

evolving information, novel technologies, and new scientific methods—into its decision making, while also maintaining as much predictability as practical.

### C. Preliminary Reports

FDA is making available for public comment a two-volume set of documents entitled “Center for Devices and Radiological Health Preliminary Internal Evaluations.” Volume I is entitled “510(k) Working Group Preliminary Report and Recommendations.” This preliminary report is intended to communicate preliminary findings and recommendations regarding the 510(k) program and actions CDRH might take to address identified areas of concern. Volume II is entitled “Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations.” This preliminary report is intended to communicate preliminary findings and recommendations regarding the incorporation of new scientific information into CDRH’s decision making and actions CDRH might take to address identified areas of concern.

Interested persons are invited to comment on either or both of these preliminary reports. CDRH will consider comments received prior to finalizing the two reports and determining which, if any, recommendations to implement in their current or a modified form.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## III. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.regulations.gov> or <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/default.htm> (select appropriate option from the menu).

Dated: July 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-19339 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]

### Tobacco Products Scientific 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:* Tobacco Products Scientific 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 August 30, 2010, from 8:30 a.m. to 12 noon.

*Location:* Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. The hotel telephone number is 301-590-0044.

*Contact Person:* Cristi Stark, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373 (choose option 4), e-mail: [TPSAC@fda.hhs.gov](mailto:TPSAC@fda.hhs.gov) or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732110002. 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 August 30, 2010, the committee will receive a report from the Tobacco Product Constituents Subcommittee and discuss a proposed initial list of harmful or potentially harmful constituents, the rationale for inclusion of each constituent, established analytical methods as well as the ancillary methods and normalization standards for the identified constituents.

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 August 23, 2010. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.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 13, 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 16, 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 Cristi Stark 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: 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](mailto: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]

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## 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.nidk.nih.gov](mailto:connaughtonj@extra.nidk.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)