We note that Mr. Bhutani has petitioned the U.S. Supreme Court for writ of certiorari of the Seventh Circuit's decision in his case. Should the outcome of further judicial proceeding result in Mr. Bhutani's conviction being reversed, under section 306(d)(3)(B)(i) of the act, the order of debarment will be withdrawn. Mr. Bhutani may file an application to terminate his debarment, under section 306(d)(4)(A) of the act. Any such application would be reviewed under the criteria and processes set forth in section 306(d)(4)(C) and (d)(4)(D) of the act. Such an application should be identified with Docket No. 2002N–0291 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(f). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 24, 2004.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–26532 Filed 12–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0493]

Draft Guidance for Industry on Recommended Approaches to Integration of Genetic Toxicology Study Results; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Recommended Approaches to Integration of Genetic Toxicology Study Results.'' This draft guidance is intended to inform industry on how the Center for Drug Evaluation and Research (CDER) views positive findings in genetic toxicology assays, and to provide recommendations to industry on how to proceed in assuring safety of healthy subjects or patients when results in genotoxicity studies suggest a potential cancer or genetic hazard.

DATES: Submit written or electronic comments on the draft guidance by January 31, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5346.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Recommended Approaches to Integration of Genetic Toxicology Study Results.'' Risk for carcinogenesis is usually determined in rodent assays, in either 2–year studies or shorter-term studies using alternative models (ICH S1B). Regulatory decisions involving both single- and repeat-dose clinical studies are discussed in this guidance. Pharmaceuticals administered through oral, intravenous, topical, and other routes, as appropriate, are subject to this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on recommended approaches to integration of genetic toxicology study results. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26533 Filed 12–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Longitudinal Investigation of Fertility and the Environment

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register**, under the title ''Determinants of Male and Female Fecundity and Fertility,'' on January 9, 2004, page 1589 and allowed 60-days for public comment. Two public comments were received from the American Society for Reproductive Medicine and the American Chemistry Council Phthalate Esters Panel regarding specific aspects of the proposed methodology. Overall, comments from the former group pertained predominantly to clinical issues while the latter group's comments provided their rationale for the omission of phthalates from the protocol. These comments were useful in modifying the proposed study and instruments. The purpose of this notice is to allow an additional 30 days for public comment.

5 CFR 1320.5 (General Requirements) Reporting and Recordkeeping

Requirements: Final Rule requires that the agency inform the potential

persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. This information is required to be stated in the 30-day **Federal Register** notice.

Proposed Collection: Title: Longitudinal Investigation of Fertility and the Environment (LIFE Study). *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The purpose of the LIFE Study is to assess the impact of environmental factors, broadly defined to include lifestyle factors, on human reproduction and development. The LIFE Study is consistent with the mission of the National Institute of Child Health and Human Development that includes conducting basic, clinical and epidemiologic research focusing on factors and processes associated with human reproduction and development, thereby, ensuring the birth of healthy infants capable of reaching full adult potential unimpaired by physical or mental disabilities.

This study will assess the relation between select environmental factors and human reproduction and development. This research proposes to recruit and retain 800 couples interested in becoming pregnant and willing to participate in a longitudinal study. Couples will be selected from geographic regions that were chosen from peer reviewed competitive proposals. Fecundity will be measured by the time required for the couples to achieve pregnancy, while fertility will be measured by the ability of couples to have a live born infant. Infertility will be recognized for couples unable to conceive within 12 months of trying. The study's primary environmental exposures include: organochlorine pesticides; polychlorinated biphenyls; polybrominated diphenyl ethers; metals; perfluorinated compounds; cotinine; and phytoestrogens. A growing body of literature suggests these compounds may exert adverse effects on human reproduction and development; however, definitive data are lacking especially for sensitive endpoints. Couples will participate in a 25-minute baseline interview and be instructed in the use of home fertility monitors and pregnancy kits for counting the time required for pregnancy and detecting pregnancy. Blood and urine samples will be collected at baseline from both partners of the couple for measurement of the environmental exposures. Two semen samples from male partners and two saliva samples from female partners also will be requested. Semen samples will be used to globally assess male fecundity as measured primarily by sperm concentration and morphology. Saliva samples will be used for the measurement of cortisol levels as a marker of stress among female partners so that the relation between environmental factors, stress and human reproduction can be assessed.

The findings will provide valuable information regarding the effect of environmental contaminants on sensitive markers of human reproduction and development, filling critical data gaps. Moreover, these environmental exposures will be analyzed in the context of other lifestyle exposures such as use of cigarettes and alcohol, consistent with the manner in which human beings are exposed. *Frequency of Response:* Following the baseline interview (25 minutes), couples will each complete a 2-minute daily diary on select lifestyle factors. Women will perform daily fertility testing (7 minutes) approximately 11 days per cycle and pregnancy testing (4 minutes) at day of expected menses using a dipstick test in urine. Approximately 60% of women will become pregnant after 2 to 3 months, at which point they will switch to the less intensive portion of the protocol. Men will provide two semen samples, a month apart, requiring approximately 20 minutes for each collection, and women will collect two saliva samples, a month apart, requiring approximately 6 minutes each. Participating couples will be given a choice to submit their information by mail or to send it electronically to the Data Coordinating Center. This option will be available throughout data collection in the event couples change their minds about how they would like to submit information. Study participants will collect semen and saliva samples and forward them in prepaid delivery packages to the study's laboratories. Research nurses will collect blood and urine samples and return them to the study's laboratories. *Affected Public:* Individuals from participating communities. *Type of Respondents:* Men aged 18+ years and women aged 18–40 years. *Estimated Number of Respondents:* Approximately 1,000 couples enrolling (minimum of 800 completing the study). *Estimated Number of Response Sets Per Respondent:* 7 per woman and 4 per man over approximately two years. *Average Burden Hours Per Response:* (1) 0.17 hours for completing the screening instrument; (2) 0.42 hours for baseline interviews with men and women; (3) 2.5 hours for daily journal while attempting pregnancy for men and women; (4) 0.38 and 0.7 hours for biospecimen collection for women and men, respectively; (5) 2.6 hours for fertility monitors; (6) 0.27 hours for pregnancy testing for women; and (7) 0.29 hours for pregnancy journals for women. *Estimated Total Annual Burden Hours Requested:* 3,280 to 9,900 hours for female participants and 2,100 to 5,480 hours for male participants depending upon the length of time required for pregnancy. There is no cost to respondents. There are no Capital Costs, Operating Costs, and/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) Evaluate 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) evaluate 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) enhance the quality, utility, and clarity of the information to be collected; and (4) 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. Germaine M. Buck Louis, Epidemiology Branch, Division of Epidemiology, Statistics and Prevention Research, NICHD, 6100 Executive Boulevard, Room 7B03, Rockville, MD 20852, (301) 496–6155. You may also e-mail your request to *gb156i@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.

Paul L. Johnson,

Project Clearance Liaison, NICHD, National Institutes of Health.

[FR Doc. 04–26539 Filed 12–1–04; 8:45 am]

BILLING CODE 4140–01–P

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.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04–26540 Filed 12–1–04; 8:45 am]

BILLING CODE 4140–01–P

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.,