Dated: August 2, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–19283 Filed 8–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Psychopharmacologic 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: Psychopharmacologic 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 September 16, 2010, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, the Great Room, 10903 New Hampshire Ave., Bldg. 31, White Oak Conference Center (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading "Resources for You" tab, click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings."

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, e-mail: *yvette.waples@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512544. 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: The committee will discuss the available safety and efficacy data for supplemental new drug application (sNDA) 21–897/015, VIVITROL (naltrexone for extended-release injectable suspension), sponsored by Alkermes, Inc., for the treatment of opioid dependence.

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 September 1, 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 August 24, 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 August 25, 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 Yvette Waples 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: July 28, 2010.

Thinh Nguyen,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–19161 Filed 8–4–10; 8:45 am]

BILLING CODE 4160–01–S

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, Ancillary Clinical Studies Review Meeting.

Date: September 1, 2010.

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

Agenda: To review and evaluate grant applications.

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.

connaughtonj@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 30, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19210 Filed 8–4–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Solicitation for Nominations for New Clinical Preventive Health Topics To Be Considered for Review by the United States Preventive Services Task Force

AGENCY: Agency for Healthcare Research and Quality (AHRQ), DHHS.

ACTION: Solicit for new topic nominations.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) invites individuals and organizations to nominate primary and secondary prevention topics pertaining to clinical preventive services that they would like the United States Preventive Services Task Force (USPSTF) to consider for review. All topics previously reviewed by the USPSTF are available on AHRQ's Web site, *http://www.preventiveservices.AHRQ.gov.*

The USPSTF is an independent panel of experts that makes evidence-based recommendations regarding the provision of clinical preventive services. Clinical preventive services include screening, counseling and preventive medications associated with primary care. The USPSTF makes recommendations about preventive services for asymptomatic people—people without recognized signs or symptoms of the specific condition targeted by the preventive service.

Topics can be nominated by individuals, organizations, evidence-based practice centers (EPC) and USPSTF members. The USPSTF will consider topic nominations in two steps. The USPSTF will first determine if the topic relates to a service is eligible, *i.e.,* constitutes primary or secondary prevention applicable to healthy asymptomatic persons; is primary care-feasible or referable from primary care; and addresses a condition with a substantial health burden. As a second step, within eligible topics, the USPSTF will prioritize based on the following set of criteria: Public health importance (burden of suffering, potential of preventive service to reduce the burden); and potential for greatest Task Force impact (*e.g.,* clinical controversy, practice does not reflect evidence, inappropriate timing in delivery of services).

Basic Topic Nomination Requirements

Nominations must be no more than 500 words in length and must include the information listed below. Nominations may include supporting documentation; reference lists and other supporting documents are not counted against the 500 word limit, but should not exceed ten pages.

Required Information

1. Name of topic.
2. Rationale for consideration by the USPSTF, describing:
   a. Characterization as primary or secondary prevention topic (screening, counseling or preventive medication).
   b. Primary care relevance (applicable clinical preventive service must be provided by a primary care provider and or initiated in the primary care setting which can be defined as family practice, internal medicine, pediatrics or obstetrics/gynecology).
   c. Public health importance (burden of disease/suffering, potential of preventive service to reduce burden, including effective interventions). Citations and supporting documents are recommended.
   d. Potential impact of USPSTF's review of the topic, *i.e.,* change in clinical practice, research focus, *etc.*

DATES: Topic nominations should be submitted by August 27, 2010 in order to be considered for 2010–2012. AHRQ will not reply to submissions in response to the request for nominations, but will consider all topic nominations during the selection process. If a topic is selected for review by the USPSTF, the nominator will be notified by AHRQ.

ADDRESSES: Please submit nominations to: Gloria Washington, ATTN: USPSTF Topic Nominations, Center for Primary Care, Prevention & Clinical Partnerships, Agency for Healthcare Research and Quality 540 Gaither Road, Room 6117, Rockville, MD 20850. *Fax:* 301–427–1595. *E-mail: qloria.washinqton@AHRQ.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Robert Cosby at *robert.cosby@AHRQ.hhs.qov* or Gloria Washington at *qloria.washington@AHRQ.hhs.gov.*

Arrangement for Public Inspection: All nominations will be available for public inspections by appointment at the Center for Primary Care, Prevention & Clinical Partnerships, 301–427–1500, weekdays between 10 a.m. and 5 p.m. (Eastern time).

SUPPLEMENTARY INFORMATION:

Background

Under Title IX of the Public Health Service Act, AHRQ is charged with enhancing the quality, appropriateness and effectiveness of health care services and access to such services. AHRQ accomplishes these goals through scientific research and promotion of improvements in clinical practice, including prevention of diseases and other health conditions. 42 U.S.C. 299(b).

The United States Preventive Services Task Force (USPSTF) is an independent expert panel, first established in 1984 under the auspices of the U.S. Public Health Service. Under AHRQ's authorizing legislation, see 42 U.S.C. 299b–4(a)(1), the Director of AHRQ is responsible for convening the USPSTF, which is to be composed of individuals with appropriate expertise. The mission of the Task Force is to review the scientific evidence related to the effectiveness, and appropriateness of clinical preventive services for the purpose of developing recommendations for the health care community. Current Task Force recommendations and associated evidence reviews are available at *http://www.preventiveservices.AHRQ.gov.*

Topic Nomination Solicitation

The purpose of this solicitation for new topics by AHRQ and the USPSTF is to create a balanced portfolio of relevant topics for the current Task Force library. Balance in the library is sought on the basis of populations, types of services (screening, counseling, preventive medications) and disease types (cancer; heart and vascular disease; injury and violence-related disorders; infectious diseases; mental disorders and substance abuse; metabolic, nutritional and endocrine diseases; musculoskeletal conditions; obstetric and gynecological conditions; pediatric disorders; and, vision and hearing disorders). Selection of suggested topics will be made on the basis of the qualifications of nominations as outlined above (*see* basic topic nomination requirements).

Dated: July 26, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–19117 Filed 8–4–10; 8:45 am]

BILLING CODE 4160–90–M