective applications. A notice will be published in the **Federal Register** to advise the public of the Coast Guard's determination.

Dated: June 14, 2005.

James C. Olson,

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

[FR Doc. 05-12729 Filed 6-27-05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[COTP Los Angeles-Long Beach 05-005]

Letter of Recommendation, Liquefied Natural Gas Facility, Long Beach, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice; public meeting and request for comments.

SUMMARY: The Coast Guard announces that the Captain of the Port (COTP) Los Angeles-Long Beach will hold a public meeting regarding the maritime safety and security aspects of the proposed San Pedro Bay, California liquefied natural gas (LNG) facility. The Coast Guard also requests public comments regarding the maritime safety and security aspects of the aforementioned proposed LNG facility.

DATES: The public meeting will be held on July 11, 2005 at 6 p.m. at the Long Beach Marriott Hotel.

Comments and related material must reach the Commanding Officer, U.S. Coast Guard Sector Los Angeles-Long Beach on or before July 27, 2005.

ADDRESSES: The public meeting will be held at the Long Beach Marriott Hotel, 4700 Airport Plaza Drive, Long Beach, CA 90815.

You may submit written comments identified by Coast Guard docket number (COTP LA-LB 05-005) to Commanding Officer, U.S. Coast Guard Sector Los Angeles-Long Beach, 1001 S. Seaside Ave, San Pedro, CA 90731. To avoid duplication, please use only one of the following methods:

- (1) Mail: To the location described in **ADDRESSES**.
- (2) E-mail: To pgooding@d11.uscg.mil.
- (3) Fax: 310-732-2029.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, contact Lieutenant Peter Gooding, Chief of the Waterways Management Division at Coast Guard Sector Los Angeles-Long Beach, CA at 310-732-2020, or E-mail your questions to pgooding@d11.uscg.mil.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to submit written comments and related material pertaining specifically to marine safety and security aspects associated with the proposed LNG facility. If you do so, please include your name and address, identify the docket number for this notice (COTP LA-LB 05-005), and give the reason for each comment. To avoid