that have interests in health systems change and personalized health care. Some examples of these organizations include:

- Community health delivery systems.
- Health maintenance organizations.
- University-based health systems.
- State and local public health departments.
- Other Federal agencies.
- Advocacy groups and public interest organizations.
- Consumer and patient interests groups.
- Health care professional societies.
- Trade industry organizations.
- Purchasers of health care.
- Health information technology industry vendors.

Dated: October 26, 2006.

John O. Agwunobi,

Assistant Secretary for Health, Office of Public Health and Science.

[FR Doc. E6–18371 Filed 10–31–06; 8:45 am]

BILLING CODE 4150–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0478]

Marketed Unapproved Drugs; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop on issues related to the application process for seeking approval for marketed unapproved drugs. This will be a 1-day workshop involving FDA staff and representatives from businesses currently marketing unapproved drugs. The purpose of the workshop is to provide clarification and direction to businesses on how to seek approval to legally market drugs through the new drug application (NDA) and abbreviated new drug application (ANDA) processes and how to legally market drugs through compliance with the over-the-counter (OTC) monographs.

DATES: The public workshop will be held on January 9, 2007, from 9 a.m. to 4 p.m. Registration is open until November 15, 2006. Submit requests for specific discussion topics by November 15, 2006.

ADDRESSES: The public workshop will be held in the Center for Drug Evaluation and Research Advisory Committee conference room, 5630 Fishers Lane, rm. 1066, Rockville, MD. The agenda for the meeting will be posted at *http://www.fda.gov/cder/drug/unapproved_drugs*.

Submit topics by mail to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit topics electronically to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed topics, except that individuals may submit one paper copy. All requests for discussion topics should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Kirchberg, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8916, e-mail: *karen.kirchberg@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 9, 2006 (71 FR 33466), FDA announced the availability of a guidance entitled ''Marketed Unapproved Drugs—Compliance Policy Guide'' (the Marketed Unapproved Drugs CPG). The guidance describes how FDA intends to exercise its enforcement discretion with regard to drugs marketed in the United States that do not have required FDA approval for marketing. The guidance explains that FDA intends to continue to give priority to enforcement actions involving unapproved drugs that have potential safety risks, lack evidence of effectiveness, and constitute health fraud, among other categories. The Marketed Unapproved Drugs CPG also explains how the agency intends to address those situations in which a company obtains approval to sell a drug that other companies have sold without FDA approval for some time. In the Marketed Unapproved Drugs CPG, FDA encourages companies to comply with the drug approval requirements of the Federal Food, Drug, and Cosmetic Act.

Following the publication of the Marketed Unapproved Drugs CPG, a number of drug companies have contacted FDA seeking clarification about how to obtain approval to legally market their unapproved drug products and whether applications for marketing are subject to user fees, among other issues. The agency is committed to working with companies to facilitate the process of ensuring that products are safe and effective and meet appropriate standards for manufacturing and labeling.

II. Scope of the Public Workshop

As part of FDA's goal to ensure that all marketed drugs comply with appropriate FDA requirements to ensure their safety and efficacy, FDA is holding a public workshop to educate businesses on the drug application and OTC monograph processes and to discuss issues of interest to participants.

Topics for discussion include the following: (1) The various routes for legal marketing—NDAs, ANDAs, and OTC monographs; (2) application processes; (3) user fee applicability and waivers; and (4) market exclusivity for newly-approved drugs. The information provided during registration will help us determine additional topics for discussion and how to further focus the workshop.

III. Participation in the Public Workshop

A. Registration

Register via e-mail to *CDER_330CATS@cder.fda.gov* by providing complete contact information for each attendee (including name, title, affiliation, e-mail address, and phone number(s)) by November 15, 2006. Please indicate ''Workshop—Unapproved Products'' in the ''subject'' line of the e-mail. FDA intends to respond to registration requests by e-mail after November 15, 2006. There is no registration fee to attend. Space is limited; therefore, interested parties are encouraged to register early and FDA may need to limit the number of attendees from each firm or organization. If you need special accommodations due to a disability, please e-mail your request at least 7 days before the meeting.

B. Suggested Topics

If you would like to request discussion of a specific topic for the workshop, submit it to the Division of Dockets Management (see **ADDRESSES**) using the docket number, found in brackets in the heading of this document, by November 15, 2006. We may not be able to include all submitted topics in the workshop agenda.

C. Parking, Transportation, and Security

Limited visitor parking is available for a fee, and the Twinbrook Metro station is within walking distance. Early arrival is encouraged, as there will be security screening. Workshop participants will be asked for government-issued picture identification by the security officers.

IV. Transcripts

Following the workshop, transcripts will be available for review at the

Division of Dockets Management (see **ADDRESSES**), Monday through Friday between 9 a.m. and 4 p.m. You may also request a copy of the transcript from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: October 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17959 Filed 10–31–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

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

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 Institute on Drug Abuse Special Emphasis Panel, NIDA–K conflicts SEP A.

Date: November 14, 2006.

Time: 4 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mark Swieter, PhD, Chief, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Suite 220, Bethesda, MD 20892–8401, (301) 435–1389, *ms80x@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, NIDA–K conflicts SEP B.

Date: November 14, 2006.

Time: 5 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Mark Swieter, PhD, Chief, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Suite 220, Bethesda, MD 20892–8401, (301) 435–1389, *ms80x@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 25, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–8984 Filed 10–31–06; 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 Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Neuro AIDS Imaging II.

Date: November 3, 2006.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Phillip F. Wiethorn, Scientific Review Administrator, DHHS/NIH/NINDS/DER/SRB, 6001 Executive Boulevard; MSC 9529, Neuroscience Center; Room 3203, Bethesda, MD 20892–9529, (301) 496–5388, *wiethorp@ninds.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 25, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–8985 Filed 10–31–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Mental Health Special Emphasis Panel, Mental Health Services in Non-Specialty Settings.

Date: November 7, 2006.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Aileen Schulte, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)