

Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, (301) 435-1024, rodewalr@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, Leukemia.

Date: April 22 2004.

Time: 1 p.m. to 2:30 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: Marcia Litwack, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6206, MSC 7840, Bethesda, MD 20892, (301) 435-1719, litwackm@csr.nih.gov.

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(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 6, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04-8283 Filed 4-12-04; 8:45 am]

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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 plans for future evaluations of Methylphenidate and Adderall®, Magnesium Sulfate, and Genistein and Soy Formula; Requests public comments on these substances; and solicits the nominations of scientists qualified to serve on expert panels evaluating these compounds.

Summary

The CERHR plans to convene 3 expert panels to evaluate potential reproductive and developmental toxicities of (1) methylphenidate (Ritalin®) and Adderall®, (2) magnesium sulfate, and (3) genistein and soy formula. For each evaluation, 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 CERHR invites the submission of public comments on any of these substances and the nomination of scientists to serve on the expert panels for their evaluation (see below). These meetings are tentatively scheduled for 2004 and 2005 although the exact dates and locations are not yet established. As plans are finalized, they will be announced in the **Federal Register** and posted on the NTP Web site (<http://ntp-server.niehs.nih.gov>). These expert panel meetings will be open to the public with time scheduled for oral public comment.

Evaluation of Methylphenidate and Adderall®

Methylphenidate (Ritalin®, CAS RN: 113-45-1) and Adderall® (amphetamine, CASRN: 300-62-9 and dextroamphetamine, CASRN: 51-64-9) are stimulants used to treat attention deficit disorder with hyperactivity and narcolepsy in children and adults. Methylphenidate is also used off-label to treat depression. CERHR selected these chemicals for expert panel evaluation because of: (1) The increasing use of these drugs in children, (2) public concern for long-term effects of these drugs on child development and behavior, (3) the availability of human exposure data, and (4) findings from developmental studies in humans and experimental animals.

Evaluation of Magnesium Sulfate

Magnesium sulfate (CASRN: 7487-88-9) is the most common magnesium salt used for seizure prophylaxis in preeclampsia or seizure control in eclampsia, and for inhibition of uterine contractions during preterm labor. CERHR selected this chemical for expert panel evaluation because of: (1) The existence of an adequate exposure database, (2) concern for the survival and development of the infant after maternal treatment, and (3) the availability of developmental toxicity data.

Evaluation of Genistein and Soy Formula

Genistein (CASRN: 446-72-0) is found in some legumes, such as soybeans and clover, or in products obtained from animals ingesting genistein-containing feed. Genistein is a phytoestrogen, defined as a non-steroidal, estrogenic, naturally occurring plant product. It is found in food, in over-the-counter dietary supplements, and is the primary phytoestrogen in soy formula. Soy formula is administered to infants as a supplement or replacement

for maternal breast milk or cow's milk. CERHR selected these substances for expert panel evaluation because of: (1) The availability of numerous reproductive and developmental studies in laboratory animals and humans, (2) exposure information in infants and women of reproductive age, and (3) public concern for effects on infant or child development.

Request for Public Comment on Substances To Be Evaluated

The CERHR invites input from the public and other interested parties on these substances, 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 (e-mail). Information and comments received by 60 days from the publication date of this notice will be made available to the CERHR staff and the appropriate expert panel for consideration in the evaluation and posted on the CERHR Web site.

Request for the Nomination of Scientists for the Expert Panels

The CERHR invites nominations of qualified scientists to serve on the individual expert panels for: (1) Methylphenidate and Adderall®, (2) magnesium sulfate, and (3) genistein and soy formula. 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, but not limited to, developmental toxicology, reproductive toxicology, neonatology and child development, epidemiology, general toxicology, pharmacokinetics, exposure assessment, and biostatistics. Nominations received by 60 days from the publication date of

this notice will be considered for these panels and for inclusion in the CERHR Expert Registry. Nominations, including contact information and a current curriculum vitae (if possible) should be forwarded to the CERHR at the address given above.

Background Information About the CERHR

The NTP established the 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 homepage (<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 (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 1, 2004.

Kenneth Olden,

Director, National Institute of Environmental Health Sciences.

[FR Doc. 04–8269 Filed 4–12–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed

projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Outcomes Performance Assessment of the Collaborative Initiative to Help End Chronic Homelessness—(OMB No. 0930–0247; Extension, no change)—This Initiative is coordinated by the U.S. Interagency Council on the Homeless and involves the participation of three Council members: the Department of Housing and Urban Development (HUD), the Department of Health and Human Services (HHS), and the Department of Veterans Affairs (VA). Within HHS, SAMHSA's Center for Mental Health Services is the lead agency.

This project will monitor the implementation and effectiveness of the Initiative. A national assessment of client outcomes is needed to assure a high level of accountability and to identify which models work best for which people, using the same methods for all sites. To this end, this project will provide a site-by-site description of program implementation, as well as descriptive information on clients served; services received; housing quality, stability, and satisfaction; and client outcomes in health and functional domains. The VA Northeast Program Evaluation Center (NEPEC), based at the VA Connecticut Healthcare System in West Haven, Connecticut, is responsible for conducting this project.

Data collection will be conducted over a 36-month period. At each site, a series of measures will be used to assess (1) program implementation (e.g., number and types of housing units produced and intensity and types of treatment and supportive services provided), (2) client descriptive information (e.g., demographic and clinical characteristics, and housing and treatment services received) and, (3) client outcomes.

Client outcomes will be measured using a series of structured instruments administered by evaluation personnel employed and funded by the local VA medical center or outpatient clinic involved at each Initiative site who will work closely with central NEPEC staff. Assessments will be conducted through face-to-face interviews and, when needed, telephone interviews. Interviews (approximately one hour in length) will be conducted at baseline, defined as the date of entry into the clinical treatment program leading to placement into permanent housing, and quarterly (every 3 months) thereafter for up to three years. Discharge data will be collected from program staff at the time of official discharge from the program, or when the client has not had any clinical contact from members of the program staff for at least 6 months. In addition to client interviews, key informant interviews with program managers at each site will be conducted annually.

At most Initiative sites, it is expected that more people will be screened and or evaluated for participation in the program than receive the full range of core housing and treatment services. Entry into the Initiative is conceptualized as a two-phase process involving an Outreach/Screening/Assessment Phase (Phase I), and an Active Housing Placement/Treatment Phase (Phase II) that is expected to lead to exit from homelessness; in some programs these two phases may be described as the Outreach and Case Management Phases. It will be important to have at least some minimal information on all clients so as to be able to compare those who enter Housing/Treatment with those who do not.

Client-level data at the time of first contact with the program (i.e., before the client receives more intensive treatment or housing services) will be collected using a screener form. The screener form will be completed by a member of the clinical staff when prospective clients are first told about the program, and express interest in participating in the program (i.e. when they enter Phase I). The purpose of this form is to identify the sampling frame of the evaluation at each site, or the pool of potential clients from which clients are then selected. Program implementation will be measured using a series of progress summaries.

Initiative sites will be responsible for screening potential participants, assessing homeless and disabling condition eligibility criteria for the program, and documenting eligibility as part of the national performance