

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

[Docket No. FDA-2004-P-0474] (formerly Docket No. 2004P-0262)

## Withdrawal of Approval of 128 Suitability Petitions; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 23, 2007 (72 FR 8184). The notice announced that FDA was withdrawing approval of 128 suitability petitions in accordance with the Pediatric Research Equity Act of 2003 (PREA). FDA has determined that approval of the suitability petition submitted by Roxane Laboratories, Inc. (Roxane), for lorazepam oral solution, 1 milligram (mg)/10 milliliters (mL) (Docket No. FDA-1994-P-0017),<sup>1</sup> should not have been withdrawn and therefore retroactively reinstates its approval of that petition. This document also corrects errors in the petition numbers for two of the suitability petitions listed in the notice.

**FOR FURTHER INFORMATION CONTACT:** Cecelia M. Parise, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5845.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 23, 2007 (72 FR 8184), FDA announced that it was withdrawing approval of 128 suitability petitions in accordance with PREA. Prior to PREA's enactment, FDA had approved these suitability petitions to permit abbreviated new drug applications (ANDAs) to be submitted for drugs that had a different active ingredient, dosage form, or route of administration than their reference listed drugs. In the notice, FDA explained that the approval of these suitability petitions was being withdrawn because ANDAs were never submitted and PREA requires that all applications submitted on or after April 1, 1999, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration contain an assessment of the safety and effectiveness of the drug

for the claimed indications in relevant pediatric subpopulations unless the requirement is waived or deferred. Thus, these suitability petitions no longer satisfied the conditions for approval. The notice became effective on March 26, 2007.

In response to the notice, Roxane sent FDA a letter dated March 1, 2007, regarding the withdrawal of approval of its suitability petition for lorazepam oral solution, 1 mg/10 mL (Docket No. FDA-1994-P-0017). Roxane stated that it submitted ANDA 74-648 for lorazepam oral solution, 1 mg/10 mL, on the basis of the approval of its suitability petition for lorazepam oral solution, 1 mg/10 mL (Docket No. FDA-1994-P-0017). Roxane also stated that during the review of the ANDA, they were asked to change the name of the product to lorazepam oral solution, 0.5 mg/5 mL, and the ANDA was approved on March 18, 1997. FDA has reviewed its records and determined that ANDA 74-648 was submitted under suitability petition no. 94P-0199/CP1 before April 1, 1999; therefore, approval of this suitability petition should not have been withdrawn. This document corrects the error and retroactively reinstates approval of the suitability petition for lorazepam oral solution, 1 mg/10 mL (Docket No. FDA-1994-P-0017).

In addition, FDA has determined that the notice contained incorrect petition numbers for two of the suitability petitions. This document corrects those errors.

In FR Doc. E7-3043, appearing on page 8184 in the **Federal Register** of Friday, February 23, 2007, the following corrections are made:

1. On page 8185, in the table, in the first column, for Petition No., "85P-0095/CP1" is corrected to read "83N-0095/CP1".

2. On page 8187, in the table, in the first column, for Petition No., "92P-0332/CP1" is corrected to read "92P-0232/CP1".

3. On page 8187, in the table, in the first column, for Petition No., "94P-0199/CP1" is deleted.

Dated: September 29, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8-23721 Filed 10-6-08; 8:45 am]

**BILLING CODE 4160-01-S**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Indian Health Service

## Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children, OPM-306

### Correction

In notice document E8-22359 beginning on page 55122 in the issue of Wednesday, September 24, 2008, make the following corrections:

1. On page 55122, in the third column, in the second full paragraph, in the 12th line "IRS" should read "IHS".

2. On page 55123, in the first column, in the third full paragraph, seven lines from the bottom "IRS" should read "IHS".

[FR Doc. Z8-22359 Filed 10-6-08; 8:45 am]

**BILLING CODE 1505-01-D**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## National Institutes of Health

## Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 23, 2008, 8 a.m. to October 24, 2008, 5 p.m., Holiday Inn Express Hotel and Suites, San Francisco Fisherman's Wharf, 550 North Point Street, San Francisco, CA, 94133 which was published in the **Federal Register** on September 19, 2008, 73 FR 54408-54411.

