

Processed Apples Institute

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April 1, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
e-mail: www.fda.gov/dockets/ecomments

RE: Prior Notice of Imported Food Under the Public Health Security and
Bioterrorism Preparedness and Response Act of 2002
Docket No. 02N-0278

The Processed Apples Institute (PAI) is a trade association composed of companies producing apple products: juices, sauces, flavors, essences, etc. Our members produce a major portion of the apple juice and applesauce manufactured annually in the United States. PAI submits the following comments on the Food and Drug Administration's proposed regulation: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was published in the February 3, 2003, *Federal Register* (68 FR 5428).

PAI believes that the scope of the information required to be submitted to the FDA is too broad and will create a burden on those firms that are required to submit the prior notice. We are concerned that due to the amount and nature of information required on the form, additional shipping time may be required forcing food companies to keep an excess of inventory on hand instead of relying on "just in time" shipments.

In addition, PAI is concerned about the requirement for grower information being included in the proposal. According to section 1.288 (g), the prior notice system is being developed to accommodate information on three growers. It is possible for as many as ten growers to supply apples to a juice manufacturer for processing. PAI recommends that the requirement for grower information be deleted from the proposal.

In addition, PAI believes there is a duplication of information required to be submitted to the FDA and to Customs. Section I of the prior notice proposal indicates that the U.S. Customs Service through its Automated Broker Interface (ABI) of the Automated Commercial System (ACS) currently provides entry information to the FDA. Information such as the entry type, the entry number (both ACS line number and FDA line identifier); the mode of transportation; the carrier code; the name and address of the manufacturer, shipper, importer, and ultimate

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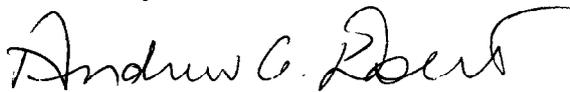
consignee; the country of origin, the FDA product code and quantity is currently being supplied to U.S. Customs and forwarded to the FDA. Section 1.287 of the proposal indicates that U.S. Customs is developing the Automated Commercial Environment (ACE) system and that the FDA intends to allow prior notice to be submitted through ACE when it becomes operational, which is not expected prior to 2005. However, there should be a data sharing system between Agencies in place prior to implementation of the proposal to prevent duplication of efforts.

The prior notice proposal is unclear on the procedures the FDA will follow if a product is refused admission due to untimely, inaccurate or incomplete prior notice. The proposal indicates in section 1.278 (b) that if a product is refused admission, it would be held at the port of entry unless FDA directs its removal to a secure facility. The prior notice proposal does not specify how the FDA will notify the purchaser or importing firm that the product has been detained. The FDA needs to establish a clear procedure for notifying the purchaser or importing firm when its product has been refused entry.

Attached are PAI's comments submitted to the Office of Management and Budget (OMB) regarding the data used to develop the estimated costs for implementing the proposal.

We appreciate your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Andrew G. Ebert". The signature is written in a cursive style with a large, sweeping initial "A".

Andrew G. Ebert
President

Attachment