

Dated: March 29, 2000.

LaVerne Y. Stringfield,

*Director, Office of Federal Advisory
Committee Policy.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Noticed 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: April 7, 2000.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Kenwood Country Club, 5601 River Road, Bethesda, MD 20816.

Contact Person: John R. Lyman grover, PHD, Scientific Review Administrator, National Institutes of Health, NIAMS, Natcher Bldg., Room 5As25N, Bethesda, MD 20892, 301-594-4952.

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. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: March 29, 2000.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Call for Public Comments on Substances, Mixtures and Exposure Circumstances Proposed for Listing in the Report on Carcinogens, Tenth Edition

Background

The National Toxicology Program (NTP) announces its intent to review additional agents, substances, mixtures and exposure circumstances for possible listing in the Report on Carcinogens (RoC), Tenth Edition. This Report (previously known as the Annual Report on Carcinogens) is a Congressionally mandated listing of known human carcinogens and reasonably 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 human carcinogens or may reasonably be anticipated to be human carcinogens, 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 nominated agents, substances, mixtures or exposure circumstances involves three separate scientific reviews: two Federal review groups and one non-government peer review body (a subcommittee of the NTP Board of Scientific Counselors) that meets in an open, public forum. Throughout the review process, multiple opportunities are provided for public input including at the Subcommittee meeting. In reviewing nominations for the RoC, all available data and public comments, which are relevant to application of the criteria for inclusion or removal of candidate agents, substances, mixtures or exposure circumstances or for a change in a candidate's classification, are evaluated. The criteria used in the review process are as follows:

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.

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 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 subpopulations, 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.

A detailed description of the review procedures, including the steps in the formal review process, is available at <http://ntp-server.niehs.nih.gov> or 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) 541-0144, email: jameson@niehs.nih.gov.