

Date: July 13, 1999.

Time: 2:00 pm to 3:00 pm.

Agenda: To review and evaluate grant application.

Place: NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Eugene Zimmerman, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, 301-435-1220, zimmerng@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, Bioengineering Partnerships Special Emphasis Panel.

Date: July 14, 1999.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Hotel, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: David T. George, National Heart Lung and Blood Institute, Review Branch, 6701 Rockledge Drive, Room 7188, Bethesda, MD 20892, (301) 435-0280, georged@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 ZRG1-BDCN-6 (02)B.

Date: July 14, 1999

Time: 8:30 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Chevy Chase Holiday Inn, Chevy Chase, MD 20815.

Contact Person: Jay Cinque, Phd, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435-1252.

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.

Date: July 14, 1999.

Time: 9:00 am to 5:00 pm.

Agenda: To review and evaluate applications.

Place: Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Camil C. Debbas, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7844, Bethesda, MD 20892, (301) 435-1018.

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.

Date: July 14, 1999.

Time: 2:00 pm to 2:30 pm.

Agenda: To review and evaluate grant applications.

Place: NIH, Rockledge, MD 20892, (Telephone Conference Call).

Contact Person: Everett E. Sinnett, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7844, Bethesda, MD 20892, (301) 435-1016. ev\_sinnett@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 PSV.

Date: July 14-16, 1999.

Time: 7:00 pm to 1:00 am.

Agenda: to review and evaluate grant applications.

Place: Houston Marriott Medical Center, 6580 Fannin Street, Houston, TX 77030.

Contact Person: Arnold Revzin, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7806, Bethesda, MD 20892, (301) 435-1153.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 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: June 30, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 99-17228 Filed 7-6-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

**National Institute of Environmental Health Sciences; National Toxicology Program; Request for Comments on Chemicals Nominated to the National Toxicology Program (NTP) for Toxicological Studies—Recommendations by the Interagency Committee for Chemical Evaluation and Coordination (ICCEC) for Study, No Studies, or Deferral To Obtain Additional Information**

### Summary

The National Toxicology Program (NTP) routinely solicits, accepts and reviews for consideration nominations from Federal agencies, industry, the public, and other interested parties for toxicological studies to be undertaken by the Program. Nominations undergo several levels of review before toxicological studies are designed and implemented. The Interagency Committee for Chemical Evaluation and Coordination (ICCEC) serves as the first

level of review for NTP nominations. At the June 1, 1999 meeting of the ICCEC, 13 nominations were reviewed. As part of an effort to earlier inform the public and obtain input into the selection of chemicals for evaluation, the NTP routinely seeks public input on (1) chemicals nominated to the Program for toxicological studies, and (2) testing recommendations made by the ICCEC. This announcement outlines the process for nomination and selection of agents for NTP study, presents the recommendations of the ICCEC from the June 1, 1999 meeting, and requests comment on these recommendations or the submission of additional information to be considered in the evaluation of these nominations.

### Background

The nomination and selection for study of chemicals and agents with the highest potential for adversely impacting public health are essential to the success of the NTP. From its inception, the NTP has had an open nomination process. Nominations are solicited from a variety of sources in academia, Federal and State regulatory and health agencies, industry, and unions, as well as from environmental groups and the general public. Particular assistance is sought with the selection of studies that permit testing of hypotheses to enhance the predictive ability of NTP studies, address mechanisms of toxicity, or identify significant gaps in knowledge of the toxicity of chemicals or classes of chemicals. Chemicals are selected for study based upon two broad criteria: (1) those chemicals of greatest concern for public or occupational health and (2) chemicals for which toxicological data is needed to fill major knowledge gaps, address mechanisms of toxicity, and reduce uncertainty in risk assessment by aiding species-to-species extrapolation and understanding dose-response relationships. Chemicals may be studied for a variety of health-related effects, including but not limited to, reproductive and developmental toxicity, genotoxicity, immunotoxicity, metabolism and disposition, as well as carcinogenicity. The possible public health consequences of exposure remain the over-riding factor in the decision to study a particular chemical or agent. Selections for government testing are based on the principle that responsible industries will evaluate their own chemicals or agents for health and environmental effects as mandated by Congress under legislative authorities. Increased efforts continue to be focused on: (1) improving the quality of the nominations of chemicals,

environmental agents, or issues for study; (2) broadening the base and diversity of nominating organizations and individuals; and (3) increasing nominations for endpoints of toxicity other than carcinogenesis.

