The proposed rule would authorize FDA to disclose confidential commercial information to international organizations, subject to the same safeguards against public disclosure of that information that apply in the case of disclosures to foreign government agencies and to disclose predecisional information to foreign governments under relaxed procedures. These disclosures would likely facilitate marketing review and approval of various FDA-regulated products in foreign countries, and disclosures would almost always occur only with the consent of the business that generated the confidential commercial information. This beneficial effect of the rule would outweigh any possible adverse impact. Thus, the agency certifies that this proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. FDA requests comment on this conclusion.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Interested persons may, on or before October 13, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 20 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 is revised to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Section 20.88 is amended by revising paragraph (e)(1)(i) to read as follows:

§ 20.88 Communications with State and local government officials.

* * * * *

(e)(1) * * *

(i) The State government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

* * * * *

3. Section 20.89 is amended by revising paragraph (d)(1)(i), by removing paragraph (d)(3), and by adding paragraph (e) to read as follows:

§ 20.89 Communications with foreign government officials.

* * * * *

(d)(1) * * *

(i) The foreign government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

* * * * *

(e) For purposes of this section, the term ''official of a foreign government agency'' includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government or by an international organization having responsibility to facilitate global or regional harmonization of standards and requirements in the Food and Drug Administration's areas of responsibility. For such officials, the statement and commitment required by paragraph (d)(1)(i) of this section shall be provided by both the organization and the individual.

Dated: July 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19898 Filed 7–24–98; 8:45 am]

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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; Correction

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of July 8, 1998 (63 FR 37057). The document extended the comment period on a proposed rule published in the **Federal Register** of April 24, 1998, to ensure the safe and sanitary processing of fruit and vegetable juices and juice products and on the related preliminary regulatory impact analysis and initial regulatory flexibility analysis published in the **Federal Register** of May 1, 1998. The document was published with an incorrect agency contact. This document corrects that error.

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, 202–205–4681.

SUPPLEMENTARY INFORMATION: In FR Doc. 98–18286, appearing on page 37057 in the **Federal Register** of Wednesday, July 8, 1998, the following correction is made:

1. On page 37057, in the second column, the agency contact is corrected to read ''**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, 202–205–4681.''

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19954 Filed 7–24–98; 8:45 am]

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