DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 8, 2005, from 8 a.m. to 6 p.m., and on September 9, 2005, from 8 a.m. to 1 p.m.

Location: Hilton Washington DC North/Gaithersburg, Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, ext. 176, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 8, 2005, the committee will hear a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will also hear an update on the status of recent devices brought before the committee. Subsequently, the committee will discuss, make recommendations, and vote on a premarket approval application for a hip joint metal/metal semi-constrained resurfacing hybrid prosthesis (cemented femoral component and uncemented acetabular component). The device is intended to relieve hip pain and improve hip function in patients who have adequate bone stock and are at risk of requiring more than one hip joint replacement over their lifetimes.

On September 9, 2005, the committee will discuss the design of clinical studies for spinal devices indicated for treatment of mild to moderate low back pain.

Background information for the topics, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panel/index.html*. Material for the September 8 session will be posted September 7, 2005; material for the September 9 session will be posted September 8, 2005.

Procedure: On September 8, 2005, from 8:30 a.m. to 6 p.m., the meeting will be open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 29, 2005. On September 8, 2005, oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of the committee deliberations and for approximately 30 minutes near the end of the deliberations. On September 9, 2005, oral presentations from the public will be scheduled from approximately 8:30 a.m. to 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 29, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On September 8, 2005, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) relating to pending issues and applications.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks at 240–276–0450, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 18, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–16787 Filed 8–23–05; 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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 28, 2005, the comment period for the draft guidance for industry entitled ''Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention.'' The draft guidance is intended to assist sponsors in conducting 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. FDA published a notice of availability of the draft guidance, with a comment period that closes on August 29, 2005. FDA is taking this action in response to a request for extension of the comment period to allow interested persons additional time to review the draft guidance and submit comments.

DATES: Submit written or electronic comments on the draft guidance by October 28, 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

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