

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 26, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

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 meeting.

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: National Institute of General Medical Sciences Special Emphasis Panel Trauma and Burn.

Date: April 6, 1999.

Time: 2 pm to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Baltimore, on the Inner Harbor, 300 Light Street, Baltimore, MD 21202.

Contact Person: Bruce K. Wetzel, PhD., Scientific Review Administrator, Office of Scientific Review, NIGMS, Natcher Building, Room 1AS-19, Bethesda, MD 20892, (301) 594-3907.

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. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: March 26, 1999.

LaVerne Y. Stringfield,

Committee Management Officer, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program: Call for Public Comment on 11 Substances, Mixtures and Exposure Circumstances To Be Reviewed in 1999 for Listing in or Delisting (Removing) From the Report on Carcinogens, Tenth Edition

Background

The National Toxicology Program (NTP) announces its intent to review additional substances, mixtures and exposure circumstances for possible listing in or delisting (removing) from the Report on Carcinogens, Tenth Edition which is scheduled for publication in 2001. This Report (previously known as the Annual Report on Carcinogens) is a Congressionally-directed listing of known human carcinogens and reasonable anticipated human carcinogens and its preparation is delegated to the National Toxicology Program by the Secretary, Department of Health and Human Services (DHHS). Section 301(b)(4) of the Public Health Service Act, as amended, provides that the Secretary, (DHHS), shall publish a report which contains a list of all substances (1) which either are known to be a human carcinogen or reasonable anticipated to be a human carcinogen, and (2) to which a significant number of persons residing in the United States (US) are exposed. The law also states that the reports should provide available information on the nature of exposures, the estimated number of persons exposed and the extent to which the implementation of Federal regulations decreases the risk to public health from exposure to these chemicals.

The scientific review of the substances, mixtures or exposure circumstances involves three separate reviews, which include two Federal review groups and one non-government peer review body (a subcommittee of the NTP Board of Scientific Counselors) which will meet in an open, public meeting and provide for public comments. All available data and public comments received that are relevant to the application of the criteria for inclusion or removal of candidate agents, substances, mixtures or exposure circumstances or for a change in the

classification in the Report will be evaluated. The criteria to be used in the review process are described below:

1. Known to be Human Carcinogens: There is sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between exposure to the agent, substance or mixture and human cancer.

2. Reasonably Anticipated to be Human Carcinogens:

There is limited evidence of carcinogenicity from studies in humans which indicates that causal interpretation is credible but that alternative explanations such as chance, bias or confounding factors could not adequately be excluded; or

There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors: (1) In multiple species, or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site or type of tumor or age at onset; or

There is less than sufficient evidence of carcinogenicity in humans or laboratory animals, however; the agent, substance or mixture belongs to a well defined, structurally-related class of substances whose members are listed in a previous Report on Carcinogens as either a known to be human carcinogen, or reasonably anticipated to be human carcinogen or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub populations, genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans.

Clarification of the Criteria

Some questions have arisen regarding information from studies involving humans and how this is applied to the listing of a substance determined to be a "known human carcinogen". The "known human carcinogen" category requires evidence from studies of humans. This can include traditional cancer epidemiology studies, data from clinical studies, and/or data derived from the study of tissues from humans exposed to the substance in question and useful for evaluating whether a relevant cancer mechanism is operating in people.