DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors Meeting, National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Board of Scientific Counselors (BSC), NIOSH.

Time and Date: 10 a.m.–3:30 p.m., July 21, 2005.

Place: National Institute for Occupational Safety and Health, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people. Visiting members of the public must present valid identification (U.S. Federal ID, State Driver's License, or other State-sanctioned ID) for entry to Taft Laboratories and must be escorted by facility staff at all times while inside the facility.

Purpose: The Secretary, Department of Health and Human Services; the Assistant Secretary for Health; and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors shall provide guidance to the Director, NIOSH, on research and preventions programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board shall evaluate the degree to which the activities of NIOSH: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters To be Discussed: Agenda items include a report from the Director of NIOSH; progress reports by BSC working groups on the National Occupational Research Agenda and the health hazard evaluation program, NIOSH emergency/terrorism preparedness, a tour of the Taft Laboratories, and closing remarks.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Roger Rosa, Executive Secretary, BSC, NIOSH, CDC, 200 Independence Avenue, SW., Room 715H, Washington, DC 20201, telephone (202) 205–7856, fax (202) 260–4464.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 22, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–12689 Filed 6–27–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0262] (formerly Docket No. 01–0262)

Draft ''Guidance for Food and Drug Administration Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments;'' Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance that was issued on August 3, 2001.

DATES: June 28, 2005.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 3, 2001 (66 FR 40708), FDA announced the availability of a draft document entitled ''Guidance for FDA Reviewers: Premarket Notification Submissions for Automated Testing Instruments Used in Blood Establishments.'' This draft guidance is being withdrawn because it no longer reflects the following: (1) All of the information FDA reviewers should expect to be included in a premarket notification submitted to the Center for Biologics Evaluation and Research for such devices and (2) the recommended approach FDA reviewers should take in reviewing premarket submissions for automated instruments testing used in blood establishments. In the future, FDA may issue for public comment draft special control guidances on instrumentation for blood borne pathogen donor screening and immunohematology testing.

Dated: June 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–12763 Filed 6–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0240]

Draft Guidance for Industry on Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention; 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 ''Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention.'' The draft guidance is intended to assist sponsors in developing clinical trials for drug products that treat or prevent gingivitis. It addresses specific protocol design elements as well as general concerns about drugs for this indication.

DATES: Submit written or electronic comments on the draft guidance by August 29, 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: Frederick Hyman, Center for Drug Evaluation and Research (HFD–540), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled

''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 antigingivitis 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 antigingivitis drugs. The guidance is intended to aid drug sponsors in developing clinical trials either for submitting additional information to the antigingivitis rulemaking, or for gaining approval for a new antigingivitis 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.

[FR Doc. 05–12764 Filed 6–27–05; 8:45 am]

BILLING CODE 4160–01–S

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.

[FR Doc. 05–12748 Filed 6–27–05; 8:45 am]

BILLING CODE 4110–10–P

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.