



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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Public Health Service  
Food and Drug Administration  
New York District Office  
850 Third Avenue  
Brooklyn, NY 11232-1593

Telephone: [718] 340-7000 [EXT 5301]

**WARNING LETTER**

APR 17 1998

**FEDERAL EXPRESS**  
**SIGNATURE REQUESTED**

Mr. Stanley Dick  
President  
Stanmar International, Inc.  
60 Columbia Way, Suite 300  
Markham, Ontario, Canada L3R 0C9

Ref: 25-NYK-98

Dear Mr. Dick:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On February 23, 1998, FDA attempted to collect samples of mango and youngberry juices at Tyler Distribution, 5-61 Bay Avenue, Elizabeth, NJ. These products were offered for admission into the United States under entry number 331-9633567-4, dated February 11, 1998. We were informed all 900 cases of the two items were distributed. Subsequently, on February 27, 1998 a portion of each product lot was returned to Tyler Distribution for FDA sample collection as follows:

ENTRY LINE#	PRODUCT	ORIGINAL QTY.	RETURNED QTY.
1-2	Youngberry juice	cases	35 cases
1-3	Mango juice	cases	31 cases

Mr. Stanley Dick, President  
Stanmar International, Inc.

The above 2 items were shipped throughout the month of February 1998, as evidenced by the Tyler Distribution's records (copy attached) without receiving clearance from the FDA.

This action taken by your firm is in violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release which merely permits you to take possession of the shipment. When other Federal agencies, such as FDA also exercise jurisdiction over a product offered for importation, their release must also be obtained before a product may be legally distributed.

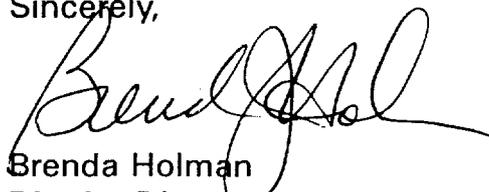
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice, such as seizure, injunction, or automatic detention to ensure that imported products are held intact until released by FDA. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the reoccurrence of the violation.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal or commercial information purged.

Your response should be addressed to the Food and Drug Administration, Attention: Joseph V. Sollazzo - Compliance Officer, Port Elizabeth Resident Post, 1201 Corbin Street, Port Elizabeth, New Jersey 07201 (telephone 1-732-645-2386 extension 20).

Sincerely,

  
Brenda Holman  
District Director  
New York District Office

Enclosure: February 1998 Distribution Records