

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the invention embodied in:

(1) U.S. Patent No. 6,194,390, issued Feb. 27, 2001, entitled "Procedure to block the replication of reverse transcriptase dependent viruses by the use of inhibitors of deoxynucleotides synthesis" (E-157-1993/7);

(2) U.S. Patent No. 6,046,175, issued April 4, 2000, entitled "Procedure to block the replication of reverse transcriptase dependent viruses by the use of inhibitors of deoxynucleotides synthesis" (E-157-1993/1);

(3) U.S. Patent No. 6,093,702, issued July 25, 2000, entitled "Mixtures of dideoxynucleosides and hydroxycarbamide for inhibiting retroviral spread" (E-157-1993/4);

(4) U.S. Patent No. 5,736,526, issued April 7, 1998, entitled "Mixtures of DDI and D4T with hydroxycarbamide for inhibiting retroviral replication" (E-157-1993/5);

(5) U.S. Patent No. 5,521,161, issued May 28, 1996, entitled "Method of treating HIV in humans by administration of ddI and hydroxycarbamide" (E-157-1993/2);

(6) U.S. Patent No. 5,736,527, issued April 08, 1998, entitled "Method of treating HIV in humans by administration of ddI and hydroxycarbamide" (E-157-1993/6);

(7) PCT/US94/05515 filed May 17, 1994, entitled "Procedure to block the replication of reverse transcriptase dependent viruses by the use of inhibitors of deoxynucleotides synthesis" (E-157-1993/1), National Stage filed May 17, 1994: in Canada application No. 2163456, in EPO application No. 94918016.0, in Japan application No. 518466/94, in Australia Patent No. 685128, issued April 30, 1998;

(8) PCT/US95/00153 filed Dec. 20, 1994, entitled "Method of treating HIV in humans by administration of ddI and hydroxycarbamide" (E-157-1993/2), National Stage filed Dec. 20, 1994: in Canada Patent No. 2179627, issued Feb. 22, 2000, in EPO Patent No. 0735890, issued April 17, 2002, in South Africa Patent No. 94/9219, issued Oct. 25, 1995, in Taiwan Patent No. NI-080011, issued Dec. 03, 1996, in Australia Patent No. 718325, issued July 27, 2000, OAIPO Patent Application No. 60849, in Brazil patent application No. PI1100041-4, in Mexico patent

application No. 9409706 to Research Institute for Genetic and Human Therapy (RIGHT), having a place of business in Washington, DC. The patent rights in these inventions have been assigned to the United States of America.

**DATES:** Only written comments and/or application for a license, which are received by the NIH Office of Technology Transfer on or before June 17, 2003 will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Sally Hu, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; E-mail: [hush@od.nih.gov](mailto:hush@od.nih.gov); Telephone: (301) 435-5606; Facsimile: (301) 402-0220.

**SUPPLEMENTARY INFORMATION:** The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The subject inventions provide for formulations and methods for inhibiting replication of reverse transcription dependent viruses in animals cells comprising administering a compound that depletes the intracellular pool of deoxyribonucleoside phosphate (e.g. hydroxyurea), and further comprising administering a compound that serves to inhibit replication of the virus by terminating DNA chain elongation (e.g. DDI).

The field of use may be limited to development of drugs of hydroxyurea alone and in combination with dNTP competitors for blocking reverse transcriptase dependent viruses, including HIV.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 10, 2003.

**Steven M. Ferguson,**

*Acting Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

[FR Doc. 03-9546 Filed 4-17-03; 8:45 am]

**BILLING CODE 4140-01-P**

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

### **Public Health Service**

#### **National Toxicology Program**

The National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) Announces the Future Evaluations of Fluoxetine Hydrochloride (Prozac®; Sarafem™, CAS RN 54910-89-3) and Acrylamide (CAS RN 79-06-1), Requests Public Comments on These Chemicals, and Solicits the Nominations of Scientists Qualified to Serve on Expert Panels Evaluating Fluoxetine Hydrochloride and Acrylamide.

**Summary:** The CERHR plans to conduct an expert panel evaluation of fluoxetine hydrochloride and a separate expert panel evaluation of acrylamide. The exact dates for these expert panel meetings are not yet set, but the meetings are tentatively planned for 2003 and early 2004. Fluoxetine hydrochloride will be evaluated first. Additional details about the meetings, including the dates and locations, will be published in future **Federal Register** notices and posted on the NTP Web site (<http://ntp-server.niehs.nih.gov>).

The CERHR will convene expert panels to evaluate the reproductive and developmental toxicities of fluoxetine hydrochloride and acrylamide. For each of these meetings, the expert panel will consist of approximately 12 scientists, selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other relevant areas of science. The expert panel meetings will be open to the public with time scheduled for oral public comment.

#### **Evaluation of Fluoxetine Hydrochloride**

Fluoxetine hydrochloride (Prozac®; Sarafem™; CAS RN 54910-89-3), an antidepressant, is a widely prescribed drug in the United States. The CERHR selected fluoxetine hydrochloride for evaluation because of (1) numerous reproductive and developmental studies in laboratory animals and humans, (2) human exposure information, and (3) changing prescription patterns. Fluoxetine hydrochloride, under the name Sarafem™, is now being

prescribed to treat premenstrual dysphoric disorder (PMDD), potentially increasing the number of exposures for women of childbearing age. Further, FDA recently approved Sarafem™ for use in 7–17-year-olds thereby increasing exposures of children. CERHR anticipates holding the expert panel evaluation in late 2003.

