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In the Federal Register of June 28, 2005 (70 FR 37102), FDA published a notice announcing the availability of a draft guidance for industry entitled "Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention."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-thecounter 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persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the draft guidance.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 The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/cder/guidance/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.

Plâce: 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 highrisk 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