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In the **Federal Register** of October 7, 2002 (67 FR 62488), FDA announced the availability of a draft guidance document entitled ''Draft Guidance for Industry: Guidance on Bulk Transport of Juice Concentrates and Certain Shelf Stable Juices.'' The purpose of the draft guidance was to provide processors of juice concentrates and certain shelf stable juice products with recommendations for the use of appropriate control measures to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 Interested persons were given until December 6, 2002, to comment on the draft guidance.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