The meeting will be held October 22, 2008, 6 p.m. to October 23, 2008, 8 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: September 30, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-23594 Filed 10-6-08; 8:45 am]

**BILLING CODE 4140-01-M**

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## National Institutes of Health

## Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

<sup>1</sup> This citizen petition was originally assigned docket number 94P-0199. The number was changed to FDA-1994-P-0017 as a result of FDA's transition to its new docketing system (<http://www.Regulations.gov>) in January 2008.

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 552bcX4) 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:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Imaging Pain.

*Date:* October 22, 2008.

*Time:* 1 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Daniel R. Kenshalo, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, 301-435-1255, [kenshalod@csr.nih.gov](mailto:kenshalod@csr.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:* Center for Scientific Review Special Emphasis Panel; EPIC Member Conflict Panel.

*Date:* October 23, 2008.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Scott Osborne, MPH, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892, (301) 435-1782, [osbornes@csi.nih.gov](mailto:osbornes@csi.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:* Center for Scientific Review Special Emphasis Panel; Member Conflicts in Psychopathology, Stress and Regulation.

*Date:* October 28–29, 2008.

*Time:* 8 a.m. to 11 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Cheri Wiggs, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3180, MSC 7848, Bethesda, MD 20892, (301) 435-1261, [wiggsc@csr.nih.gov](mailto:wiggsc@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; F05 Fellowships.

*Date:* November 2–3, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Catamaran Resort Hotel, 3999 Mission Boulevard, San Diego, CA 92109.

*Contact Person:* Alessandra M. Bini, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301-435-1024, [binia@csr.nih.gov](mailto:binia@csr.nih.gov).

*Name of Committee:* AIDS and Related Research Integrated Review Group; Behavioral and Social Science Approaches to Preventing HIV/AIDS Study Section.

*Date:* November 6–7, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* The Fairmont Washington, DC, 2400 M Street, NW., Washington, DC 20037.

*Contact Person:* Jose H. Guerrier, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, 301-435-1137, [guerriej@csr.nih.gov](mailto:guerriej@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Rehabilitation Sciences.

*Date:* November 6–7, 2008.

*Time:* 8 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Mayflower Park Hotel, 405 Olive Way Seattle, WA 98101.

*Contact Person:* Jo Pelham, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, MSC 7814, Bethesda, MD 20892, (301) 435-1786, [pelhamj@csr.nih.gov](mailto:pelhamj@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Cognition, Language, and Perception Fellowship Study Section.

*Date:* November 7, 2008.

*Time:* 8:30 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

*Contact Person:* Maribeth Champoux, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3170, MSC 7848, Bethesda, MD 20892, 301 594-3163, [champoum@csr.nih.gov](mailto:champoum@csr.nih.gov).

*Name of Committee:* AIDS and Related Research Integrated Review Group, AIDS Discovery and Development of Therapeutics, Study Section.

*Date:* November 10, 2008.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

*Contact Person:* Shiv A. Prasad, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220,

MSC 7852, Bethesda, MD 20892, 301-443-5779, [prasads@csr.nih.gov](mailto:prasads@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Genetics of Filamentous Fungi.

*Date:* November 12–13, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Michael K. Schmidt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2214, MSC 7890, Bethesda, MD 20892, (301) 435-1147, [mschmidt@mail.nih.gov](mailto:mschmidt@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Diversity Program.

*Date:* November 12, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Bonnie L. Burgess-Beusse, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2191C, MSC 7818, Bethesda, MD 20892, 301-435-1783, [beusseb@mail.nih.gov](mailto:beusseb@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Program Project: Risk, Dementia, and Aging.

*Date:* November 12, 2008.

*Time:* 9 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Maribeth Champoux, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3146, MSC 7759, Bethesda, MD 20892, 301-594-3163, [champoum@csr.nih.gov](mailto:champoum@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Biophysical and Physiological Neuroscience.

*Date:* November 12–13, 2008.

*Time:* 6 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel and Suites, 2033 M Street, NW., Washington, DC 20036.

