DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting 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 Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Clinical Trial Review Meeting.

Date: May 3, 2010.

Time: 3:30 p.m. to 5 p.m.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: John F. Connaughton, PhD, Chief, Chartered Committees Section, Review Branch, DEA, NIDDK, National Institutes of Health, Room 753, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797, connaughton@extra.niddk.nih.gov.

SUMMARY: To review and evaluate grant applications.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice]

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the Federal Register of March 8, 2010 (75 FR 10490). The amendment is being made to reflect a change in the Agenda portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT:

Anuja Patel, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: Anuja.Patel@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), codes 3014512532 and 3014512535. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 8, 2010, FDA announced that a joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee would be held on May 12, 2010. On page 10490, in the second column, the Agenda portion of the document is changed to read as follows:

Agenda: The committees will discuss new drug application (NDA) 22–478, naproxen 375 milligram capsule, sponsored by Nicox S.A. Naproxen is a non-steroidal anti-inflammatory drug (NSAID) product indicated for the treatment of the signs and symptoms of osteoarthritis.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee]

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a joint meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the Federal Register of March 8, 2010 (75 FR 10490). The amendment is being made to reflect a change in the Agenda portion of the document. There are no other changes.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Peripheral and Central Nervous System 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: Peripheral and Central Nervous System 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 June 10, 2010, from 8 a.m. to 5 p.m.


Contact Person: Diem-Kieu Ngo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: diem.ngo@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512543. 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 June 10, 2010, the committee will discuss new drug application (NDA) 22–527, with the
proposed trade name GILENIA (fingolimod hydrochloride) 0.5 milligram (mg) capsules, by Novartis Pharmaceuticals Corp. The proposed indication for this new drug product is treatment of relapsing forms of multiple sclerosis.

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 May 26, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 May 18, 2010. 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 May 19, 2010.

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 Diem-Kieu Ngo 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: April 1, 2010.

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

[FR Doc. 2010–7698 Filed 4–5–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2010–N–0004]

Memorandum of Understanding Between the Food and Drug Administration, United States Department of Health and Human Services and the National Alliance for Hispanic Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration, U.S. Department of Health and Human Services and the National Alliance for Hispanic Health. The purpose of the MOU is to establish the terms for collaboration to enhance the diversity pool of candidates and to promote shared interests in increasing science and public health internship opportunities for socio-economically disadvantaged students.

DATES: The agreement became effective January 21, 2010.

FOR FURTHER INFORMATION CONTACT: Mary C. Hitch, Senior Policy Advisor, Office of External Relations, Food and Drug Administration, 5600 Fishers Lane, rm. 15A07, Rockville, MD 20857, 301–827–4406.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the Federal Register, the agency is publishing notice of this MOU.


Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–S