

withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the agency will continue to list BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to BUSPAR. Additional ANDAs for buspirone hydrochloride tablets, 10 mg, 15 mg, and 30 mg, may also be approved by the agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: October 13, 2010.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

[FR Doc. 2010-26214 Filed 10-18-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute; 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 Eye Institute Special Emphasis Panel, NIH Training Grants.

*Date:* December 6, 2010.

*Time:* 8:30 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Daniel R. Kenshalo, PhD, Scientific Review Officer, Division of

Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300. 301-451-2020. [kenshalod@nei.nih.gov](mailto:kenshalod@nei.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: October 13, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-26310 Filed 10-18-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Notice of Meeting; National Commission on Children and Disasters

**AGENCY:** Administration for Children and Families, Department of Health and Human Services.

**ACTION:** Notice of Meeting.

**DATES:** The meeting will be held on Monday, November 15, 2010, from 9:30 a.m. to 3:30 p.m.

**ADDRESSES:** The meeting will be held at the Administration for Children and Families, 901 D Street, SW., Washington, DC 20024. To attend either in person or via teleconference, please register by 5 p.m., Eastern Time, November 10, 2010. To register, please e-mail [Jacqueline.Officer@acf.hhs.gov](mailto:Jacqueline.Officer@acf.hhs.gov) with "Meeting Registration" in the subject line, or call (202) 205-9560. Registration must include your name, affiliation, and phone number. If you require a sign language interpreter or other special assistance, please call Jacqueline Officer at (202) 205-9560 or e-mail [Jacqueline.Officer@acf.hhs.gov](mailto:Jacqueline.Officer@acf.hhs.gov) as soon as possible and no later than 5 p.m. Eastern Time, November 1, 2010.

**Agenda:** The Commission will: (1) Discuss a recommendation to establish a National Resource Center on Children and Disasters; (2) Discuss implementation strategies for recommendations published in the 2010 Report to the President and Congress; and (3) Discuss potential issues for future study and changes to subcommittee structure.

Written comments may be submitted electronically to [Juliana.Sadovich@acf.hhs.gov](mailto:Juliana.Sadovich@acf.hhs.gov) with "Public Comment" in the subject line. The Commission recommends that you include your name, mailing address and an e-mail address or other contact information in the body of your comment. This ensures that you can be

identified as the submitter of the comment, and it allows the Commission to contact you if further information on the substance of the comment is needed or if your comment cannot be read due to technical difficulties. The Commission's policy is that the Commission will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment placed in the official record.

The Commission will provide an opportunity for public comments during the public meeting on November 15, 2010. Those wishing to speak will be limited to three minutes each; speakers are encouraged to submit their remarks in writing in advance to ensure their comment is received in case there is inadequate time for all comments to be heard on November 15, 2010.

**Additional Information:** Contact CAPT Juliana Sadovich, RN, PhD Director, Office of Human Services Emergency Preparedness and Response, e-mail [Juliana.Sadovich@acf.hhs.gov](mailto:Juliana.Sadovich@acf.hhs.gov) or call (202) 401-9306.

**SUPPLEMENTARY INFORMATION:** The National Commission on Children and Disasters is an independent Commission directed to conduct a comprehensive study to examine and assess the needs of children as they relate to preparation for, response to, and recovery from all hazards, building upon the evaluations of other entities and avoiding unnecessary duplication by reviewing the findings, conclusions, and recommendations of these entities. The Commission submitted reports to the President and the Congress on the Commission's independent and specific findings, conclusions, and recommendations to address the needs of children as they relate to preparation for, response to, and recovery from all hazards, including major disasters and emergencies.

Dated: October 13, 2010.

**David A. Hansell,**

*Acting Assistant Secretary for Children and Families.*

[FR Doc. 2010-26231 Filed 10-18-10; 8:45 am]

**BILLING CODE 4184-06-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Toxicology Program (NTP); Office of Liaison, Policy and Review Meeting of the NTP Board of Scientific Counselors

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

**ACTION:** Meeting announcement and request for comments.

**SUMMARY:** Pursuant to Public Law 92-463, notice is hereby given of a meeting of the NTP Board of Scientific Counselors (BSC). The BSC is a federally chartered, external advisory group composed of scientists from the public and private sectors that provides primary scientific oversight to the NTP Director and evaluates the scientific merit of the NTP's intramural and collaborative programs.

