document on interpretation of the law, experience with CLIA complexity determinations, and comments and information from stakeholders.

The draft of this guidance was issued September 7, 2005 (70 FR 53231). FDA received and considered approximately 40 sets of comments on the draft guidance document. After taking the comments into consideration, FDA has updated the document to provide clarifications as needed. The guidance has also been revised to allow for additional supplementation of the actual patient specimens in the clinical study with alternative samples, preferably banked patient samples. The revised guidance recommends that, when neither patient specimens nor banked samples are available, it may be acceptable to supplement with other types of prepared samples, e.g., spiked, or diluted samples that mimic patient samples in terms of analyte and matrix. The revised guidance specifies that up to a total of one third of the clinical study samples may be supplemented with these types of alternative samples. The revised guidance also provides more flexibility in selecting the comparator method as well as more consistency in terms of the criteria for accuracy for waived tests as compared with moderate and high complexity tests.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on reporting results from studies evaluating diagnostic tests. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1171 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.fda.gov/ohrms/dockets/default.htm*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0598.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: January 22, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–1557 Filed 1–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Case-Cohort Study of Cancer and Related Disorders Among Benzene-Exposed Workers in China (OMB No. 0925–0454)

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:* Case-Cohort Study of Cancer and Related Disorders Among Benzene-Exposed Workers in China. *Type of Information Collection Request:* Emergency Extension. *Need and Use of Information Collection:* Since 1987, the National Cancer Institute has collaborated with the Chinese Academy of Preventive Medicine (currently designated Chinese Centers for Disease Control) in a factory-based investigation of cancer mortality and incidence of lymphohematopoietic disorders in a cohort of 75,000 and 36,000 comparison workers in 12 cities in China. Our initial study revealed elevated risks of leukemia, myelodysplastic syndromes, non-Hodgkin lymphoma, benzene poisoning, and lung cancer among the benzene-exposed workers. During the past five years, data have been collected to enable more precise quantification of risks of the malignancies and related disorders with an additional 12 years of follow-up of the subjects using a case-control study design. Cases included all workers from the exposed and unexposed groups who were diagnosed with leukemia, myelodysplastic syndromes, non-Hodgkin lymphoma and all other hematopoietic disorders; benzene poisoning; and lung cancer. Controls were frequency matched to cases and selected from the exposed (N=1200) and unexposed (N=300) cohort members. Data have been collected from factories, hospitals, and directly from interviews of all living and next of kin of deceased cases and controls. Information collected from the interviews focuses on potential confounding exposures including smoking, non-occupational benzene exposure, level of education, medical conditions, use of specific medications, and family cancer history. This study

will provide better understanding of occupational and environmental risks from benzene exposure in the United States. It will be important to complete all data collection for the study to realize the full scientific benefit of this 20 year international collaboration. However, due to unexpected and unforeseen personnel problems and training issues in China, the researchers are requesting an emergency extension of three months to complete data collection. A detailed plan has been discussed and developed with the collaborators in China to complete all remaining data collections in the next three months.

Frequency of Response: One-time study. *Affected Public:* Individuals or households.

Type of Respondents: Workers or their next of kin. The annual reporting burden is reported in the following table:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Workers	2156	1	[1].37	317
Total				317

[1] (22 minutes).

There are no Capital Costs to report. There are also no Operating 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) 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: Dr. Richard Hayes, Project Officer, OEB/EBP/DCEG/NCI 6120 Executive Blvd., EPS Room 8114, Bethesda, MD 20892–7364, or call non-toll-free number (301) 435–3973 or fax your request to (301) 402–1819 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 60-days of the date of this publication.

Dated: January 24, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E8–1550 Filed 1–29–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Complementary & Alternative Medicine; 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., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel, Training and Education.

Date: February 20, 2008.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Laurie Friedman Donze, PhD., Scientific Review Administrator, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–402–1030, *donzel@mail.nih.gov.*

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel, Clinical Studies on CAM.

Date: February 25–26, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Jeanette M. Hosseini, PhD., Scientific Review Administrator, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594–9096, *jeanetteh@mail.nih.gov.*

Name of Committee: National Center for Complementary and Alternative Medicine Special Emphasis Panel, Mechanisms of Immune Modulation.

Date: March 27–28, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Marriott Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20814.

Contact Person: Martina Schmidt, PhD., Scientific Review Administrator, Office of Scientific Review, National Center for Complementary & Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301–594–3456, *schmidma@mail.nih.gov.*

Dated: January 23, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 08–378 Filed 1–29–08; 8:45 am]

BILLING CODE 4140–01–M