

Written comments will be available for public inspection in accordance with the Freedom of Information Act, 5 U.S.C. 552, and FTC regulations, 16 CFR 4.9, Monday through Friday between the hours of 8:30 a.m. and 5 p.m. at the Public Reference Room, Room 130-H, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580. This notice and, to the extent possible, all comments will also be posted on the FTC Web site, <http://www.ftc.gov>.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Opportunity for Cooperative Research and Development Agreements (CRADAs) To Develop Novel Mechanical and Biological Treatments in Interventional Cardiovascular Medicine Using X-ray Fluoroscopy and Real-Time Magnetic Resonance Imaging

AGENCY: National Heart, Lung, and Blood Institute.

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) announces the opportunity for Cooperative Research and Development Agreements (CRADAs) to develop novel mechanical and biological treatments in interventional cardiovascular medicine using x-ray fluoroscopy and real-time magnetic resonance imaging. The NHLBI seeks potential Collaborators wishing to provide expertise in (1) novel biological treatments for cardiovascular disease, including adult-derived stem cell and cardiovascular progenitor cells, (2) novel agents for therapeutic angiogenesis for myocardial or peripheral artery applications, (3) novel mechanisms of drug, gene, or cell delivery to the myocardium or skeletal muscle to treat manifestations of coronary or peripheral artery atherosclerosis, and (4) intravascular devices for real-time magnetic resonance imaging-guided treatments including but not limited to angioplasty balloons, recanalization systems, percutaneous cardiac valves, stents, endografts, and bypass grafts.

The NHLBI seeks capability statements from parties interested in

entering into a potential CRADA to manufacture, prototype, and test the above-specified agents or devices leading to early clinical testing and development. Collaborator applicants developing capability statements may also include proposals to provide funding for possible commercial uses of interest to the Collaborator. The availability of private sector support may increase the feasibility of particular aspects of the final design, but the primary criterion for selecting potential collaborators is the scientific merit of proposals for developing a plan to identify novel putative therapeutic agents and devices.

The NHLBI can provide extensive preclinical and clinical support in the development of Collaborator deliverables, including animal experiments, advanced x-ray fluoroscopic and magnetic resonance imaging laboratories, and investigations conducted in the Warren G. Magnuson Clinical Center at the Bethesda campus of the National Institutes of Health.

The control of clinical trials shall reside entirely with the Institute and the scientific participants of the trial. In the event that any adverse effects are encountered which, for legal or ethical reasons, may require communication with the U.S. Food and Drug Administration, the relevant collaborating institutions will be notified. Neither the conduct of the trial nor the results should be represented as an NHLBI endorsement of the agent, drug, or device under study.

DATES: Only written CRADA capability statements received by the NHLBI within 21 days of publication of this notice will be considered during the initial design phase. Confidential information must be clearly labeled. Potential collaborators may be invited to meet with the Selection Committee at the Collaborators' expense to provide additional information. The Institute may issue an additional notice of CRADA opportunity during the design phase if circumstances change or if the design alters substantially.

FOR FURTHER INFORMATION CONTACT:

Capability statements should be submitted to Ms. Peg Koelble, Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute, National Institutes of Health, 31 Center Drive, Room 1B30, Bethesda, MD 20892-2490; Tel: 301-594-4095; Fax: 301-594-3080; e-mail: koelblep@nhlbi.nih.gov.

Capability Statements: A Selection Committee will use the information provided in the "Collaborator Capability Statements" received in response to this

announcement to help in its deliberations. It is the intention of the NHLBI that all qualified Collaborators have the opportunity to provide information to the Selection Committee through their capability statements. The Capability Statement should not exceed 10 pages and should address the following selection criteria:

1. The statement should provide specific details of the method to be used in the development of novel candidate biological treatments, delivery systems, or real-time MRI-guided mechanical treatments for cardiovascular disease.

2. The statement should include a detailed plan demonstrating the ability to provide sufficient capacity in drug, gene, or stem cell development and manufacturing or in mechanical device prototyping, testing, development, and manufacturing.

3. The statement may include outline measures of interest to the Collaborator. The specifics of the proposed outcome measures and the proposed support should include but not be limited to: expertise in the proposed field, specific personnel allocation to the proposed collaboration, specific internal or external funding commitment to support the advancement of scientific research, services, facilities, equipment, or other resources that would contribute to the conduct of the commercial development.

4. The statement must address willingness promptly to publish research results and ability to be bound by PHS intellectual property policies (see CRADA: <http://ott.od.nih.gov/newpages/crada.pdf>).

