



July 20, 1999

WARNING LETTER  
SJN-99-11

**Certified Mail**  
**Return Receipt Requested**

Ms. Nereida Malavé  
President  
Don Tomas Foods, Inc.  
P.O. Box 361164  
San Juan, PR 00936-1164

Dear Ms. Malavé:

On September 14 and 17, 1998, and on February 16 & 17, 1999, the Food and Drug Administration (FDA) conducted inspections of your fruit juice manufacturing facility, located at 4 St., Lot #10, Zona Industrial Las Palmas, Cataño, PR. Our Investigator collected samples of Don Thomas® Parcha/Passion Fruit juice and Don Tomas® Guayaba/Guava juice. Analysis of these two products manufactured by your firm reveals that the products are adulterated and misbranded within the meaning of sections 402 (c) and 403 (k) of the Federal Food Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), part 101 – Food Labeling, as follows:

1. The product Don Tomas® Parcha/Passion Fruit juice is adulterated and misbranded because it contains FD&C Yellow #5, which is not listed on the ingredient statement on the product label. This color must be declared on the label as a safe condition of use. The product also contains undeclared FD&C Red #40. This color must be declared in the ingredient statement as required by 21 CFR 101.22 (k)(1).
2. The product Don Tomas® Guayaba/Guava juice is misbranded because it contains FD&C Red #40, which is not listed in the ingredient statement on the product label as required by 21 CFR 101.22(k)(1).
3. Both products are misbranded because they contain sodium benzoate as a chemical preservative, which is not declared on the label as required by 21 CFR 101.22.

Nereida Malavé  
Page 2  
7/20/99

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Copies of revised labeling for the products should also be submitted. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the Food & Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Mary L. Mason, Compliance Officer.

Sincerely,



Mildred R. Barber  
District Director