DATES: *Public Comment Period:* Comments must be received by December 20, 2010.

ADDRESSES: Written comments may be submitted to the NIOSH Docket Office, identified by Docket Number NIOSH–220, by any of the following methods:

- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.
- *Facsimile:* (513) 533–8285.
- *E-mail: nioshdocket@cdc.gov.*

All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, 4676 Columbia Parkway, Room 111, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH web page at *http://www.cdc.gov/niosh/docket,* and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided. All electronic comments should be formatted as Microsoft Word. Please make reference to Docket Number NIOSH–220.

FOR FURTHER INFORMATION CONTACT: Stanley A. Shulman, PhD., telephone (513) 841–4258, e-mail *mailto: sas2@cdc.gov,* or Amy Feng, M.S., telephone (513) 841–4128, e-mail *haf0@cdc.gov,* NIOSH, MS–R3, 4676 Columbia Parkway, Cincinnati, OH 45226.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2010–26221 Filed 10–18–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0234]

Determination That BUSPAR (Buspirone Hydrochloride) Tablets, 10 Milligrams, 15 Milligrams, and 30 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that BUSPAR (buspirone hydrochloride) Tablets, 10 milligrams (mg), 15 mg, and 30 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6237, Silver Spring, MD 20993–0002, 301–796–3543.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug. Under § 314.161(a)(2), FDA must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, are the subject of NDA 18–731, held by Bristol-Myers Squibb, and initially approved on September 29, 1986 (10 mg strength), and April 22, 1996 (15 mg and 30 mg strengths). BUSPAR is indicated for the management of anxiety disorders or the short-term relief of the symptoms of anxiety. BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, are currently listed in the "Discontinued Drug Product List" section of the Orange Book. There are approved ANDAs for buspirone hydrochloride tablets, 10 mg, 15 mg, and 30 mg; these ANDAs are listed in the Orange Book and, following the discontinuation of BUSPAR, one of them was designated as the reference listed drug to which new ANDAs should refer.

Lachman Consultant Services, Inc., submitted a citizen petition dated May 4, 2010 (Docket No. FDA–2010–P–0234), under 21 CFR 10.30, requesting that the agency determine whether BUSPAR (buspirone hydrochloride) Tablets, 15 mg and 30 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 10 mg strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing agency records, FDA has determined under § 314.161 that BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of BUSPAR (buspirone hydrochloride) Tablets, 10 mg, 15 mg, and 30 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was

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.*

(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* 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* 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* 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 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.