

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887, hamelinc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 13-213; Outcome Measures for Use in Treatment Trials for Individuals with Intellectual and Developmental Disabilities (R01).

Date: October 18, 2013.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435-4445, doussarj@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 13-008 Robotic Bioanalytical Shared Instrumentation.

Date: October 18, 2013.

Time: 2:00 p.m. to 5:00 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: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5181, MSC 7804, Bethesda, MD 20892, belangerm@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 18, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information: The National Toxicology Program Requests Information on Use, Human Exposure, and Toxicity of Vinpocetine

SUMMARY: To facilitate the design of toxicological studies for vinpocetine (CAS RN: 42971-09-5), the National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences (NIEHS) requests the submission of available information regarding (1) exposure, pharmacokinetics, toxicity, safety, or

efficacy in humans; (2) production, use, and consumption patterns in the United States; (3) genotoxicity, repeated dose toxicity, prenatal developmental toxicity, reproductive toxicity, chronic toxicity, and carcinogenicity studies in experimental animals; and (4) any other information relative to the safety or toxicity of vinpocetine not listed above.

DATES: The deadline for receipt of information is November 4, 2013.

ADDRESSES: Submission of information via email to surhi@niehs.nih.gov is preferred.

FOR FURTHER INFORMATION CONTACT: Dr. Inok Surh, Research Fellow, Toxicology Branch, Division of the NTP, NIH/NIEHS, P.O. Box 12233, MD K2-12, Research Triangle Park, NC 27709. Phone: (919) 541-3862, Fax: (919) 541-4255, Email: surhi@niehs.nih.gov. Hand Delivery/Courier: 530 Davis Drive, Room 2067, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background: The National Cancer Institute nominated the dietary supplement vincamine to the NTP for genotoxicity, subchronic toxicity, and mechanistic studies due to a lack of information on its potential toxicity following long-term administration (<http://ntp.niehs.nih.gov/go/1123>). Currently, vincamine appears to be infrequently marketed in the United States, while vinpocetine, a semi-synthetic derivative of vincamine, is widely available as a dietary supplement. In a review of the available literature, the NTP found that published data on genotoxicity, carcinogenicity, and reproductive and developmental toxicity for vinpocetine are very limited (http://ntp.niehs.nih.gov/ntp/htdocs/Chem_Background/ExSumPdf/Vinpocetine091613_508.pdf). To address the lack of data and potential widespread exposure, the NTP is developing a research program for toxicological characterization of vinpocetine.

Request for Information: The NTP seeks to identify relevant information on the use, human exposure, and toxicity of vinpocetine in humans and experimental animal models. In particular, information is sought from unpublished or ongoing research studies or other sources not readily available. Any information provided by respondents will be used to supplement information the NTP has already gathered, and will be considered during the design of one or more types of experimental toxicology studies of vinpocetine. Specifically, the NTP requests the submission of information regarding:

(1) Exposure, pharmacokinetics, toxicity, safety, or efficacy of vinpocetine in humans. (2) Production, use, and consumption patterns of vinpocetine in the United States. (3) Genotoxicity, repeated dose toxicity, prenatal developmental toxicity, reproductive toxicity, chronic toxicity, and carcinogenicity studies of vinpocetine in experimental animals. (4) Any other information relative to the safety or toxicity of vinpocetine not listed above.

Responses are requested from all interested parties, such as the research community, health professionals, educators, policy makers, industry, and the public. Responses to this request for information are voluntary. The NTP does not intend to publish a summary of responses received or any other information provided. Despite this, no proprietary, classified, confidential, or sensitive information should be included in your response. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information. Persons submitting information should include their name, affiliation, mailing address, phone, fax, email address, and sponsoring organization (if any) with the submission. The deadline for receipt of the requested information is November 4, 2013.

Background Information on the NTP: The NTP is an interagency program established in 1978 (43 FR 53060) to strengthen the Department's activities in toxicology research and testing, and develop and validate new and better testing methods. Other activities of the program focus on strengthening the science base in toxicology and providing information about potentially toxic chemicals to health regulatory and research agencies, scientific and medical communities, and the public. The NTP is located administratively at the NIEHS. Information about the NTP and NIEHS is found at <http://www.niehs.nih.gov> and <http://ntp.niehs.nih.gov>, respectively.

Dated: September 18, 2013.

John R. Bucher,

Associate Director, National Toxicology Program.

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