

location remains the same. The meeting is closed to the public.

Dated: April 22, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04-9674 Filed 4-28-04; 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 amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

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:* Center for Scientific Review Special Emphasis Panel, Immunotoxins.

*Date:* May 4, 2004.

*Time:* 10 a.m. to 11:30 a.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Marcia Litwack, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6206, MSC 7804, Bethesda, MD 20892. (301) 435-1719; [litwackm@csr.nih.gov](mailto:litwackm@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, NHLBI Competitive Supplements for Human Embryonic Stem Cell Research.

*Date:* May 25, 2004.

*Time:* 8:30 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:* Neelakanta Ravindranath, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5140,

MSC 7843, Bethesda, MD 20892, 301-435-1034; [#ravindm@csr.nih.gov](mailto:#ravindm@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: April 22, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

#### National Toxicology Program (NTP); National Institute of Environmental Health Sciences; The NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) Expert Panel Report on the Developmental and Reproductive Toxicity of Fluoxetine: Notice of Availability and Request for Public Comments

**SUMMARY:** Notice is hereby given of the availability on April 19, 2004, of the Expert Panel Report on the Developmental and Reproductive Toxicity of Fluoxetine. This report includes the summaries and conclusions of the expert panel's evaluation of the scientific data for potential reproductive and/or developmental hazards associated with exposure to fluoxetine. The CERHR held this expert panel meeting March 3-5, 2004. CERHR is seeking public comment on this report and additional information about recent, relevant toxicology or human exposure studies.

#### Availability of Reports

This expert panel report will be available by April 19, 2004 on the CERHR Web site (<http://cerhr.niehs.nih.gov>) and in printed copy or compact disc by contacting the CERHR [P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709; telephone: (919) 541-3455; fax: (919) 316-4511; or e-mail: [shelby@niehs.nih.gov](mailto:shelby@niehs.nih.gov)].

#### Request for Public Comments

The CERHR invites public comments on this expert panel report and input regarding any recent, relevant toxicology or human exposure studies. The CERHR requests that all comments and other information be submitted to the CERHR at the address above by June 17, 2004.

All public comments received by the date above will be reviewed and included in the final NTP-CERHR monograph on fluoxetine to be prepared by NTP staff. The NTP-CERHR monograph will include the NTP brief, expert panel report, and all public comments received on the report. The brief will provide the NTP's interpretation of the potential for adverse reproductive and/or developmental effects to humans from exposure to fluoxetine. The NTP-CERHR monograph will be sent to appropriate federal agencies and will be available to the public and the scientific community on the CERHR web site, in hardcopy, or on compact disk.

#### Background

Fluoxetine hydrochloride (Prozac®; Sarafem™), an antidepressant, is a widely prescribed drug in the United States. The CERHR selected fluoxetine for evaluation because of (1) sufficient reproductive and developmental studies, (2) sufficient human exposure information, (3) changing prescription patterns, and (4) public concern about potential reproductive and/or developmental hazards associated with exposure. Fluoxetine hydrochloride, under the name Sarafem™, is prescribed to treat premenstrual dysphoric disorder (PMDD), potentially increasing the number of exposures for women of childbearing age. Furthermore, the Food and Drug Administration recently approved Prozac® for use in 7-17 year-olds thereby increasing exposures of children.

A 12-member expert panel composed of scientists from the federal government, universities, and private companies conducted an evaluation of the reproductive and developmental toxicities of fluoxetine hydrochloride (**Federal Register** Vol. 68, No. 216, pages 63122-63123, November 2003). Public deliberations by the panel took place March 3-5, 2004, at the Holiday Inn Old Town Select in Alexandria, Virginia. Following the March meeting, the draft expert panel report was revised to incorporate the panel's conclusions and subsequently reviewed by Fluoxetine Expert Panel, NTP scientists, and CERHR personnel.

#### Additional Information About CERHR

The NTP and the NIEHS established the NTP CERHR in June 1998 (**Federal Register** Vol. 63, No. 239, page 68782, December 1998). The purpose of the CERHR is to provide scientifically based, uniform assessments of the potential for adverse effects on reproduction and development caused