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FOR FURTHER INFORMATION CONTACT: Ms. Lynn Spector, Division of Health Center Development, Bureau of Primary Health Care, HRSA. Ms. Spector may be contacted by e-mail at lspector@hrsa.gov or via telephone at (301) 594-4300.

Dated: February 1, 2005.

Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Physical Activity and Its Components In Relation To Plasma Inflammatory Markers of Cancer Risks Among Chinese Adults

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Physical Activity And Its Components In Relation To Plasma

Inflammatory Markers Of Cancer Risks Among Chinese Adults.

Type of Information Collection Request: NEW.

Need and Use of Information Collection: The specific objectives of the current study are to: (1) Develop a comprehensive physical activity questionnaire that includes standardized questions about all types of physical activity (e.g., recreational, household, occupational, and transportation), and all parameters of physical activity (e.g., frequency, intensity; and duration in hours per week; (2) to assess the validity and reliability of this comprehensive physical activity questionnaire and the currently used baseline physical activity questionnaire in two existing study cohorts using objective measures of physical activity/physical fitness (activity monitors and step test), and; (3) to evaluate whether types and parameters of physical activity are associated with circulating levels of specific inflammatory markers that have been linked to cancer risk, independent of body mass and other potentially confounding variables. The specific markers are C-reactive protein (CRP), interleukin 6 (IL-6), and soluble tumor necrosis factor alpha (TNF-”).

The findings of this study will contribute to research in several important ways. They will allow the collection of objective physical activity measurements using activity monitors within a population with a wide range of between-person variation in physical

activity; add to our understanding of the relationship of individual types of physical activity (e.g., recreational, household, occupational, and transportation), and parameters of physical activity (e.g., frequency, intensity, and duration in hours per week) to cancer outcomes; allow the use of physical activity information together with detailed, prospectively collected information regarding other lifestyle factors, such as diet and body mass, factors that are highly correlated with physical activity and also represent strong independent determinants of inflammatory mediator production, and; should the anticipated associations be found, the current study will likely stimulate future studies aimed at independently and jointly evaluating physical activity and chronic low-grade systemic inflammation in relation to cancer of several sites.

Frequency of Response: Once a month during a twelve-month period.

Affected Public: Approximately 600 men and women from a current cohort study among 75,000 women and 73,000 men and residing in Shanghai, China who agree to participate in this study.

Type of Respondents: Adult men and women aged 40 to 70 years old who are residents of Shanghai, China and current participants in another ongoing study. The annual reporting burden is as follows:

Estimated Number of Respondents: 600.

Estimates of Respondent Hour Burden and Annualized Cost to Respondents:

Type of respondents	Survey instruments per respondents	Number of participants	Frequency of response	Average burden hours per response	Total annual hour burden
Adults (40-70 yrs old)	Physical Activity Questionnaire	600	2	0.5	600
	7-Day Physical Activity Record	600	4	1.4	3360
	1-Week Physical Activity Recall	600	12	0.25	1800
TOTAL	600	5,760

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance

the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Michael F. Leitzmann, M.D., Dr. P.H., Nutritional Epidemiology Branch, Division of

Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS, 6120 Executive Blvd., EPS-MS-C 7232, Bethesda, MD, 20892, U.S.A. or call non-toll-free number 301-402-3491 or E-mail your request, including your address to: leitzmann@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 25, 2005.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 05-2127 Filed 2-3-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Center for the Evaluation of Risks to Human Reproduction (CERHR); Announcement of Plans for Future Evaluation of Di(2-ethylhexyl)phthalate; Request for Public Comments on this Chemical; and Solicitation for the Nomination of Scientists Qualified to Serve on an Expert Panel

AGENCY: National Institute for Environmental Health Sciences (NIEHS); National Institutes of Health (NIH), Department of Health and Human Services (HHS).

ACTION: Notice of expert panel evaluation of the reproductive and developmental toxicities of di(2-ethylhexyl)phthalate.