Nominated chemicals are first reviewed by a multi-disciplinary NIEHS committee to determine whether the nominated agent has undergone adequate toxicological testing or has been previously considered by the NTP. For chemicals not eliminated from consideration or deferred at this stage, the available literature is examined in detail to prepare Toxicological Summaries which evaluate and summarize the relevant data for each chemical. Included in each Toxicological Summary are chemical and physical information, production levels, use and exposure categories and levels, regulatory status, toxicological effects, and rationale for the nomination. The Toxicological Summaries are distributed to the Interagency Committee for Chemical Evaluation and Coordination (ICCEC), composed of representatives from the Agency for Toxic Substances and Disease Registry, Consumer Product Safety Commission, Department of Defense, Environmental Protection Agency, Food and Drug Administration's National Center for Toxicological Research, Occupational Safety and Health Administration, National Cancer Institute, National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, and the National Library of Medicine. ICCEC members are assigned as reviewers for each chemical after consideration of the nature of its uses and exposure so that, to the extent possible, appropriate regulatory concerns will be addressed. Members are requested to identify their agency's interests, if any, in the chemical, and to search databases unique to their agencies for further information on the nominated chemicals and structurally related substances. During the evaluation process, the NTP works actively with regulatory agencies and interest groups to supplement the information about chemicals nominated and to ensure that the chemical selection process meets regulatory agency needs.

At its meeting to consider the nominated chemicals, the ICCEC assigns testing priorities, and also may make recommendations for study in addition to those requested by the nominator.

Summaries of the ICCEC recommendations and any public comments received on these chemicals are then presented to the NTP Board of Scientific Counselors (the Program's external scientific advisory committee) for review and comment in an open public session. The ICCEC recommendations, NTP Board of Scientific Counselors recommendations, and public comments are incorporated into recommendations that are then submitted to the NTP Executive Committee, the Federal interagency policy oversight body. For each chemical nominated for the various types of studies, the NTP Executive Committee reviews and approves action to move forward to test, defer testing, or remove from testing consideration, and recommends testing priorities. The selection of a chemical or agent by the Executive Committee does not automatically commit the NTP to its evaluation. The priority of the chemicals and the proposed studies are assessed during the nomination process and reassessed during the study design process. During any of these stages, a chemical or study may be withdrawn if applicable research data is identified, higher priority studies are identified, or if a study proves impractical. A broad range of regulatory and toxicological concerns are addressed during the nomination and selection process through the participation of representatives from Federal agencies concerned with public health issues. In addition, representatives from non-government organizations, including industry, labor, and public interest, sit on the NTP Board of Scientific Counselors, and thus have input into chemical selection decisions.

Following Executive Committee action, each selected chemical is assigned to an NIEHS, FDA, or NIOSH staff scientist (project leader) who assesses the data compiled during the chemical evaluation process and other information obtained from detailed searches of the published literature and public comments. The project leader also consults with industrial or commercial sources on such issues as mode of production, uses, worker exposure, planned or ongoing testing, and availability of the chemical for study. The project leader together with a study design team develops a study plan to address the research needs. The study plan is reviewed and modified as necessary before being carried out via

the most appropriate mechanisms. Results of toxicological studies of selected chemicals are routinely peer-reviewed. The results are published as NTP Technical Reports and/or in the open scientific literature. Test results are also available from the NTP subsequent to peer-review but prior to publication.

#### **Request for Comment**

At their meeting on June 1, 1999, the ICCEC reviewed 13 agents nominated for NTP study. For 9 of these agents, metabolism, toxicity, or carcinogenicity studies were recommended, no additional study was recommended for 2 chemicals, and studies of 2 other chemicals were deferred pending receipt of additional data from other organizations or from related studies anticipated or in progress by the NTP, or information on production, exposure, and use patterns. Additionally, the ICCEC reviewed 7 chemicals recommended for study in previous ICCEC meetings. Following review of initial NTP studies and additional data received from the public or elsewhere, these 7 chemicals were withdrawn as priority candidates for study.

Chemicals with CAS numbers, nomination source, types of studies under consideration, and rationale and other information are given in the attached tables. Interested parties are encouraged to provide comments or supplementary information on the chemicals and recommendations that appear in this announcement. The Program would welcome receiving toxicology and carcinogenesis information from completed, ongoing, or planned studies, as well as information on current production levels, human exposure, use patterns, or environmental occurrence for any of the chemicals listed in this announcement. To provide comments or information, please contact Dr. William Eastin at the address given below by September 7, 1999.

Contact may be made by mail to: Dr. William Eastin, NIEHS/NTP, P. O. Box 12233, Research Triangle Park, North Carolina 27709; by telephone at (919) 541-7941; by FAX at (919) 541-3687; or by email at [eastin@niehs.nih.gov](mailto:eastin@niehs.nih.gov). The URL for the NTP homepage is <http://ntp-server.niehs.nih.gov>.

Dated: June 24, 1999.

