



July 20, 1999

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

WARNING LETTER
SJN-99-12

Certified Mail
Return Receipt Requested

Mr. Rolando Alvarez
President
Delogar Foods, Inc.
P.O.Box 10931
San Juan, PR 00922-0931

Dear Mr. Alvarez

On May 6, 11, & 12/99, an Investigator from this office of the Food and Drug Administration conducted an inspection at your candy and fruit paste manufacturer located at Road #2, Km. 17.2, Bo. Candelaria, Toa Baja, Puerto Rico 00959. During that inspection, copies of your "pilonos" lollypop and tropical fruit paste product labeling were obtained, and a FDA-483, Inspectional Observations form was issued to you. Review of your labels and the inspection evidence reported reveals serious violations of the Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR) Part 101 – Food Labeling and Part 110 – Good Manufacturing Practices, as follows:

1. Your products are adulterated within the meaning of Section 402(a)(4) of the Act because they were not manufactured in accordance with 21 CFR 110, Current Good Manufacturing Practices in Manufacturing, Packaging, and Holding Human Foods. Poor sanitation conditions and practices were observed such as; old, worn-out, and damaged plywood boards use as processing surface for foods, improper cleaning and storage of manufacturing utensils, and poorly sanitized and maintained equipment, walls, and floors. We refer you to FDA-483 issued to you by our investigator.

Pilonos

2. The product is misbranded within the meaning of Section 403(i)(1) and (i)(2) of the Act in that it fails to bear a label that contains the common or usual name of the food in accordance with 21 CFR 101.3; and the common or usual name of the ingredients in the food as required by 21 CFR 101.4.
3. The product is also misbranded within the meaning of Section 403(e)(1) and (e)(2) of the Act in that it fails to bear a label that contains the name and place of business of the manufacturer, packer, or distributor as required by 21 CFR 101.5; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count as required by 21 CFR 101.105.
4. The product is misbranded within the meaning of section 403(q)(1) of the Act in that the product fails to bear a label that provides mandatory nutritional information as required by 21 CFR 101.9.
5. The product is also misbranded within the meaning of 401(k) of the Act because its label fails to declare the presence of added colors, i.e., FD&C Red #40 and FD&C Yellow #6. Both FD&C Red #40 and Yellow #6 are certified colors that are required to be declared on the label in accordance with 21 CFR 101.22(k).

Delogar Paste and Polvorones

6. Several of your Delogar fruit paste products and the "Polvorones" Caribbean Cookies are misbranded within the meaning of Section 403(a)(1) and 403(k) of the Act in that they contain artificial vanilla and artificial almond flavor but their labels fail to state the presence of these ingredients as follows:
 - (a) The labels for Sweet Potato Paste (1.5 oz.), Sweet Potato with Pineapple (8 oz.), Sweet Potato with Almond (8 oz.), Sweet Potato with Coconut (8 oz.), (1.5 oz.) Papaya Paste (manufactured by Fabrica Mercado Foods, Inc., San German, PR for Delogar) and (1.0 oz.) "Polvorones" Caribbean Cookies (manufactured by Los Genuinos, Bayamon, PR for Delogar Foods Inc.) declare vanilla as an ingredient but these products actually contain artificial vanilla.
 - (b) The labels for "Polvorones" Caribbean Cookies and Sweet Potato with Almonds declare almond emulsion and vanilla as ingredients, however, these ingredients should be declared on the label as artificial almond flavor and artificial vanilla.
7. The Sweet Potato paste (8 oz.) is misbranded within the meaning of Section 403(i)(2) of the Act in that the product contains artificial vanilla as an ingredient but the label fails to declare artificial vanilla in the ingredient statement in accordance with 21 CFR 101.22.

We acknowledge receipt of your letter postmarked May 5, 1999 in which you state that you are evaluating the observations listed on the FD-483 and those brought to your attention during the inspection. In that letter you requested a prorogate period of one month before looking into corrective actions to the observations. Since then, we have not received any follow-up correspondence, and at the present time we are not aware of the implementation of any specific corrections.

The above violations are not meant to be an all-inclusive list of deficiencies at your plant. Other labeling violations can subject the food to legal action. It is your responsibility to assure that all of your products are properly labeled and that their labeling are in compliance with all applicable laws and regulations enforced by FDA.

You should take prompt action to correct these violations and prevent their future recurrence. Failure to promptly correct these violations may 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. Copies of revised labels for the specified products should also be submitted. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Andres Toro, Compliance Officer at 466 Fernandez Juncos Ave, Puerta de Tierra, San Juan, PR 00901. If you have any questions concerning the violations noted please contact the above named Compliance Officer at telephone number (787) 729-6894 ext. 2131.

Sincerely



Mildred R. Barber
District Director