public health. These discussions will begin the process for the TPSAC’s required report to the Secretary of Health and Human Services regarding the issue of the nature and impact of the use of dissolvable tobacco products on the public health, including such use among children. The final report should take into consideration the following: (1) The risks and benefits to the population as a whole, including users and nonusers of tobacco products; (2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (3) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

FDA intends to make redacted background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

Procedure: On July 21, 2011, from 9 a.m. to 5 p.m., and on July 22, from 8 a.m. to 12 noon, the meeting is 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 on or before July 5, 2011. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. on both July 21, 2011, and July 22, 2011. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before June 27, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can reasonably accommodate during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 28, 2011.

Closed Committee Deliberations: On July 22, 2011, from 1 p.m. to 5 p.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)). This portion of the meeting must be closed because the Committee will be discussing trade secret and/or confidential data regarding dissolvable tobacco products provided by the tobacco companies.

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 Caryn Cohen at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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

Dated: May 25, 2011.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–13779 Filed 6–2–11; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Gastrointestinal Drugs 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). The meeting will be open to the public.

Name of Committee: Gastrointestinal Drugs 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 July 21, 2011, from 8 a.m. to 4 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel’s phone number is 301–589–5200.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, e-mail: GIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 21, 2011, the committee will discuss the results from a clinical trial of supplement biologics license application 103772/5301, REMICADE (infliximab), by Centocor Ortho Biotech Inc., in the treatment of pediatric patients with moderately to severely active ulcerative colitis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

Procedure: 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 on or before July 6, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before June 27, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 28, 2011.

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 Kristine T. Khuc at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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

Dated: May 25, 2011.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–13778 Filed 6–2–11; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 15, 2011, 12 p.m. to June 15, 2011, 1 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the Federal Register on May 25, 2011, 76 FR 30372–30373.

The meeting will be held June 14, 2011, 1 p.m. to 2 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 26, 2011.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–13792 Filed 6–2–11; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 28–29, 2011. Time: 7:30 a.m. to 2:30 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: May 27, 2011.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–13794 Filed 6–2–11; 8:45 am]
BILLING CODE 4140–01–P