



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, Florida 32809

HF 1-20
D1127B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-19

January 27, 1997

Reinaldo Navarro, Jr., President
Flan Lila's, Incorporated
12309 Southwest 130th Street
Miami, Florida 33186

Dear Mr. Navarro:

Inspection of your food manufacturing operation on January 3, 1997, by FDA Investigator Stephen J. Tunks, revealed serious violations of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and the Food Labeling Regulations promulgated in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), in conjunction with food products labeled by your firm.

Our review of your labels for Lila's Flan (25 and 4 ounce), Lila's Rice Pudding (16 and 5 ounce), and Lila's Tres Leche (5 ounce) reveals that the products are misbranded in that they fail to bear nutrition labeling as required by Section 403(q)(1) of the Act and 21 CFR 101.9. These products are not exempt from this requirement under Section 403(q)(5) of the Act, and have been labeled on or after May 8, 1996.

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies regarding food products labeled by your firm. Other label violations can also subject your food products to regulatory action. It is your responsibility to assure that all of your products are labeled in compliance with the Act, and the requirements of the food labeling regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, Ext. 263.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is fluid and cursive, with a long horizontal line extending to the right.

Douglas D. Tolen
Director, Florida District