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November 11, 2002

U.S. Food and Drug Administration
Dockets Management Branch
Room 1 - 23
12420 Parklawn Drive
Rockville, MD 20857

RE: Docket Number 02D-0333

Dear Gentlemen:

This letter represents Bowman Apple Products Company, Inc. comments and suggestions to the DRAFT Juice HACCP Hazards and Controls Guidance -First Edition. Bowman Apple Products is a privately held company that produces fresh pressed apple juice for bottling at its own facility or for sale in tankers. Additionally, apple juice concentrate is procured, reconstituted and bottled at our facilities.

First, we would like to express our appreciation to FDA for the guidance provided by this document and the opportunity to provide feedback. We find the document to be quite comprehensive. However, exception is taken to the following.

Section V. D. 1.3 refers to processors who make apple juice from purchased concentrate and their reliance on the producer's HACCP program for control of patulin levels. While an effective HACCP program should reduce patulin risk, we are concerned about non-United States regulatory monitoring and enforcement. This Country's consumers should be afforded the same high level of oversight for foreign concentrate products. Supplier guarantees along with a lot sampling program should be made a requirement for concentrate with a non-United States origin.

Section V. E. 1.1 refers to the physical hazard of glass fragments. The wording "anticipate that you will conclude that glass fragments are a hazard that is reasonably likely to occur" implies container breakage is a critical control point (CCP). By its nature this inference translates to a higher standard of justification for non-CCP treatment. We do not believe there is a basis for such an inference in clear or semi-clear liquids.

Once again thank you for the opportunity to comment. If you have questions, do not hesitate to contact me at (540) 477-3111.

Sincerely,


Benjamin H. Amoss
Executive Vice President

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