TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Center	Subject	No. of Focus Groups per Study	No. of Focus Groups Sessions Conducted Annually	No. of Participants per Group	Hours of Duration for Each Group (includes screening	Total Hours
Center for Biologics Evaluation and Research	May use focus groups when appropriate	1	5	9	1.58	71
Center for Drug Evaluation and Research	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication	10	100	9	1.58	1,422
Center for Devices and Radiological	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves	4	16	9	2.08	300
Center for Food Safety and Applied Nutrition	Varies (e.g., food safety, nutrition, dietary supplements, consumer education)	8	40	9	1.58	569
Center for Veterinary Medicine	Varies (e.g., animal nutrition, supplements, labeling of animal Rx)	5	25	9	2.08	468
Total		28	186		1.78	2,830

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4655 Filed 3–2–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0333]

Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document related to the processing of juice entitled ''Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition.'' The guidance document supports and complements FDA's regulation that requires a processor of juice to evaluate its operations using Hazard Analysis Critical Control Point (HACCP) principles and, if necessary, to develop and implement HACCP systems for its operations. The guidance represents FDA's views on potential hazards in juice products and recommends how to control such hazards, and is designed to assist juice processors in the development of their HACCP plans.

DATES: You may submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Division of Dockets Management (HFA–305), 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022, e-mail: *mkashtoc@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 12, 2002 (67 FR 57829), FDA announced the availability of a draft guidance document entitled ''Draft Guidance for Industry: Juice HACCP Hazards and Controls Guidance, First Edition.'' Under FDA's HACCP regulations in part 120 (21 CFR part 120), juice processors are required to evaluate their operations using HACCP principles and, if necessary, to develop and implement HACCP systems for their operations. Under § 120.9, juice products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)), if a processor fails to have and implement a HACCP plan when one is necessary, or otherwise fails to meet any of the requirements of the regulations. The primary purpose of the guidance is to help processors of juice products evaluate the likelihood that a food safety hazard may occur in their product, and to guide them in the preparation of appropriate HACCP plans for those

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]

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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