

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Food and Drug Administration**

[Docket No. 97N-0025]

**Agency Information Collection Activities; Announcement of OMB Approval**
**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled, "Medical Devices Standards Activities Report" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. This document announces the OMB approval number.

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 21, 1997 (62 FR 8024), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). OMB has approved the information collection and has assigned OMB control number 0910-0219. The approval expires on April 30, 2000. Under 5 CFR 1320.5(b), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: May 21, 1997.

**William K. Hubbard,**
*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-13959 Filed 5-28-97; 8:45 am]

BILLING CODE 4160-01-F

*Name of SEP:* Review of Conference Grant (R13) (Telephone Conference Call).

*Date:* June 11, 1997.

*Time:* 1:00 p.m.

*Place:* National Institute of Environmental Health Sciences, North Campus, Building 17 Conference Room 1713, Research Triangle Park, NC 27709.

*Contact Person:* Dr. John Braun, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541-1446.

*Purpose/Agenda:* To review and evaluate grant applications.

This notice is being published less than fifteen days prior to this meeting due to the urgent need to meet timing limitations imposed by the grant/contract review and funding cycle.

*Name of SEP:* Review of Conference Grant (R13) (Telephone Conference Call).

*Date:* June 24, 1997.

*Time:* 1:00 p.m.

*Place:* National Institute of Environmental Health Sciences, North Campus, Building 17, Conference Room 1713, Research Triangle Park, NC 27709.

*Contact Person:* Dr. John Braun, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, NC 27709, (919) 541-1446.

*Purpose/Agenda:* To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Grant applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health.)

Dated: May 23, 1997.

**LaVerne Y. Stringfield,**
*Committee Management Officer, NIH.*

[FR Doc. 97-14041 Filed 5-28-97; 8:45 am]

BILLING CODE 4140-01-M

Biennial Report on Carcinogens. The NTP solicits and encourages the broadest participation from interested individuals or parties in nominating agents, substances or mixtures for listing in or delisting from the BRC. The criteria for listing or for removing an agent substance or mixture in the Biennial Report on Carcinogens were revisited during 1994 and 1995 in a series of open public meetings. In recognition of the advances made in understanding the biological events involved in carcinogenesis, it was recommended that the criteria for listing an agent be expanded to include a broader array of information related to the carcinogenic process. The revised criteria for listing a substance in the Biennial Report on Carcinogens were approved by the Secretary, HHS on September 13, 1996, and are as follows:

**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 Annual or Biennial 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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**National Institutes of Health**
**National Institute of Environmental Health Sciences; Notice of Closed Meetings**

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 National Institute of Environmental Health Sciences Emphasis Panel (SEP) meetings:

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Public Health Service**
**National Toxicology Program; Call for Nominations for Listing or Delisting Substances in the Biennial Report on Carcinogens (BRC)**
**Background**

The National Toxicology Program (NTP) has the responsibility within the U.S. Department of Health and Human Services (DHHS) for preparation of the