## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket Nos. 97N-0511, 93N-0325, and 97N-0296]

RIN 0910-AA43

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; preliminary regulatory impact analysis; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) published in the Federal Register of April 24, 1998 (63 FR 20450), a proposed rule to ensure the safe and sanitary processing of fruit and vegetable juices and juice products. In addition, FDA published in the Federal **Register** of May 1, 1998 (63 FR 24254), the preliminary regulatory impact analysis (PRIA) and initial regulatory flexibility analysis (IRFA) on the costs and benefits of two FDA juice proposals, including one proposal to require the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juice and juice products (the juice HACCP proposal). Interested persons were given until July 8, 1998, to comment on the juice HACCP proposal

and the corresponding economic impact analyses. FDA has received a number of requests for an extension of the comment period. In response to these requests, the agency is extending the comment period until August 7, 1998, on the juice HACCP proposal and on those aspects of the PRIA and IRFA relevant to HACCP for juice and juice products.

**DATES:** Written comments must be received by August 7, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS– 158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 24, 1998 (63 FR 20450), FDA issued a proposed rule (the juice HACCP proposal) to ensure the safe and sanitary processing of fruit and vegetable juice and juice products. In addition, FDA published in the Federal Register of May 1, 1998 (63 FR 24254), the PRIA that it prepared under Executive Order 12866 and IRFA that it prepared under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement and Fairness Act, on the costs and benefits of the juice HACCP proposal and a related juice labeling proposal (63 FR 20486). FDA issued the juice HACCP proposal and the juice labeling proposal because of the recent outbreaks of

foodborne illness and deaths associated with the consumption of juice products that had not been pasteurized or otherwise processed to control pathogenic microorganisms.

Interested persons were given until July 8, 1998, to comment on the juice HACCP proposal and on those aspects of the PRIA and IRFA relevant to HACCP for juice and juice products. FDA has received a number of requests for an extension of the comment period. After evaluating these requests, the agency has decided to extend the comment period on the juice HACCP proposal and the corresponding economic analyses until August 7, 1998.

To be considered, written comments regarding the juice HACCP proposal and those aspects of the PRIA and IRFA relevant to the juice HACCP proposal must be received by August 7, 1998, 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 Docket No. 97N-0511 (juice HACCP proposal) and/or Docket Nos. 93N-0325 and 97N-0296 (juice HACCP aspects of the PRIA and IRFA), as appropriate. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 6, 1998.

## William K. Hubbard,

Associate Commissioner for Policy Coordination.

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