

Dated: November 19, 2004.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

[OMB No. 0925-0454]

Submission for OMB Review; Comment Request; Case-Cohort Study of Cancer and Related Disorders Among Benzene-Exposed Workers in China

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** and allowed 60 days for public comment. No public comments were received. The purpose

of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Case-Cohort Study of Cancer and Related Disorders Among Benzene-Exposed Workers in China. Reinstatement With Change. Need and Use of Information Collection: A case-cohort study will be performed to examine the risks of lymphohematopoietic cancers, other lymphohematopoietic disorders, benzene poisoning, and lung cancer among workers exposed to benzene. The study will attempt to determine with greater precision the risks of these disorders at low levels of benzene exposure, and to characterize the dose and time-specific relationship between benzene exposure and disease risk. Cases and controls will be selected from an existing cohort of 75,000 benzene-exposed workers and 36,000 comparison workers in 12 Chinese cities. There are 2 changes to the study from that previously approved by OMB in July 2001: (1) 386 more subjects

(including 155 more cases with benzene poisoning, 111 more cases with lung cancer, and 120 more controls) will be evaluated in the currently planned case-cohort study, which is now targeting a total of 2,156 subjects compared with 1,770 subjects as previously estimated; and (2) the questionnaire has been revised somewhat, although the average total time estimated for a subject to complete the questionnaire is unchanged from previously.

Frequency of Response: Single-time study. *Affected Public:* Individuals or households. *Type of Respondents:* Cases with lymphohematopoietic malignancies and related disorders, benzene poisoning and lung cancer among Chinese benzene-exposed and comparison workers; controls consist of a random sample of the Chinese worker cohort. The annual reporting burden is as follows: *Estimated Number of Respondents:* 862; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 0.3674; and *Estimated Total Annual Burden Hours Requested:* 396. The annualized cost to respondents is estimated at \$476. There are no Capital Costs to report. There are also no Operating or Maintenance Costs to report.

ESTIMATES OF HOUR BURDEN: BURDEN REQUESTED

Type of respondents	Estimated number of respondents	Estimated frequency of responses per respondent	Average burden time (in hours) per response	Estimated average annual hour burden
Workers in factories in China using or producing benzene and in comparison factories in which no benzene is used	1,078	1	0.37	396

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.

Direct Comments To OMB: Written comments and/or suggestions regarding

the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Richard Hayes, OEB/EBP/DCEG/NCI 6120 Executive Boulevard, EPS Room 8114, Bethesda, MD 20892, or call non-toll-free number (301) 435-3973 or e-mail your request, including your address to: *HayesR@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: November 19, 2004.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 meetings.

The meetings 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.,