**DATES:** The BSC meeting will be held on November 30—December 1, 2010. The deadline for submission of written comments is November 9, 2010, and for pre-registration to attend the meeting, including registering to present oral comments, is November 16, 2010. Persons needing interpreting services in order to attend should contact 301-402-8180 (voice) or 301-435-1908 (TTY). For other accommodations while on the NIEHS campus, contact 919-541-2475 or e-mail [niehsoeoo@niehs.nih.gov](mailto:niehsoeoo@niehs.nih.gov). Requests should be made at least 7 business days in advance of the event.

**ADDRESSES:** The BSC meeting will be held in the Rodbell Auditorium, Rall Building at the NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709. Public comments on all agenda topics and any other correspondence should be submitted to Dr. Lori White, Designated Federal Officer for the BSC, NTP Office of Liaison, Policy and Review, NIEHS, P.O. Box 12233, K2-03, Research Triangle Park, NC 27709; telephone: 919-541-9834; fax: 919-541-0295; [whitel@niehs.nih.gov](mailto:whitel@niehs.nih.gov). Courier address: NIEHS, 530 Davis Drive, Room K2136, Morrisville, NC 27560.

**FOR FURTHER INFORMATION CONTACT:** Dr. Lori D. White (telephone: 919-541-9834 or [whitel@niehs.nih.gov](mailto:whitel@niehs.nih.gov)).

**SUPPLEMENTARY INFORMATION:**

**Preliminary Agenda Topics and Availability of Meeting Materials**

- Report of the NIEHS/NTP Director.
- Report of the NTP Associate Director.
- Contract Concept: NTP Sperm Count and Vaginal Cytology.
- Review of the Biomolecular Screening Branch.
- Testing Program Proposed Research Projects.

The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting Web site (<http://ntp.niehs.nih.gov/go/165>) or may be requested in hardcopy from the

Designated Federal Officer for the BSC (see **ADDRESSES** above). Updates to the preliminary agenda will also be posted to this site. The draft research concepts for the NTP testing program nominations should be available on the BSC meeting page (<http://ntp.niehs.nih.gov/go/165>) by October 19, 2010.

Following the meeting, summary minutes will be prepared and made available on the BSC meeting Web site.

**Attendance and Registration**

The meeting is scheduled for November 30—December 1, 2010, beginning at 8 a.m. (Eastern Standard Time) and continuing to approximately 5:30 p.m. on November 30 and until adjournment on December 1. This meeting is open to the public with attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the BSC meeting Web site (<http://ntp.niehs.nih.gov/go/165>) by November 16, 2010, to facilitate planning for the meeting. Registered attendees are encouraged to access the meeting Web site to stay abreast of the most current information regarding the meeting. The NTP is making plans to videocast the meeting through the Internet at <http://www.niehs.nih.gov/news/video/live>.

**Request for Comments**

Written comments submitted in response to this notice should be received by November 9, 2010. Comments will be posted on the BSC meeting Web site and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), phone, e-mail, and sponsoring organization (if any) with the document.

Time will be allotted during the meeting for the public to present oral comments to the BSC on the agenda topics. In addition to in-person oral comments at the meeting at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The available lines will be open from 7:30 a.m. until 5:30 p.m. on November 30, and 7:30 a.m. until adjournment on December 1, although public comments will be received only during the formal public comment periods, which are indicated on the preliminary agenda. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10

minutes at the discretion of the BSC chair. Persons wishing to present oral comments are encouraged to pre-register on the NTP meeting Web site and indicate whether they will present comments in-person or via the teleconference line. The access number for the teleconference line will be provided to registrants by e-mail prior to the meeting. Registration for oral comments will also be available on both meeting days, although time allowed for presentation by these registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked to send a copy of their statement or PowerPoint slides to the Designated Federal Officer for the BSC (see **ADDRESSES** above) by November 16, 2010, to enable review by the BSC prior to the meeting. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the BSC and NTP staff and to supplement the record.