Dated: December 6, 2002.

Carl Roth,

Associate Director for Scientific Program Operation, National Heart, Lung, and Blood Institute.

[FR Doc. 02-31630 Filed 12-16-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

The National Toxicology Program (NTP) Announces the Availability of the Report on Carcinogens, Tenth Edition

The Report on Carcinogens, Tenth Edition was submitted to the Congress by the Secretary HHS and also released publicly on December 11, 2002. It is available on the Internet and can be accessed from the Environmental Health Perspectives web site at: <http://www.ehponline.org> or from the NTP

Web site at: <http://ntp-server.niehs.nih.gov>. Hard copies of the Report on Carcinogens, Tenth Edition can also be obtained by contacting Environmental Health Perspectives, ATTN: Order Processing, 1001 Winstead Drive Suite 355, Cary, NC 27513; Telephone: 866-541-3841 or 919-653-2586; Fax (919) 678-8696; email: ehponline@niehs.nih.gov.

Background

The Report on Carcinogens (RoC) (previously known as the Annual Report on Carcinogens) is a Congressionally mandated listing of known human carcinogens and reasonably anticipated human carcinogens whose 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 biennial 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 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 RoC is an informational scientific and public health document that identifies and discusses agents, substances, mixtures, or exposure circumstances that may pose a carcinogenic hazard to human health. It serves as a meaningful and useful

compilation of data on the (1) carcinogenicity, genotoxicity, and biologic mechanisms of the listed substances in humans and/or animals, (2) the potential for exposure to these substances, and (3) the regulations promulgated by Federal agencies to limit exposures. The report does not present quantitative assessments of carcinogenic risk, an assessment that defines the conditions under which the hazard may be unacceptable. Listing of substances in the report, therefore, does not establish that such substances present carcinogenic risks to individuals in their daily lives. Such formal risk assessments are the purview of the appropriate Federal, State, and local health regulatory and research agencies.

New Listings to the RoC, Tenth Edition

The RoC, Tenth Edition, contains 228 entries, 15 of which have not appeared in earlier RoCs. The Tenth Edition of the RoC also changes the listing of beryllium and beryllium compounds from reasonably anticipated to be human carcinogens to known to be human carcinogens, with corresponding revisions of the earlier profile for these chemicals. The Tenth Edition of the RoC lists estrogens, steroidal as known human carcinogens. This listing of steroidal estrogens supersedes the previous listing of individual estrogens in the RoC (including conjugated estrogens, estradiol-17 β , estrone, ethinylestradiol, and mestranol) and applies to all chemicals of this steroid class. The profile for steroidal estrogens includes information on carcinogenicity, properties, use, production, exposure, and regulations for steroidal estrogens as a class, as well as some specific information for individual estrogens. The table below

summarizes the actions taken for the substances or exposure circumstances reviewed for possible listing in or change in the listing in the RoC, Tenth Edition.

The new entries for the Report on Carcinogens, Tenth Edition, including those whose listing changed, underwent a multiphase peer review. This review included three scientific peer reviews, two consisting of scientists within the Federal government and the other consisting of an outside peer review by both government and non-government scientists. During the entire review period, there was extensive opportunity for public comment and stakeholder review. The three scientific review committees evaluated all available data relevant to the criteria for inclusion of candidate nominations in the report. The criteria used in the review process and a detailed description of the review procedures, including the steps in the current formal review process, can be obtained from the NTP Web site at <http://ntp-server.niehs.nih.gov/> or by contacting: Dr. C. W. Jameson, Head—Report on Carcinogens, National Toxicology Program, 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.

Questions or comments concerning the RoC, Tenth Edition should be directed to: Dr. Mary Wolfe, Office of Scientific Review and NTP Liaison, MDA3-01, P.O. Box 12233, Research Triangle Park, NC 27709; phone: (919) 541-0530, fax: (919) 541-0295, e-mail: wolfe@niehs.nih.gov.

Dated: December 9, 2002.

Kenneth Olden,
Director, National Toxicology Program.

