



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

HTF 35

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Food and Drug Administration
466 Fernandez Juncos Avenue
San Juan, Puerto Rico, 00901

Telephone: 787-474-9510
FAX: 787-729-6658

July 6, 2004

WARNING LETTER
SJN 04-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Miguel R. Domínguez
Owner
La Sabrosita Candy
Bahand Drive, Apt 305
Tampa, Florida 33613

Dear Mr. Domínguez:

On January 20, 21, and February 06 and 11, 2004, an investigator from the Food and Drug Administration conducted an inspection at your firm located at Carr. 181, KM. 9.5, Sector Aleman Medero, Dos Bocas, Trujillo Alto, Puerto Rico 00760. During this inspection, the investigator collected label samples of the following products:

- Dulce de Leche (Milk Candy) (1 oz and 6 oz)
- Dulce de Leche con Coco (Milk Candy with Coconut) (7 oz)
- Dulce de Leche con Guayaba (Milk Candy with Guava) (6 oz)
- Dulce de Coco (Coconut Candy) (1 oz)

Review of the product labels and inspectional evidence finds your candy products to be misbranded under Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act). The pertinent regulations are in Title 21, *Code of Federal Regulations*, Part 101 (21 CFR Part 101). The Act and regulations may be found on our website, www.fda.gov.

Your Dulce de Leche (6 oz), Dulce de Leche (1 oz), Dulce de Leche con Coco (7 oz), Dulce de Leche con Guayaba (6 oz), and Dulce de Coco (1 oz) products are misbranded under section 403(i)(2) of the Act, in that the products fail to declare all of the ingredients in the ingredient statement by their common or usual names, as required by 21 CFR 101.4(a). During the inspection, it was documented that all Dulce de Leche products contain both UHT Milk and powdered milk. Therefore, both ingredients must be listed in the ingredient statement separately and by their common or usual names.

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In addition, the label for your Dulce de Coco (1 oz) lists "Black Sugar" as an ingredient. The ingredient "Black Sugar" must be listed by its common or usual name in the ingredient statement.

Your Dulce de Leche product in 1 oz packages is misbranded within the meaning of section 403(i)(1) of the Act because its label fails to bear the appropriate common or usual name of the food. Unlike your Dulce de Leche product in 6 oz packages, the Dulce de Leche product in 1 oz packages contains guava as an ingredient. Hence, the 1 oz size must be labeled with an appropriately descriptive name that differentiates it from the 6 oz size by mentioning the guava ingredient [21 CFR 101.3(b)(3)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. Other violations can subject the products to legal action. It is your responsibility to ensure that all products distributed by your firm are in compliance with all applicable statutes and regulations enforced by the FDA.

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

In addition to the violations listed above, we wish to comment on two other labeling violations that were discussed with you during the January-February 2004 inspection. Your labels bear information both in English and Spanish, but not all information required to be on the label appears in both languages. For example, the nutrition information on your Dulce de Leche (6 oz) product appears only in English, but the statement of identity (product name), ingredient list, and net weight appear only in Spanish. According to 21 CFR 101.15(c), product labels may bear information exclusively in English, or, for products distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, exclusively in the predominant language (in this case, Spanish). Bilingual labeling is also permitted, provided that all information required to be on the label appears in both languages. Because your product labels use both English and Spanish, you must include all required information in both.

Furthermore, during our inspection we found that your Dulce de Leche (1 oz) and Dulce de Leche con Guayaba (6 oz) products contained a color additive subject to certification (i.e., FD&C Red No. 40) which was not declared on the products' labels. Failure to declare certified color additives causes a product to be misbranded under sections 403(i)(2) and 403(k) of the Act and may also cause the product to be adulterated under section 402(c) of the Act (depending on whether the regulation authorizing use of the color additive in food requires it to be declared on the label of the food as a condition of safe use). We note, however, that your firm has taken immediate corrective action to address this labeling issue by including a sticker on the existing labels stating that the products contain FD&C Red No. 40. We also note you stated your plans to declare the FD&C Red No. 40 on your new labels after your current stock of labels is depleted. For your information, under 21 CFR 101.22(k)(1), color additives subject to certification must be individually declared in the ingredient statement by their common or usual names (e.g., FD&C Red No.40). The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Red 40).

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Please notify this office in writing, within fifteen (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 fifteen (15) days, state the reasons for the delay and the time at which the corrections will be completed.

Your written reply should be addressed to the Food and Drug Administration, attention: Carlos I. Medina, 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) 474-9539.

Sincerely,



Donald J. Voeller
District Director
San Juan District

Enclosures

cc:

Juan F. Dominguez
General Manager
La Sabrosita Candy
PO Box 594
St. Just, PR 00978