**Background Information on NTP Testing Program Nominations and Proposed Research Projects**

The NTP actively seeks to identify and select for study chemicals and other substances for which sufficient information is not available to adequately evaluate potential human health hazards. The NTP accomplishes this goal through a formal, open nomination and selection process. Substances considered appropriate for study generally fall into two broad, yet overlapping categories: (1) Substances judged to have high concern as possible public health hazards based on the extent of human exposure and/or suspicion of toxicity and (2) substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks, e.g., by facilitating cross-species extrapolation or evaluating dose-response relationships. Nominations are subject to a multi-step, formal process of review before selections for testing are made and toxicological studies are designed and implemented. The nomination review and selection process is accomplished through the participation of representatives from the NIEHS, the BSC, the NTP Executive Committee—the NTP Federal interagency policy body, and the public. The nomination review and selection process is described in further detail on the NTP Web site (<http://>

[ntp.niehs.nih.gov/](http://ntp.niehs.nih.gov/), select “Nominations to the Testing Program”).

The NTP invites interested parties to submit written comments, provide supplementary information, or present oral comments at the BSC meeting on the nominated substances and preliminary study recommendations (see “Request for Comments” below). The NTP welcomes toxicology study information from completed, ongoing, or anticipated studies, as well as information on current U.S. production levels, use or consumption patterns, human exposure, environmental occurrence, or public health concerns for any of the nominated substances. The NTP is interested in identifying appropriate animal and non-animal experimental models for mechanistic-based research, including genetically modified rodents and high-throughput *in vitro* test methods, and as such, solicits comments regarding the use of specific *in vivo* and *in vitro* experimental approaches to address questions relevant to the nominated substances and issues under consideration. Although the deadline for submission of written comments to be considered at the BSC meeting is November 16, 2010 (see “Request for Comments” above), the NTP welcomes comments or additional information on these study nominations at any time.

To facilitate review of the proposed research project by the BSC and the public, NTP staff developed a draft research concept document for the nomination recommended for study. A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program tailored for each nomination. The purpose of a research concept is to outline the general elements of a program of study that would address the specific issues that prompted the nomination and the preliminary study recommendations. A research concept may also encompass larger public health issues or topics in toxicology that could be appropriately addressed through studies on the nominated substance(s). Draft research concepts should be available on the BSC meeting page (<http://ntp.niehs.nih.gov/go/165>) by October 19, 2010.

#### **Background Information on the NTP Board of Scientific Counselors**

The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts

periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. The BSC usually meets biannually.

Dated: October 5, 2010.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

[FR Doc. 2010-26023 Filed 10-18-10; 8:45 am]

**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2010-N-0001]**

#### **Endocrinologic and Metabolic 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:* Endocrinologic and Metabolic 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 December 7, 2010, from 8 a.m. to 5 p.m.

*Location:* FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (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”, click on “White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings”.

*Contact Person:* Paul Tran, 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: 301-847-8540, e-mail: [paul.tran@fda.hhs.gov](mailto:paul.tran@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512536.

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 December 7, 2010, the committee will discuss the safety and efficacy of new drug application (NDA) 20-0063, proposed tradename CONTRAVE (naltrexone HCl/bupropion HCl) extended-release tablets, manufactured by Orexigen Therapeutics, Inc., for the treatment of obesity and weight management, including weight loss and maintenance of weight loss in patients with an initial body mass index (BMI) of equal to or greater than 30 kilograms (kg) per square meter, or a BMI equal to or greater than 27 kg per square meter with one or more risk factors (e.g. diabetes, dyslipidemia, or hypertension). The BMI is a measure of body weight (mass) based on a person's weight and height, and is a widely-used tool for doctors in assessing optimum weights for a patient.

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 November 22, 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 November 12, 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 November 15, 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