SUMMARY FOR AGENTS, SUBSTANCES, MIXTURES OR EXPOSURE CIRCUMSTANCES BEING ADDED TO OR CHANGING THE LISTING IN THE TENTH EDITION OF THE REPORT ON CARCINOGENS

Nominations	Primary uses or exposures	Action
2-Amino-3-methylimidazo[4,5-f] quinoline (IQ)/CAS# 76180-96-6.	One of a series of heterocyclic amines that is formed in food during heating or cooking and is found in cooked meats and eggs. It is also found in cigarette smoke.	Listed as reasonably anticipated to be a human carcinogen.
Beryllium and Beryllium Compounds	Used in fiber optics and cellular network communications systems, aerospace, defense and other industry applications.	Listing changed to known to be human carcinogens.
2,2-bis-(Bromomethyl)-1,3-propanediol (Technical Grade)/CAS# 3296-90-9.	Used as a flame retardant in unsaturated polyester resins, for molded products, and in the production of rigid polyurethane foam.	Listed as reasonably anticipated to be a human carcinogen.
Broad Spectrum UV Radiation and UVA Radiation, UVB Radiation and UVC Radiation.	Solar and artificial sources of ultraviolet radiation	Broad Spectrum UV Radiation listed as known to be a human carcinogen, UVA Radiation, UVB Radiation and UVC Radiation each listed as reasonably anticipated to be a human carcinogen.
Chloramphenicol/CAS# 56-75-7	Used as an antibiotic since the 1950s but currently has restricted use in the United States because it causes blood dyscrasia.	Listed as reasonably anticipated to be a human carcinogen.

SUMMARY FOR AGENTS, SUBSTANCES, MIXTURES OR EXPOSURE CIRCUMSTANCES BEING ADDED TO OR CHANGING THE LISTING IN THE TENTH EDITION OF THE REPORT ON CARCINOGENS—Continued

Nominations	Primary uses or exposures	Action
2,3-Dibromo-1-Propanol/CAS# 96-13-9	Used as an intermediate in the preparation of flame retardants and as an intermediate in the manufacture of pesticides and pharmaceuticals.	Listed as reasonably anticipated to be a human carcinogen.
Dyes Metabolized to Dimethoxybenzidine	Dyes used in leather, paper, plastics, rubber, and textile industries.	Listed as reasonably anticipated to be human carcinogens.
Dyes Metabolized to Dimethylbenzidine ..	Dyes used in printing textiles, as biological stains, and in color photography.	Listed as reasonably anticipated to be human carcinogens.
Estrogens, Steroidal	Comprise a group of structurally related hormones that control sex and growth characteristics and are commonly used in hormone replacement therapy (HRT) to treat symptoms of menopause and in oral contraceptives.	Listed as known to be human carcinogens.
Methyleugenol/CAS# 93-15-2	Occurs naturally in oils, herbs and spices and is used in its natural or synthetic forms as a flavoring agent, insect attractant, anesthetic and in sunscreens.	Listed as reasonably anticipated to be a human carcinogen
Nickel and Nickel Compounds	Used in many industrial and commercial applications including alloys, catalysts, batteries, pigments, and ceramics.	Metallic Nickel listed as reasonably anticipated to be a human carcinogen, Nickel Compounds listed as known to be human carcinogens, Nickel alloys not listed.
Styrene7,8-oxide/CAS# 96-09-3	Used mainly as an intermediate in the production of styrene glycol and its derivatives, in the production of reinforced plastics, and as a chemical intermediate for cosmetics, surface coatings, agricultural and biological chemicals.	Listed as reasonably anticipated to be a human carcinogen.
Trichloroethylene/CAS# 79-01-6	Used as an industrial solvent for vapor degreasing and cold cleaning of fabricated metal parts.	Remains listed as reasonably anticipated to be a human carcinogen.
Vinyl Bromide/CAS# 593-60-2	Used predominantly in polymers in the production of fabrics and fabric blends used in sleepwear (mostly children's) and home furnishings, as well as in leather, fabricated metal products and in the production of pharmaceuticals and fumigants.	Listed as reasonably anticipated to be a human carcinogen.
Vinyl Fluoride/CAS# 75-02-5	Used mainly in the production of polyvinyl fluoride and other fluoropolymers that are widely used because they are resistant to weather and have great strength, chemical inertness, and low permeability to air and water.	Listed as reasonably anticipated to be a human carcinogen.
Wood Dust	Created when machines or tools are used to cut or shape wood. High amounts of wood dust are produced in sawmills, dimension mills, furniture making industries, cabinetmaking, and carpentry.	Listed as a known to be a human carcinogen.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**[Docket No.FR-4734-N-73]****Notice of Submission of Proposed Information Collection to OMB: Customer-Survey of Households Living in Federally Assisted Units****AGENCY:** Office of the Chief Information Officer, HUD.**ACTION:** Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is

soliciting public comments on the subject proposal.

DATES: Comments Due Date: January 16, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2528-0170) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395-6974; E-mail Lauren_Wittenberg@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, AYO, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708-2374. This is not a

toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35). The notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including