



3/4/98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

Ref: Customs Entry No. M21-0713161-9
Product: Candy, Eggnog, Cheese and Chocolate

WARNING LETTER

FLA-98-26

February 3, 1998

Mr. Juan Colon
President, Dominican Products
1765 N.W. 17th Street
Miami, Florida 33125

Dear Mr. Colon:

The Food and Drug Administration (FDA) attempted to examine a shipment of candy, eggnog, cheese and chocolate offered for entry into the United States by your firm on December 23, 1997, under the above referenced entry number, and found that the shipment was not available. Regulation Title 21, Code of Federal Regulations (CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

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 of future shipments. 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.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Mr. Juan Colon
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Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, sweeping initial "D".

Douglas D. Tolen
Director, Florida District

Enclosure