

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 28, 2005 (70 FR 37102), FDA published a notice announcing the availability of a draft guidance for industry entitled "Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention."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 conducting clinical trials for drug products that treat or prevent gingivitis. The 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, over-the-counter 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). The initial comment period closes on August 29, 2005.

II. Extension of Time

On July 15, 2005, the Consumer Healthcare Products Association requested a 60-day extension beyond the August 29, 2005, deadline for the submission of comments. The request stated that additional time is needed to assemble a comprehensive submission that requires coordinating extensive input from representatives of their member companies. FDA considers an extension of time for submission of comments to be in the public interest. Accordingly, FDA is extending the comment period for 60 days to October 28, 2005, as requested.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one 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 The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cder/guidance/>

index.htm or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-16754 Filed 8-23-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Advisory Commission on Childhood Vaccines; Request for Nominations for Voting Members**

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice; amendment.

SUMMARY: The Health Resources and Services Administration is amending a notice that appeared in the **Federal Register** of July 8, 2005, FR Doc. 13422, pages 39517-38518, requesting nominations for voting members to fill three vacancies on the Advisory Commission on Childhood Vaccines. The deadline date for receiving nominations was on or before August 8, 2005. This document amends the notice by extending the deadline date for receiving nominations.

DATES: The agency must receive nominations on or before September 16, 2005.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl Lee at 301-443-2124 or e-mail clee@hrsa.gov.

Dated: August 18, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05-16789 Filed 8-23-05; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****National Advisory Council on the National Health Service Corps; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps.

Dates and Times: September 8, 2005, 1 p.m.-7:30 p.m.; September 9, 2005, 8:30

a.m.-6 p.m.; and September 10, 2005, 9 a.m.-5:30 p.m.

Place: Hamilton Crowne Plaza, 1001 14th Street NW., Washington, DC 20005, 202-682-0111.

Status: The meeting will be open to the public.

Agenda: The Council will continue its discussion on the National Health Service Corps legislation in preparation for the upcoming reauthorization. Program staff and Agency management will provide guidance on program operations possible implications of legislative changes.

For Further Information Contact: Tira Robinson-Patterson, Division of National Health Service Corps, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A-55, 5600 Fishers Lane, Rockville, MD 20857; telephone: (301) 594-4140.

Dated: August 17, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05-16791 Filed 8-23-05; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: September 29, 2005, 8:30 a.m.-4:30 p.m. and September 30, 2005, 8 a.m.-2 p.m.

Place: The Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

Status: The meeting will be open to the public.

Purpose: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105-392. At this meeting the Advisory Committee will begin work on its sixth report which will be submitted to Congress and to the Secretary of the Department of Health and Human Services in November 2006. The report will focus on the role of Title VII, section 747 grant programs in preparing primary care practitioners to care for underserved high-risk groups and vulnerable populations.

Agenda: The meeting on Thursday, September 29, will begin with opening comments from the Chair of the Advisory Committee who will welcome new members. Introductory remarks will be given by the

Division of Medicine and Dentistry, Health Resources and Services Administration, and remarks have been invited from the Bureau of Health Professions and the Agency. A plenary session will follow in which speakers will address the Advisory Committee on the topic of health-outcomes disparities in at-risk populations and the interface of Title VII, section 747 training programs with community groups to enhance care for vulnerable populations. In plenary session and in small workgroups, the Advisory Committee will make plans for the report. There also will be annual elections for a new chair and two vice chairs. An opportunity will be provided for public comment.

On Friday, September 30, the Advisory Committee will open its meeting with an address on the topic of a theoretical framework for understanding vulnerability as it relates to individual patients and patient populations. The Advisory Committee will continue work on the sixth report and select members to serve on a Writing Group whose members will guide the report preparation process. An opportunity will be provided for public comment.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerilyn K. Glass, M.D., Ph.D., Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 9A-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-6785. The Web address for information on the Advisory Committee is <http://bhpr.hrsa.gov/medicine-dentistry/actpcmd>.

Dated: August 17, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05-16788 Filed 8-23-05; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the NIH Advisory Board for Clinical Research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: NIH Advisory Board for Clinical Research.

Date: September 23, 2005.

Time: 10 a.m. to 2 p.m.

Agenda: To discuss progress of activities related to research opportunities, training,

planning and funding in the NIH intramural clinical research program.

Place: National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4-2551, Bethesda, MD 20892.

Contact Person: Maureen E. Gormley, Executive Secretary, Mark O. Hatfield Clinical Research Center, National Institutes of Health, Building 10, Room 6-1610, Bethesda, MD 20892, 301/496-2897.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Dated: August 17, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-16757 Filed 8-23-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the National Advisory Neurological Disorders and Stroke Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Neurological Disorders and Stroke Council,

Training, Career Development, and Special Programs Subcommittee.

Date: September 14, 2005.

Open: 8 p.m. to 9:30 p.m.

Agenda: To discuss the training programs of the Institute.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Closed: 9:30 p.m. to 10 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Margaret Jacobs, Acting Training and Special Programs Officer, National Institute of Neurological Disorders and Stroke, National Institutes of Health, 6001 Executive Blvd., Suite 2154 MSC 9527, Bethesda, MD 20892-9527, 301-496-4188, mj22o@nih.gov.

Name of Committee: National Advisory Neurological Disorders and Stroke Council, Clinical Trials Subcommittee.

Date: September 15, 2005.

Open: 8 a.m. to 9 a.m.

Agenda: To discuss clinical trials policy.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 6, Bethesda, MD 20892.

Closed: 9 a.m. to 10 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, C Wing, Conference Room 6, Bethesda, MD 20892.

Contact Person: John Marler, MD, Associate Director for Clinical Trials, National Institute of Neurological Disorders and Stroke, National Institutes of Health, 6001 Executive Blvd., Suite 2216, Bethesda, MD 20892, (301) 496-9135, jm137f@niah.gov.

Name of Committee: National Advisory Neurological Disorders and Stroke Council, Basic and Preclinical Programs Subcommittee.

Date: September 15, 2005.

Open: 8 a.m. to 10 a.m.

Agenda: To discuss basic and preclinical programs policy.

Place: National Institutes of Health, Building 31, 31 Center Drive, A Wing, Conference Room 8A-28, Bethesda, MD 20892.

Contact Person: Robert Baughman, MD, Associate Director for Technology Development, National Institute of Neurological Disorders and Stroke, National Institutes of Health, 6001 Executive Blvd., Suite 2137, MSC 9527, Bethesda, MD 20892-9527, (301) 496-1779.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: <http://www.ninds.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.