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