hazards that are reasonably likely to occur. Interested persons were given until November 12, 2002, to comment on the draft guidance.

FDA received 11 written comments on the draft guidance document. The agency reviewed and evaluated these comments and has modified the guidance where appropriate.

The guidance document is being issued as level 1 guidance, consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the potential hazards that are associated with various juice products and processing operations, and how such hazards can be avoided using HACCP controls when the hazards are reasonably likely to occur, as required under part 120. 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 it 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 regarding this guidance document at any time. Two paper copies of any 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 guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Interested persons also may access the guidance document at *http://www.cfsan.fda.gov/guidance.html*.

Dated: February 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E4–452 Filed 3–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Pilot Study Evaluating the Cross-Cultural Equivalency of the Tobacco Use Supplement to the Current Population Survey (TUS–CPS)

SUMMARY: In compliance with the requirement of Section 3506()(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: Pilot Study Evaluating the Cross-Cultural Equivalency of the Tobacco Use Supplement to the Current Population Survey (TUS–CPS). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* NCI recognizes the need for research studies that assess trends in tobacco-related risk factors, behaviors, and health services to determine changes over time and the influence of these trends on cancer incidence, morbidity, mortality, and survival. Through population-based surveys, NCI is able to monitor a number of issues related to individual tobacco use behavior such as prevalence of use, how often and how much people use tobacco, age of initiation, and quitting history. To understand all the dynamics of tobacco control, NCI actively monitors the progress of tobacco control efforts that are primarily funded and carried out at the state level. Information from these surveys allow us to monitor Americans' progress in reducing tobacco use, evaluate tobacco use, evaluates tobacco control programs, and conduct other tobacco-related research. NCI monitors progress in reducing tobacco use, evaluates tobacco control programs, and conducts other tobacco-related research. The NCI- and CDC-sponsored Tobacco Use Supplement to the Current Population Survey (*http://riskfactor.cancer.gov/studies/tus-cps/*) is a survey of tobacco use that has been administered by the US Census Bureau in 1992–93, 1995–96, 1998–99, 2001–02 and 2003. The TUS–CPS is a key source of national and state level data on smoking and other tobacco use in the US household population because it uses a large, nationally representative sample that contains information on about 240,000 individuals within a given survey period. These data can be used by researchers to monitor progress in the control of tobacco use; conduct tobacco-related research; and evaluate tobacco control programs. In an effort to better capture the tobacco-related patterns and behaviors of U.S. communities with limited English proficiency, the TUS–CPS has been translated into Spanish, Chinese, Vietnamese and Korean. The translated versions of the TUS–CPS were evaluated in cognitive interviews, will be made available to the public, and are scheduled for cultural equivalency testing. The primary purpose of this study is to evaluate the cross-cultural equivalency of the TUS–CPS in English, Spanish, Chinese, Korean and Vietnamese. Each version of the questionnaire will be administered to 50 native speakers. The Chinese version will be administered to both mandarin and Cantonese speakers. Each interview will be behavior coded to ensure that respondents are interpreting the items correctly and any translation problems are identified item by item. Twenty percent of respondents will be retrospectively debriefed on the interview to determine how well the items are understood and examine whether any translation issues exist. The findings will provide valuable information concerning the clarity of the survey prior to full-scale administration.

Frequency of response: One-time study. *Affected Public:* Individuals. *Type of Respondents:* Adults who are native Chinese (Mandarin and Cantonese), Korean, Vietnamese, and Spanish speakers. The annual reporting burden is as follows:

Data collection task	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimate total hour burden
Screener	2,568	1	0.167	429
TUS–CPS	300	1	1	300
Retrospective Debriefing	60	1	.50	30
Total	2,568			759

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, (2q) 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. Deirdre Lawrence, Project Office, National Cancer Institute, EPN 4005, 6130 Executive Blvd., MSC 7344, Bethesda, MD 20892–7344, or call non-toll-free number 301–594–3599, or Fax your request to 301–435–3710, or E-mail your request, including your address, to: *DL177n@nih.gov.*

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

Dated: February 23, 2004.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04–4646 Filed 3–2–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

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 meeting.

The meeting 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Review of RFA: HL–04–007, ''Interventions to Improve Hypertension Control Rates in Africans Americans''.

Date: April 20, 2004.

Time: 8 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Double Tree Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Zoe Huang, MD, Health Scientist Administrator, Review Branch, Room 7190, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, MSC 7924, Bethesda, MD 20892–7924, 301–435–0314.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 25, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–4641 Filed 3–2–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Muscular Dystrophy Coordinating Committee.

the meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the contact person listed below in advance of the meeting.

Name of Committee: Muscular Dystrophy Coordinating Committee.

Date: March 22, 2004.

Time: 8:30 a.m. to 4 p.m.

Agenda: The Muscular Dystrophy Coordinating Committee (MDCC) is mandated by the MD–CARE Act to ''develop a plan for conducting and supporting research and education on muscular dystrophy through the national research institutes.'' The purpose of this meeting is to review and discuss a draft muscular dystrophy research and education plan for NIH.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, Maryland 20817.

Contact Person: Lorraine Fitzsimmons, Executive Secretary, Muscular Dystrophy Coordinating Committee, Director, Office of Science Policy and Planning, National Institute of Neurological Disorders and Stroke, NIH, 31 Center Drive, Room 8A023, MSC 2540, Bethesda, MD 20892, E-mail: *fitzsiml@ninds.nih.gov,* Phone: (301) 496–9271.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS).

Dated: February 25, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–4637 Filed 3–2–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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.,