



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
466 Fernandez Juncos Avenue
San Juan PR 00901-3223

Telephone: (787) 729-6842
FAX: (787) 729-6857

December 21, 1999

WARNING LETTER

SJN-00-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Osvaldo Acevedo, Owner
Fábrica de Flanes Acevedo
Manuel Ruiz González Street, #118
PO Box 726
Aguada, P.R. 00602

Dear Mr. Acevedo:

On September 23 & 29, 1999 the Food and Drug Administration (FDA) conducted an inspection of your food manufacturing facility located at Manuel Ruiz González St., #118 Aguada, Puerto Rico. Review of the inspectional information and labels for you products: vanilla custard, grape, strawberry, and orange gelatins, finds that they are adulterated and misbranded within the meaning of sections 402 and 403 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. A product that contains FD&C Yellow No. 5, but does not bear labeling stating so, is adulterated [402(c)]. Specifically, your 'Gelatina Acevedo' grape flavored gelatin is adulterated because it contains FD&C yellow No. 5, but the product labeling does not list it as an ingredient. This is a violation of the food additive regulations [21 CFR 101.22(k)(l)] because listing this color on the product label is a condition for safe use. People sensitive to this color, who consume your product, may become ill based on the absence of this declaration on the label.
2. A product that is made with two or more ingredients is misbranded if the labeling does not declare the common or usual name of each ingredient. Specifically, your "Gelatina Acevedo" grape, orange, and strawberry flavored gelatins are misbranded because they do not declare the common or usual name for each of the certifiable colors (e.g. FD&C Yellow No. 6, FD&C Red No. 40, FD&C Blue No. 1) used in the products, respectively. [403(i)(2) 21 CFR 101.4, and 21 CFR 101.22(k)(l)].

We also noted that none of the product labels contain a nutritional labeling statement. Regulations under 21 CFR 101.9 require that nutrition information be provided on the labeling for all food products. A list of exemption from this requirement is included in 21 CFR section 101.9 (j). If you believe your firm is entitled to an exemption from the nutritional labeling requirements, in accordance with the

Oswaldo Acevedo
December 21, 1999
Page 2

instructions found in 21 CFR 101.9 (j)(18), a notice of the reasons for such exemption should be filed to:

Office of Food Labeling
Center for Food Safety and Applied Nutrition
200 C St., S.W.
Washington, D.C. 20204

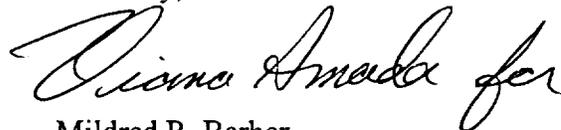
The above violations are not meant to be an all-inclusive list of deficiencies at your plant. It is your responsibility to assure that all your products are labeled in compliance with all applicable statutes enforced by the FDA.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify the San Juan District office in writing, within 15 working days of the 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 these or similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernández Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Sonia de la Torre, Legal Instruments Examiner.

Sincerely,



Mildred R. Barber
District Director