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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120
[Docket No. 97N-0511]

JR per
Ruth Pentecost

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice: Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to (insert *date 30 days after date of publication in the Federal Register*), the comment period for the proposal to require the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices and juice products (the juice HACCP proposal) that published in the **Federal Register** of April 24, 1998 (63 FR 20450). FDA is announcing the availability of the transcripts from two technical scientific workshops sponsored by FDA regarding implementation of the agency's warning statement requirement for fruit and vegetable juices and juice products. FDA is reopening the comment period for the juice HACCP proposal in order to receive comment on data and other information from the two technical scientific workshops. FDA is also reopening the comment period in order to receive comments and other information regarding the application of the 5-log pathogen reduction standard.

DATES: Written comments must be submitted by (*insert date 30 days after date of publication in the Federal Register*).

ADDRESSES: Submit written comments and requests for single copies of the transcripts to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5023.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 24, 1998 (63 FR 20450), FDA proposed to adopt regulations to ensure the safe and sanitary processing of fruit and vegetable juices and juice products. In addition, in the **Federal Register** of July 8, 1998 (63 FR 37030), FDA published a final rule requiring that juice products not specifically processed to destroy harmful bacteria (i.e., processed to achieve a 5-log reduction in the most resistant pathogen of public health concern) bear a warning statement informing consumers of the potential risk of foodborne illness associated with the product (the warning statement rule). The compliance date for the warning statement rule was September 8, 1998, for apple juice and apple cider; the compliance date for juices other than apple juice or apple cider was November 5, 1998.

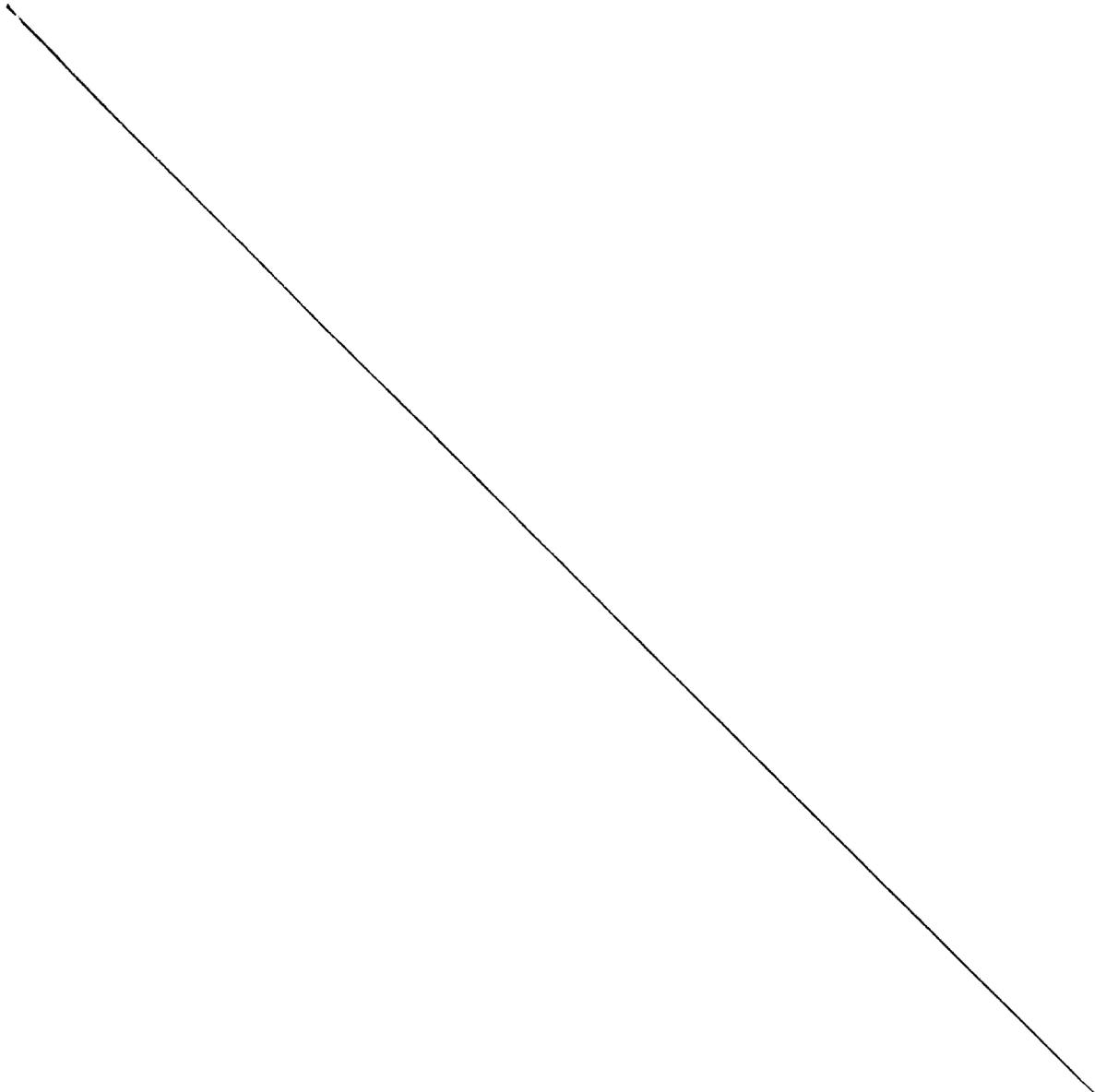
In the **Federal Register** of October 28, 1998 (63 FR 57594), FDA announced two technical scientific workshops to discuss and clarify issues related to the implementation of the warning statement rule for citrus juice products not specifically processed to destroy harmful bacteria. These workshops were held November 12, 1998, and November 19, 1998. Although the issues discussed in the workshops pertain to the implementation of the warning statement requirement, these issues also bear upon certain provisions of the HACCP proposal. FDA is announcing the availability of the transcripts from the two technical scientific workshops.

Interested persons were initially given until July 8, 1998, to comment on the HACCP proposal. On July 8, 1998 (63 FR 37057), in response to requests, the comment period was extended to August 7, 1998. FDA has decided to reopen the comment period to allow comment on data and other information that were presented at or developed as a result of these workshops to be included in the record of the HACCP rulemaking. In addition, FDA seeks comments on the application of the 5-log pathogen reduction standard. FDA requests comments on four specific topics: (1) Appropriate baselines for the calculation of the 5-log pathogen reduction; (2) feasible interventions

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or practices for the cultivation and harvest of fruits and vegetables, and acquisition of supplies and materials that may contribute to achieving a 5-log pathogen reduction; (3) feasible interventions for the production process that may contribute to achieving a 5-log pathogen reduction; and (4) acceptable methods for measuring and validating 5-log reductions.

To be considered, written comments must be received by (*insert date 30 days after date of publication in the **Federal Register***), by the Dockets Management Branch (address above). Two copies of any 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 23, 1998

November 23, 1998

William B. Schultz

William B. Schultz
Deputy Commissioner for Policy

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