Dated: April 18, 2003.

Lester M. Crawford,

Deputy Commissioner.

[FR Doc. 03–10150 Filed 4–23–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02P–0009]

Guidance for Industry: Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices.'' The purpose of the guidance is to provide industry with FDA's recommendations for appropriate control measures to use in the bulk transport of juice concentrates and certain shelf stable juices.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to Amy Green, Center for Food Safety and Applied Nutrition (*see* **FOR FURTHER INFORMATION CONTACT**). Send one self-addressed adhesive label to assist that office in processing your requests or include a fax number to which the guidance document may be sent. Submit written comments on the guidance document to the Dockets Management Branch (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 guidance.

FOR FURTHER INFORMATION CONTACT: Amy Green, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2025, FAX: 301–436–2651.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 7, 2002 (67 FR 62488), FDA announced the availability of a draft guidance document entitled ''Draft Guidance for Industry: Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices.'' The purpose of the draft guidance was to provide processors of juice concentrates and certain shelf stable juice products with recommendations for the use of appropriate control measures to ensure that juice concentrates and certain shelf stable juice products do not become contaminated or recontaminated with a microbial pathogen during bulk transport. Interested persons were given until December 6, 2002, to comment on the draft guidance.

In response to the draft guidance document, FDA received one letter from a State agency requesting that FDA require many of the draft guidance's recommended control measures in the guidance document. FDA disagrees with these requests. Under the agency's good guidance practices regulation (GGPs) (21 CFR 10.115), a guidance document is not legally binding on the agency or the public and mandatory words, such as ''shall,'' ''must,'' ''require,'' and ''requirement,'' are not to be used unless they describe or discuss a statutory or regulatory requirement. The purpose of the guidance document is to provide juice processors with recommendations, rather than requirements, pertaining to control measures that may be adequate for ensuring the safety of juice concentrates and certain shelf stable juices during bulk transport. While some juice processors may choose to adopt the State agency's suggested control measures (if such measures are effective), an alternate approach may be used if that approach offers an adequate level of protection from contamination or recontamination with a microbial pathogen during bulk transport. Therefore, FDA is not adopting in the guidance document any of the State agency's comments.

II. Conclusion

The agency is adopting as guidance the recommended control measures as presented in the draft guidance document. After carefully considering the comment from a State agency suggesting that FDA require in this guidance more stringent and prescriptive control measures for bulk transport, the agency has determined that no changes are warranted.

The guidance document is being issued as a level 1 guidance, consistent with FDA's GGPs (21 CFR 10.115). The guidance represents the agency's current thinking on appropriate control measures for bulk transport of juice concentrates and certain shelf stable juices to ensure that contamination or recontamination with a microbial pathogen during bulk transport does not occur. 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.

III. Comments

Interested persons may submit to the Dockets Management Branch (*see* **ADDRESSES**), written or electronic comments regarding this guidance document at any time. Two copies of any mailed comments are to be submitted, except that individuals may submit one 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

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

Dated: April 15, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–10074 Filed 4–23–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and

clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 340B Drug Pricing Program Survey—NEW

Section 340B of the Public Health Act provides that a manufacturer that sells outpatient drugs to covered entities must agree to charge a price that will not exceed the amount determined under a statutory formula. The entities eligible to access such drug pricing (*i.e.*, certain HHS grantees, certain disproportionate share hospitals, and other specified categories of entities) total approximately 10,000 sites. Most of these safety net providers serve the economically disadvantaged or medically uninsured.

A customer survey is being developed to collect information by mail on various aspects of the 340B Drug Pricing Program, including whether information on the program is reaching the covered entities, reasons some entities are not participating, satisfaction with the savings realized, and interest in possible modifications to the program. Both participating and nonparticipating entities will be included in the survey. The results will be used to improve the design and management of the program.

The estimated response burden is as follows:

Respondents	Number of respondents	Responses per respondent	Total responses	Minutes per response	Total burden hours
Covered Entities	1,000	1	1,000	.65	650

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 16, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–10075 Filed 4–23–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 Cancer Institute Special Emphasis Panel Cancer Control in Multiethnic Working Class Populations.

Date: June 1–3, 2003.

Time: 6 p.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: The Inn at Longwood Medical, 342 Longwood Ave., Boston, MA 02115.

Contact Person: Peter J. Wirth, PhD., Scientific Review Administrator, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8131, Bethesda, MD 20892–8328, 301–496–7565, *pw2q@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 17, 2003.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–10182 Filed 4–23–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, RFP No1–CP–31018–50: U.S. Radiologic Technologist Cohort.

Date: May 1, 2003.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852. (Telephone conference call.)

Contact Person: Kirt Vener, PhD, Branch Chief, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8061, Bethesda, MD 20892, (301) 496–7174, *venerk@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS.)

Dated: April 15, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–10189 Filed 4–23–03; 8:45 am]

BILLING CODE 4140–01–M