



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

94972d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

**WARNING LETTER
NWE-34-04W**

VIA FEDERAL EXPRESS

August 26, 2004

Vincent Savioli, Owner
American Fruit Distributors, Inc.
34 Market Street
Everett, MA 02149

Dear Mr. Savioli:

On July 19, 2004, Food and Drug Administration (FDA) investigators entered your food processing facility located at 34 Market Street, Everett, MA, during your firm's hours of operation for the purpose of conducting an inspection of your facility. Upon arrival at your facility, our investigators displayed their credentials and provided you with a written Notice of Inspection (Form FDA 482). In addition, our investigators provided you with a copy of FDA's guidance document, "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance for Industry." At that time, you refused to allow our investigators to conduct the inspection of your facility. On July 20, 2004, our investigators, accompanied by Special Agents of FDA's Office of Criminal Investigators and an Inspector from the State of Massachusetts, conducted an inspection of your facility.

Processors of food products are responsible for assuring that their overall operation and the products that they process and distribute are in compliance with the Federal Food, Drug, and Cosmetic Act (the Act). Section 704 of the Act, 21 U.S.C. 374, provides FDA investigators the legal authority to inspect food establishments to verify their compliance. Refusal to permit an inspection under Section 704 of the Act, upon presentation of official notice by appropriately identified FDA officers, is a prohibited act and exposes any person responsible for such refusal to criminal penalties under Section 301(f) and Section 303 of the Act, 21 U.S.C. 331(f) and 21 U.S.C. 333.

FDA lawfully attempted to inspect your food processing facility on July 19, 2004. This attempt was made at a reasonable time, within reasonable limits, and in a reasonable manner. Your refusal to permit a lawful inspection of your facility on that date is a prohibited action, as it violates Section 704 of the Act, and exposes you to potential

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criminal penalties. Failure to permit any future lawful inspection of your food processing facility may result in judicial action without further notice.

Please respond in writing within fifteen (15) working days from your receipt of this letter, and provide us with your written assurance that such actions will not recur. Correspondence concerning this matter should be directed to the Food and Drug Administration, One Main Street, 4th floor, Stoneham, MA 02180, Attention Ann Simoneau, Compliance Officer.

Sincerely yours,


Gail T. Costello
District Director