*Contact Person:* Michael A. Lang, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7850, Bethesda, MD 20892, (301) 435-1265, [langm@csr.nih.gov](mailto:langm@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Risk Prevention and Health Behavior Fellowships.

*Date:* November 13, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Georgetown Suites, 1000 29th Street, NW., Washington, DC 20007.

*Contact Person:* Karen Lechter, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3128, MSC 7759, Bethesda, MD 20892, 301-496-0726, [lechterk@csr.nih.gov](mailto:lechterk@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Diversity Fellowships in Neuroscience.

*Date:* November 13, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Cathy J. Wedeen, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3213, MSC 7808, Bethesda, MD 20892, 301-435-1191, [wedeenc@csr.nih.gov](mailto:wedeenc@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowship: Behavioral Neuroscience (FO2A).

*Date:* November 13-14, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Lombardy Hotel, 2019 I Street, NW., Washington, DC 20006.

*Contact Person:* Aidan Hampson, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7850, Bethesda, MD 20892, (301) 435-0634, [hampsona@csr.nih.gov](mailto:hampsona@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Predoctoral Fellowship to Promote Diversity in Health Related Research (DCPS).

*Date:* November 14, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Georgetown Suites, 1000 29th Street, NW., Washington, DC 20007.

*Contact Person:* Gabriel B. Fosu, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3215, MSC 7808, Bethesda, MD 20892, (301) 435-3562, [fosug@csr.nih.gov](mailto:fosug@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; AIDS International Training and Research Program.

*Date:* November 14, 2008.

*Time:* 8 a.m. to 2:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

*Contact Person:* Manana Sukhareva, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301-435-1116, [sukharem@csr.nih.gov](mailto:sukharem@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Health of the Population SBIR-2.

*Date:* November 14, 2008.

*Time:* 8:30 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Karin F. Helmers, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, 301-435-1017, [helmersk@csr.nih.gov](mailto:helmersk@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Program Project: Aging and Mortality Across Species.

*Date:* November 14, 2008.

*Time:* 9 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Ayres Hotel Manhattan Beach, 14400 Hindry Avenue, Hawthorne, CA 90250.

*Contact Person:* Valerie Durrant, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 435-3554, [durrantv@csr.nih.gov](mailto:durrantv@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 07-143, Pathways Linking Environment, Behaviors and HIV/AIDS.

*Date:* November 14, 2008.

*Time:* 11 a.m. to 2 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Sandra L. Melnick Seitz, DRPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3028D, MSC 7770, Bethesda, MD 20892, 301-435-1251, [melnicks@csr.nih.gov](mailto:melnicks@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; International Clinical, Operations and Health Services, Research Training Awards for AIDS and TB.

*Date:* November 14, 2008.

*Time:* 3 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.

*Contact Person:* Manana Sukhareva, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301-435-1116, [sukharem@csr.nih.gov](mailto:sukharem@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 30, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-23597 Filed 10-6-08; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HOMELAND SECURITY

### National Protection and Programs Directorate; Submission for Review: US-CERT Incident Reporting

**AGENCY:** National Protection and Programs Directorate, National Cyber Security Division, DHS.

**ACTION:** 30-Day Notice and request for comments.

**SUMMARY:** The Department of Homeland Security (DHS) invites the general public and other federal agencies the opportunity to comment on new information collection request 1670-NEW, US-CERT Incident Reporting. As required by the Paperwork Reduction Act of 1995, (Pub. L. 104-13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104-106), DHS is soliciting comments for this collection. The information collection was previously published in the **Federal Register** on June 11, 2008 at 73 FR 33101 allowing for a 60-day public comment period. No comments were received on this information collection. The purpose of this notice is to allow an additional 30 days for public comments.

**DATES:** Comments are encouraged and will be accepted until November 6, 2008. This process is conducted in accordance with 5 CFR 1320.1.

**ADDRESSES:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for National Protection and Programs Directorate, DHS or sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for National Protection and Programs Directorate, DHS or sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-6974.

**SUPPLEMENTARY INFORMATION:** The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;