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

September 19, 2002

WARNING LETTER  
SJN-02-14

**Certified Mail**  
**Return Receipt Requested**

Mr. Jose Antonio Gracia Reyes  
Owner  
Silgra Bakery, Inc.  
Carretera 836 Km 4.0  
Santa Isabel, PR 00757

Dear Mr. Gracia:

An Investigator from this office of the Food and Drug Administration (FDA) conducted an inspection on March 13, 14, 19 & 21, 2002 of your bakery located at the above address. Review of the inspectional information and labels for your candy products finds that the products 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), parts 101 and 110, as follows:

- 1) The product "Sabrosos Pilonos de Coco y Pina" coconut/pineapple flavored lollipops is adulterated under section 402(c) of the Federal Food, Drug, and Cosmetic Act (the Act) because the product contains FD&C Yellow No. 5, and the presence of that ingredient is not declared on the product's label. You must specifically declare the presence of FD&C Yellow No. 5 in the ingredient statement on your product's label to comply with 21 CFR 74.705(d)(2). The declaration of FD&C Yellow No. 5 as an ingredient is a condition for safe use of this color additive in food products.
- 2) The product "Sabrosos Pilonos de Coco y Pina" coconut/pineapple flavored lollipops is misbranded under section 403(i)(2) of the Act because the product contains certified color additives that are not declared in the ingredient statement. Under section 403(i)(2) and 21 CFR 101.22(k)(1), certified color additives must be individually declared in the ingredient statement by their common or usual names (e.g., FD&C Yellow No. 5, FD&C Yellow No. 6, FD&C Red No. 40). The product is further misbranded under section 403(i)(2) because it fails to list shredded coconut as an ingredient.

- 3) The products manufactured by your firm are also adulterated within the meaning of Section 402(a)(4) of the Act because they were manufactured under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health, as evidenced by the following:
- a) Extensive evidence of pests in your facility. The presence of pests can cause foods to become contaminated with filth, such as dead insects and rodent pellets.
  - b) The presence of inadequately labeled containers of color and flavor additives. Color and flavor additives used in the processing of candy were removed from their original containers and placed in plastic dishwasher soap containers without adequate labeling. This practice can lead to the accidental inclusion of a color or flavor in a finished food and may lead to harm if people who have an intolerance to the color or flavor consume the food.

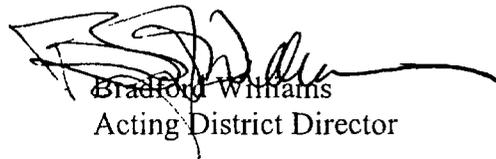
The above violations are not meant to be an all-inclusive list of deficiencies at your firm. Manufacturing and label violations can subject the food to legal action. It is your responsibility to assure that all of your products are manufactured and labeled in compliance with applicable statutes and regulations enforced by FDA.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could 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, including an explanation of each step being taken to prevent the recurrence of similar violations. Copies of revised labeling for the products should also be submitted. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the Food & Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Mary L. Mason, Compliance Officer.

Sincerely,

  
Bradford Williams  
Acting District Director