**Samuel H. Wilson,**  
Deputy Director, NIEHS.

## Attachment—Chemicals Nominated to the NTP for Study, and Testing Recommendations made by the ICCEC on June 1, 1999

Chemical [CAS Number]	Nominated by	ICCEC recommendations	Study rationale; other information
<b>Chemicals Recommended for Testing</b>			
Aloe vera gel [8001-97-6] [94349-62-9]	NCI	—Cell transformation assay —Phototoxicity —Tumor promotion in Tg.AC mice	—Widespread use as a dietary supplement and cosmetic. —Inadequate toxicity information.
Ammonium molybdate [12027-67-7] [12054-85-2] [13106-76-8]	NCI	— <i>In vitro</i> chromosome aberration assay — <i>In vitro</i> micronucleus assay —Subchronic toxicity (inhalation studies)	—Representative soluble molybdenum compound. —Potential for worker and general population exposure. —Inadequate toxicity information.
5,6-Benzoflavone [6051-87-2]	NCI	—Toxicological characterization —Reproductive toxicity —Carcinogenicity	—Potential use as chemopreventive agent. —Lack of industry sponsorship. —Testing dependent on confirmation from nominator that recommended studies are needed for further development as therapeutic agent.
1,3-Dichloro-2-butene [926-57-8]	NIEHS	—Toxicological characterization —Metabolism studies —Carcinogenicity (inhalation studies)	—High production industrial chemical with potential for worker exposure. —Structural similarity to known carcinogen. —Inadequate toxicity information.
Ginseng and ginsenosides [50647-08-0]	NCI	—Genotoxicity —Reproductive toxicity —Neurotoxicity —Carcinogenicity	—Widespread use as a dietary supplement. —Inadequate toxicity information. —Subchronic testing will determine if ginseng or a specific ginsenoside will be subject to carcinogenicity testing.
Indole-3-carbinol [700-06-1]	NCI	—Reproductive toxicity —Toxicological characterization —Carcinogenicity	—Widespread and rapidly increasing use as a dietary supplement. —Potential use as chemopreventive agent.
Kava kava extract [9000-38-8] [84696-40-2]	NCI	—Genotoxicity —Reproductive toxicity —Neurotoxicity —Subchronic toxicity —Carcinogenicity	—Widespread use as a dietary supplement. —Reported human toxicity. —Inadequate toxicity information.
Milk thistle extract [84604-20-6]	NCI	—Genotoxicity —Metabolism studies —Reproductive toxicity —Subchronic toxicity	—Widespread use as a dietary supplement. —Reported hepatoprotective and anti-carcinogenic action. —Inadequate toxicity information.
3-Picoline [108-99-6]	NIEHS	—Subchronic toxicity —Carcinogenicity (pending results of subchronic studies)	—High production industrial chemical with potential for worker and general population exposure. —Inadequate toxicity information.
<b>Chemicals for Which No Testing is Recommended</b>			
1-Bromo-3-chloropropane [109-70-6]	NIEHS	—Toxicological characterization —Carcinogenicity	—Available data indicate low toxicity. —Low potential for human exposure.
N,N-Diethylhydroxylamine [3710-84-7]	NCI	—Subchronic toxicity	—Available data indicate low toxicity. —Low potential for human exposure.
<b>Chemicals Deferred for Additional Information</b>			
1,3,5-Triazine-1,3,5 (2H,4H,6H)-triethanol [4719-04-4]	NCI	—Carcinogenicity	—Reconsider as part of class study of formaldehyde-releasing compound.

Chemical [CAS Number]	Nominated by	ICCEC recommendations	Study rationale; other information
s-Trioxane [110-88-3]	NIEHS	—Toxicological characterization —Carcinogenicity	—Reconsider as part of class study of formaldehyde-releasing compounds.
<b>Chemicals to be Withdrawn from Consideration</b>			
Arsenic Trioxide [1327-53-3]	NIEHS; Private Individual	—Mechanistic studies —Carcinogenicity	—Lack of an appropriate animal model for human carcinogenicity.
2,3-Butanedione [431-03-8]	NCI	—Genotoxicity —Metabolism studies —Carcinogenicity	—Rapid and near complete metabolism to carbon dioxide.
t-Butylcatechol [98-29-3]	NCI/FDA	—Toxicological characterization —Metabolism studies —Carcinogenicity	—Toxicity in subchronic studies at doses as high as 12,500 ppm in the diet was limited to forestomach lesions.
Camphor [464-49-3] [76-22-2]	NCI	—Teratogenicity —Reproductive toxicity —Carcinogenicity	—Teratogenicity studies completed —Toxicity in subchronic dermal studies limited to hyperplasia at the site of application.
Fluasterone [112859-71-9]	NCI	—Toxicological characterization —Carcinogenicity	—Difficulty in obtaining sufficient material for study. —Industry sponsor has responsibility for toxicological evaluation of this chemical if pursued as a chemotherapeutic agent.
Luminol [521-31-3]	Private Individual	—Toxicological characterization —Carcinogenicity	—Lack of absorption from skin. —Rapid metabolism and elimination of oral doses as nontoxic metabolites.
Propylene Glycol Monomethyl Ether [107-98-2]	NCI	—Carcinogenicity	—Availability of industry-sponsored reproductive toxicity and carcinogenicity studies.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or

revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: <http://www.health.org/workpl.htm>.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443-6014.

**Special Note:** Please use the above address for all surface mail and correspondence. For all overnight mail service use the following address: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

**SUPPLEMENTARY INFORMATION:** Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. Subpart C of the Guidelines,

"Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414-328-7840, (formerly: Bayshore Clinical Laboratory)  
Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400