

The logo for the Juice Products Association features a stylized sunburst or starburst icon above the text "Juice Products" in a large, serif font. Below "Juice Products" is a horizontal line, and underneath that line, the word "ASSOCIATION" is written in a smaller, all-caps, sans-serif font.

Juice Products
ASSOCIATION

September 7, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Via Fax: 301/827 - 6870

RE: Food; Current Good Manufacturing Practice Regulations;
Public Meetings
[Docket No. 2004N-0230]

Dear Sir or Madam:

The Juice Products Association (JPA) is a trade association whose international membership consists of major packers and distributors of a wide variety of fruit and vegetable juices and juice beverages. Our members represent a significant majority of the juice and juice beverage processors in the United States. JPA submits the following comments on the Food and Drug Administration's (FDA) May 21, 2004 *Federal Register* (69 FR 29220) notice regarding review and modernization of the current good manufacturing practice (CGMP) regulations for food as defined in 21 Code of Federal Regulations part 110.

The CGMPs include provisions regarding food industry personnel; plants and grounds; sanitary facilities, controls and operations; equipment and utensils, warehousing, and distribution; and natural or unavoidable defect levels. These regulations help to ensure the safe and sanitary manufacturing, processing and holding of food for humans. JPA looks forward to reviewing specific details regarding the Agency's review of the CGMP regulations and proposed revisions. During this process, JPA believes the Agency should ensure the regulations remain flexible and broad and separate from any HACCP-type controls. In addition, the economic impact of any proposed changes should be considered. Our detailed comments follow.

JPA believes the CGMPs must provide flexibility to accommodate the variations that exist in food manufacturing. Food manufacturing facilities in the U.S. produce a variety of food products utilizing a myriad of processes. These facilities also differ in size with varying levels of resources available to them. New technologies and processes are continually being developed to ensure a safe food supply, and specifying methods would limit the food industry's ability to quickly adopt any emerging technologies. As such, the CGMP regulations should remain broad in scope and provide a general foundation for the manufacture of safe foods. It is also important to note that a number of foods are covered by other food safety regulations. For example, the

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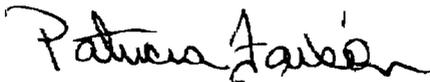
juice industry must comply with the juice Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR 120), which require in part, the development of sanitation standard operating procedures (SSOPs), a written hazard analysis and HACCP plan.

The FDA notes one area of Agency focus is potential hazards in the food supply, which include physical, chemical and microbiological hazards that may be present during the production or warehousing of food. In addition, several of the 11 questions posed by FDA mention preventive controls with regard to these hazards. JPA does not support the inclusion of HACCP-type controls in the CGMP regulations. HACCP is a comprehensive approach for managing food safety and is specific for each food product and each manufacturing facility. In addition, the CGMP regulations are a prerequisite program for HACCP. As noted above, the CGMP regulations should remain broad, which allows for flexibility in food manufacturing.

We encourage the FDA to consider the economic impact to large and small food manufacturers of any revisions to the CGMP regulations. If the Agency mandates certain training, recordkeeping, testing or audit programs as part of these regulations, manufacturers will bear the associated costs. Such costs should be closely weighed against the public health benefits.

JPA appreciates your consideration of these comments. We look forward to providing additional industry comments as details are provided by the Agency.

Sincerely,



Patricia Faison, M.S.
Technical Manager