SUMMARY: The CERHR plans to convene an expert panel to evaluate the scientific evidence regarding the potential reproductive and/or developmental toxicity associated with exposure to di(2-ethylhexyl)phthalate (DEHP). The expert panel will consist of approximately 8-12 scientists selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other relevant areas of science. The CERHR invites the submission of public comments on DEHP and the nomination of scientists to serve on the expert panel for its evaluation (*see SUPPLEMENTARY INFORMATION below*). This meeting is tentatively scheduled for fall 2005, although the exact date and location are not yet established. As plans are finalized, they will be announced in the **Federal Register** and posted on the CERHR Web site (<http://cerhr.niehs.nih.gov>). CERHR expert panel meetings are open to the public with time scheduled for oral public comment.

DATES: Information and comments received by March 21, 2005, will be made available to the CERHR staff and the expert panel for consideration in the evaluation and posted on the CERHR Web site. Nominations of scientists received by March 21, 2005, will be

considered for this panel and for inclusion in the CERHR Expert Registry.

ADDRESSES: Information and comments should be sent to Dr. Michael D. Shelby, CERHR Director, NIEHS, P.O. Box 12233, MD EC-32, Research Triangle Park, NC 27709 (mail), (919) 316-4511 (fax), or shelby@niehs.nih.gov (e-mail). Courier address: CERHR, 79 T.W. Alexander Drive, Building 4401, Room 103, Research Triangle Park, NC 27709.

FOR FURTHER INFORMATION CONTACT: Dr. Michael D. Shelby, CERHR Director, (919) 541-3455, shelby@niehs.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

DEHP is a high production chemical used as a plasticizer of polyvinyl chloride in the manufacturer of a wide variety of consumer products, such as building products, car products, clothing, food packaging, children's products (but not in toys intended for mouthing) and in polyvinyl chloride medical devices. In 1999-2000, a NTP-CERHR expert panel evaluated DEHP and six other phthalates for reproductive and developmental toxicities. Since release of the NTP-CERHR expert panel report on DEHP in 2000, approximately 70 papers relevant to human exposure and reproductive and/or developmental toxicity of DEHP have been published. Because this is a chemical with wide human exposure and public and government interest, CERHR plans to convene an expert panel to conduct an updated evaluation of the potential reproductive and developmental toxicities of DEHP.

Request for Comments

The CERHR invites the public and other interested parties to submit information and comments on DEHP including toxicology information from completed and ongoing studies, information on planned studies, and information about current production levels, human exposure, use patterns, and environmental occurrence.

Request for the Nomination of Scientist for the Expert Panel

The CERHR invites nominations of qualified scientists to serve on the expert panel. Panelists are primarily drawn from the CERHR Expert Registry and/or the nomination of other scientists who meet the criteria for listing in that registry which include: formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, membership in relevant professional societies, and certification by an appropriate scientific board or other

entities. Expert panel members are required to sign conflict of interest forms in accordance with Federal Advisory Committee Act Guidelines (5 U.S.C. Appendix 2).

All panel members serve as individual experts and not as representatives of their employers or other organizations. Scientists on the expert panel will be selected to represent a wide range of expertise including, but not limited to, developmental toxicology, reproductive toxicology, epidemiology, general toxicology, pharmacokinetics, exposure assessment, and biostatistics. Nominations should include contact information and a current curriculum vitae (if possible) and be forwarded to the CERHR at the address given above.

Background Information on the CERHR

The NTP established the CERHR in June 1998 (**Federal Register**, December 14, 1998: Volume 63, Number 239, page 68782). The CERHR is a publicly accessible resource for information about adverse reproductive and developmental health effects associated with environmental exposures. Expert panels conduct scientific evaluations of agents selected by the CERHR in public forums.

Information about CERHR and its process for nominating agents for review or scientists for its expert registry can be obtained from its Web site (<http://cerhr.niehs.nih.gov>) or by contacting Dr. Shelby (contact information provided above). The CERHR selects chemicals for evaluation based upon several factors, including production volume, extent of human exposure, public concern, and extent of the database on reproductive or developmental toxicity studies.

CERHR follows a formal, multi-step process for review and evaluation of selected chemicals. The formal evaluation process was published in the **Federal Register** (July 16, 2001: Volume 66, Number 136, pages 37047-37048) and is available on the CERHR Web site under "About CERHR" or in printed copy from the CERHR.

Dated: January 27, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

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