#### Evaluation of Acrylamide

Acrylamide (CAS RN 79–06–1) is used in the production of polyacrylamide, which is used in water treatment, pulp and paper production, and mineral processing. It is used in the synthesis of dyes, adhesives, contact lenses, soil conditioners, and permanent press fabrics and in molecular biology procedures such as electrophoresis. Acrylamide is a neurotoxicant and in animal studies has been shown to be a carcinogen, germ cell mutagen, and reproductive toxicant. The CERHR selected acrylamide for expert panel evaluation because of recent public concern for human exposures through its presence in starchy foods treated at high temperatures, *e.g.*, french fries and potato chips. In addition, recent data are available on occupational exposure, bioavailability, and reproductive toxicity. It is anticipated that the expert panel evaluation on acrylamide will occur in 2004.

#### Request for Public Input

The CERHR invites input from the public and other interested parties on fluoxetine hydrochloride and acrylamide, including toxicology information from completed and ongoing studies, information on planned studies, and information about current production levels, human exposure, use patterns, and environmental occurrence. Information and comments should be forwarded to the CERHR at P.O. Box 12233, MD EC–32, Research Triangle Park, NC 27709 (mail), (919) 541–3455 (phone), (919) 316–4511 (fax), or [shelby@niehs.nih.gov](mailto:shelby@niehs.nih.gov) (e-mail). Information and comments received by July 17, 2003 will be made available to the CERHR staff and the expert panel for consideration in the evaluation and posted on the CERHR Web site.

The CERHR also invites nominations of qualified scientists to serve on the expert panel for the fluoxetine hydrochloride evaluation and the acrylamide evaluation. Panelists are primarily drawn from the CERHR Expert Registry and/or the nomination of other scientists who meet the criteria for listing in that registry that include: formal academic training and experience in a relevant scientific field,

publications in peer-reviewed journals, membership in relevant professional societies, certification by an appropriate scientific board or other entities, and participation in similar committee activities. All panel members serve as individual experts in their specific areas of expertise and not as representatives of their employers or other organizations. Scientists on the expert panel will be selected to represent a wide range of expertise, including developmental toxicology, reproductive toxicology, epidemiology, general toxicology, pharmacokinetics, exposure assessment, and biostatistics. Nominations received by July 17, 2003 will be considered for the fluoxetine hydrochloride and acrylamide panels and for inclusion in the CERHR Expert Registry. Nominations should be forwarded to the CERHR at the address given above.

#### Background Information About the CERHR

The NTP established the NTP CERHR in June 1998 (**Federal Register**, December 14, 1998 (Volume 63, Number 239, page 68782)). The CERHR is a publicly accessible resource for information about adverse reproductive and/or developmental health effects associated with exposure to environmental and/or occupational exposures. Expert panels conduct scientific evaluations of agents selected by the CERHR in public forums.

Information about CERHR and its process for nominating agents for review or scientists for its expert registry can be obtained from its Home page (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (contact information provided above). The CERHR selects chemicals for evaluation based upon several factors, including production volume, extent of human exposure, public concern, and published evidence of reproductive or developmental toxicity.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process was published in the **Federal Register** notice July 16, 2001 (Volume 66, Number 136, pages 37047–37048) and is available on the CERHR Web site under “About CERHR” or in printed copy from the CERHR.

Dated: April 9, 2003.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

[FR Doc. 03–9545 Filed 4–17–03; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[CGD08–03–016]

### Lower Mississippi River Waterway Safety Advisory Committee

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The Lower Mississippi River Waterway Safety Advisory Committee (LMRWSAC) will meet to discuss various issues relating to navigational safety on the Lower Mississippi River and related waterways. The meeting will be open to the public.

**DATES:** The next meeting of LMRWSAC will be held on Tuesday, May 6, 2003, from 9 a.m. to 12 p.m. This meeting may adjourn early if all business is finished. Requests to make oral presentations or submit written materials for distribution at the meeting should reach the Coast Guard on or before April 30, 2003. Requests to have a copy of your material distributed to each member of the committee in advance of the meeting should reach the Coast Guard on or before April 25, 2003.

**ADDRESSES:** The meeting will be held in the Crescent City Room Suite 1830 at the World Trade Center Building, 2 Canal Street, New Orleans, Louisiana. This notice is available on the Internet at <http://dms.dot.gov>.

#### FOR FURTHER INFORMATION CONTACT:

LTJG Matt Dooris, Committee Administrator, telephone (504) 589–4251, Fax (504) 589–4241.

Written materials and requests to make presentations should be mailed to Commanding Officer, Marine Safety Office New Orleans, Attn: LTJG Dooris, 1615 Poydras Street, New Orleans, LA 70112.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

#### Agenda of Meeting

*Lower Mississippi River Waterway Safety Advisory Committee (LMRWSAC).* The agenda includes the following:

- (1) Introduction of committee members.
- (2) Remarks by CAPT R. W. Branch, Executive Director.
- (3) Approval of the November 12, 2002 minutes.
- (4) Old Business:
  - (a) Captain of the Port status report.
  - (b) VTS update report.
  - (c) PORTS update report.