

(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.

[FR Doc. 99-8101 Filed 4-1-99; 8:45 am]

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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.

Public Comment Requested

Nominations for the Report on Carcinogens to be reviewed in 1999 are provided in the following table with their Chemical Abstracts Services (CAS) Registry numbers (where available) and pending review action. NTP invites public comment on any of these nominations. In addition, NTP requests relevant information on the carcinogenic properties of the substances from completed or ongoing experimental animal or human epidemiology studies, as well as current production data, use patterns, and human exposure information. Comments received by April 30, 1999 will allow the time for their consideration by the initial review

groups and by the NTP in the preparation of the background document prepared for each substance. Comments or questions should be directed to Dr. C. W. Jameson at the address listed below.

Public Nominations for Delisting or Listing Encouraged

The NTP solicits and encourages the broadest participation from interested individuals or parties in nominating agents, substances, mixtures or exposure circumstances for listing in or delisting from the Reports on Carcinogens. Nominations from the public should contain a rationale for listing or delisting. Appropriate background information and relevant data (e.g.

Journal articles, NTP Technical Reports, IARC listings, exposure surveys, release inventories, etc.) which support a nomination should be provided or referenced when possible.

A detailed description of the review procedures, including the steps in the formal review process, is available at <http://ntp-server.niehs.nih.gov> and can be obtained by contacting: Dr. C. W. Jameson, National Toxicology Program, Report on Carcinogens, MD EC-14, P.O. Box 12233, Research Triangle Park, NC 27709; phone: (919) 541-4096, fax: (919) 541-0947, email: jameson@niehs.nih.gov.

Dated: March 22, 1999.

Kenneth Olden,

Director, National Toxicology Program.

SUMMARY FOR AGENTS, SUBSTANCES, MIXTURES OR EXPOSURE CIRCUMSTANCES TO BE REVIEWED IN 1999, FOR CONSIDERATION OF LISTING IN OR DELISTING FROM THE TENTH REPORT ON CARCINOGENS

Nomination to be reviewed/CAS No.	Primary uses or exposures	To be reviewed for
Beryllium and Beryllium Compounds/7440-41-7	Fiber optics and cellular network communications systems, aerospace, defense and other industry applications.	Possible updating of current listing of beryllium and certain beryllium compounds to a known human carcinogen.
2,2-bis-(bromomethyl) - 1,3-propanediol/3296-90-9	Used as a fire retardant in unsaturated polyester resins, in molded products, and in rigid polyurethane foam.	Listing in the 10th Report.
2,3-Dibromo-1-Propanol/96-13-9	Used as a flame retardant, as an intermediate in the preparation of the flame retardant tris(2,3-dibromopropyl) phosphate, and as an intermediate in the manufacture of pesticides and pharmaceutical preparations.	Listing in the 10th Report.
Dyes Metabolized to Dimethoxybenzidine (Dimethoxybenzidine Dyes as a Class).	Dyes widely used for leather, paper, plastics, rubber, and textile industries.	Listing in the 10th Report.
Dyes Metabolized to Dimethoxybenzidine (Dimethoxybenzidine Dyes as a Class).	Dyes widely used for leather, paper, plastics, rubber, and textile industries.	Listing in the 10th Report.
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)/76180-96-6.	Found in cooked meat and fish	Listing in the 10th Report.
Styrene=7,8=oxide/96-09-3	Used mainly in the preparation of fragrances and in some epoxy resin formulations.	Listing in the 10th Report.
Toluene Diisocyanate/26471-62-5	Commercially produced as an approximately 80:20 mixture of the 2,4- and 2,6-isomers it is primarily for use in the manufacture of flexible polyurethane foams.	Delisting from the Report on Carcinogens.
UV Radiation/separate consideration of three segments of the wavelength spectrum; UVA (315-400 nm), UVB (280-315 nm), and UVC (100-280 nm).	Solar and artificial sources of ultraviolet radiation ...	Listing in the 10th Report.
Vinyl Bromide/593-60-2	Used commercially since 1968, primarily in the manufacture of flame retardant synthetic fibers.	Listing in the 10th Report.
Vinyl Fluoride/75-02-5	Used commercially since the 1960's, in the production of polyvinylfluoride which is used for plastics.	Listing in the 10th Report.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of

information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Drug and Alcohol Services Information System (DASIS) (OMB No. 0930-0106)—Revision—The DASIS consists of three related data systems: the National Master Facility Inventory (NMFI), the Uniform Facility Data Set (UFDS), and the Treatment Episode Data