



May 2, 1997

m 878 H

FOOD & DRUG ADMINISTRATION  
466 FERNANDEZ JUNCOS AVENUE  
SAN JUAN, P.R. 00901-3223

**WARNING LETTER**  
SJN-97-13

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Angel Rodríguez  
General Manager  
Rovira Biscuit Corp.  
101 Avenida Cuatro Calles  
Ponce, P.R. 00731-5517

Dear Mr. Rodríguez:

Our review of the labels for "Rositas" (Iced Gems) collected at your firm in Ponce, Puerto Rico, reveals this product to be misbranded within the meaning of section 403 of the Federal Food, Drug and Cosmetic Act and Title 21, Code of Federal Regulations, Part 101, Food Labeling, as follows:

"Rositas" (Iced Gems) is misbranded within the meaning of Section 403(a)(1) of the Act in that the label does not identify the source of vegetable shortening [e.g. vegetable shortening(soybean and cottonseed oil)] as required by 21 CFR 101(b)(14).

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure or injunction.

Please notify the San Juan District 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.

Your reply should be directed to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Avenue, San Juan, P.R. 00901-3223, Attention: Daniel Gonzalez, Compliance Branch Director.

Sincerely,

  
Samuel Jones  
District Director