DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

San Juan District
Compliance Branch
466 Fernández Juncos Ave.
San Juan, Puerto Rico 00901
Telephone: 787-474-9500
FAX: 787-729-6658

March 7, 2007

WARNING LETTER
SJN-07-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Elliot Cianchini, President
Tres Leches Factory
Valles del Lago 1036
Caguas, Puerto Rico 00725

Dear Mr. Cianchini:

This letter is in reference to the inspection of your facility located at Road 156, Building # 1, Local # 3, Caguas Oeste Industrial Park, Caguas PR 00725, on November 15-20, 2006, by an investigator from the U.S. Food and Drug Administration (FDA). During the inspection, labels of several of your products were collected. Our review of your labeling and other evidence collected by the investigator indicates serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR). You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

Your [redacted] Cheese Cake De Guayaba (guava cheesecake), Tres Leches Factory chocolate chip cookies, and Tres Leches Factory coconut candy kisses (besitos de coco) are misbranded under Section 403 of the Act, as specified below.

Ingredient Labeling

1. Your [redacted] Cheese Cake De Guayaba product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. 343(i)(2)] because it is fabricated from two or more ingredients and its label fails to declare all of the ingredients in the food by their common or usual names as required by 21 CFR 101.4(b). The label of this product declares the following ingredients in Spanish: cream cheese, sugar, eggs, vanilla, lemon, guava filling, corn starch, and water. However, according to the product formulation records our investigator collected

during the inspection, the label omits a number of the ingredients in this product (e.g., margarine and water, among others).

Under 21 CFR 101.4(b)(2), "sub-ingredients" (i.e., component ingredients of multi-component foods used to make a finished food) must be declared in the ingredient statement of the finished food. For example, the label of the bulk guava filling used in your product lists the following ingredients: guava puree, sugar, pectin, citric acid, sodium benzoate, potassium sorbate and FD&C Red No. 40. However, some of these sub-ingredients are not listed on your finished product label as required by 21 CFR 101.4(b)(2). The requirement to declare sub-ingredients may be met by either parenthetically listing the component ingredients after the common or usual name of the multi-component ingredient (in this case, the guava filling), or by listing the component ingredients without listing the multi-component ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

Further, your product is also misbranded under section 403(k) of the Act because it contains undeclared artificial coloring. As noted above, the guava filling used in your [redacted] Cheese Cake De Guayaba contains FD&C Red No. 40, which is a certified color additive [see 21 CFR 74.1340(d)]. Under 21 CFR 101.22(k)(1), a certified color additive must be individually declared in the ingredient statement by the name specified in the color additive's listing regulation (in this case, FD&C Red No. 40). The name of the color additive may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Red 40).

2. Your chocolate chip cookies and coconut candy kisses bearing the Tres Leches Factory label are misbranded within the meaning of section 403(i)(1) of the Act [21 USC 343(i)(1)] in that the product labels fail to bear the common or usual name of the food [see 21 CFR 101.3]. These products are also misbranded within the meaning of section 403(i)(2) of the Act [21 USC 343(i)(2)] in that their labels fail to bear a list of the ingredients in the food. The product's ingredients must be listed by their common or usual names in descending order of predominance by weight on either the principal display panel or the information panel of the product label, as required by 21 CFR 101.4(a)(1). According to information gathered by our investigator during the inspection, the Tres Leches Factory label is used on products packaged for sale at your retail location, including, but not limited to, chocolate chip cookies and coconut candy kisses. This generic label includes only your company name, logo, license number, and the phone numbers of your manufacturing and retail facilities; it does not provide any of the product-specific information required by the Act.

Allergen Labeling

Further, your [redacted] Cheese Cake De Guayaba product is misbranded within the meaning of section 403(w) of the Act [21 U.S.C. 343(w)] in that the label fails to declare all major food allergens present in the product, as required by section 403(w)(1). Section 201(qq) of the Act [21 U.S.C. 321(qq)] defines as major food allergens milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

1. The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredient, [section 403(w)(1)(A) of the Act, 21 U.S.C. 343(w)(1)(A)],
or
2. The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen) [section 403(w)(1)(B) of the Act, 21 U.S.C. 343(w)(1)(B)].

Guidance on the allergen labeling requirements in section 403(w) may be found on FDA's website at www.cfsan.fda.gov/~dms/wh-alrgy.html.

The label of your [redacted] Cheese Cake De Guayaba declares cream cheese as an ingredient. Milk is a component of cream cheese (see 21 CFR 133.133); however, the label of [redacted] Cheese Cake De Guayaba fails to declare milk as required by the Act. Further, according to the formulation information we obtained during the inspection, this product also contains graham cracker cookie. If the graham cracker cookie is made from flour and the flour is made from wheat, your label must also declare "wheat" as required by the Act.

Other Required Information

Further, your products listed above are misbranded under section 403(e)(2) of the Act [21 U.S.C. 343(e)(2)] because the product labels fail to declare the net quantity of contents as required by 21 CFR 101.105. In addition, your products are misbranded under section 403(e)(1) of the Act because the product labels fail to specify the place of business of the manufacturer, packer, or distributor as required by 21 CFR 101.5.

You should take prompt action to correct the violations described above. Failure to correct the violations promptly may result in enforcement action without further notice, including seizure and/or injunction.

This letter is not intended to be an all inclusive review of your products and their labeling. You are responsible for ensuring that your business operates in compliance with the Act and applicable regulations.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations and to prevent similar violations. You should include in your response documentation for our evaluation of your corrective actions. If you cannot complete all corrections within 15 working days, we expect you to explain the reasons for your delay and state when you will correct any remaining deviations.

In addition, our investigator issued a Form FDA-483, Inspectional Observations, at the end of the November 2006 inspection, and he discussed these observations with you at that time. The observations listed on the FDA-483 pertained to good manufacturing practices (GMP) to protect food from contamination, and not to the labeling violations listed above. During the discussion with our investigator, you promised immediate corrective action to address the GMP observations. We will verify the implementation of these corrections during a future establishment inspection.

For your information when revising your product labels, please note the following:

- Section 403(q) of the Act [21 USC 343(g)] requires packaged foods to bear nutrition labeling unless the food qualifies for an exemption. Your products currently do not bear nutrition labeling. The exemptions from nutrition labeling are described in 21 CFR 101.9(j).

- Product labels that use both English and Spanish must include all required information in both languages. For example, your Cheese Cake De Guayaba label bears information both in English and Spanish, but not all information required to be on the label appears in both languages. Products intended to be distributed in the Commonwealth of Puerto Rico may be labeled solely in Spanish [21 CFR 101.15(c)(1)]. However, if the product label contains any representations in English, then all information required to appear on the label must appear in both Spanish and English [21 CFR 101.15(c)(2)].

Please send your reply to the Food and Drug Administration, Attention: Miguel A. Hernandez, Compliance Officer. If you have questions regarding any issue in this letter, please contact Mr. Hernandez at 787-474-9519.

Sincerely,

Jorge L. Gonzalez
Acting District Director

Enclosure: FDA 483