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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

San Juan District
Compliance Branch
466 Fernandez Juncos Avenue
San Juan, Puerto Rico 00901-3223

Telephone: 787-474-9500
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September 14, 2004

WARNING LETTER
SJN-04-14

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Elena Lopez
President/Owner
E. Franco & Co.
Calle Manuel Pirallo # 3
Mayagüez, Puerto Rico 00680

Dear: Ms. Lopez:

This letter is in reference to the inspection of your facility located, at Calle Manuel Pirallo # 3, Mayagüez, Puerto Rico 00680on April 19 thru 22, 2004 by an Investigator from the U.S. Food and Drug Administration .

During that inspection, copies of your pastry product label and samples of your Guava Filled Rolls (Brazo Gitano con Guayaba) were obtained. An FDA-483, Inspectional Observations, was issued and our investigator discussed the observations with you. This inspection documented violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR). You can find the Act and FDA regulations through links on FDA's home page at www.fda.gov.

We have reviewed the inspectional observations and your product labels and have identified numerous violations of the Act and applicable regulations. These violations cause your products to be adulterated or misbranded, as discussed below.

Manufacturing Practices
At the conclusion of the inspection, you were issued Form FDA-483 which delineated a number of significant insanitary conditions present at your facilities at the time of the inspection. These conditions cause products manufactured in your facility to be adulterated under Section 402(a)(4) of the Act in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth,

or may have been rendered injurious to health. Objectionable conditions observed include the following:

- Failure to exclude pests from the food plant [21 CFR 110.35(c)] Specifically:
  - Two live cockroaches were observed in direct contact with the metal trays used to hold batter for baking and cooling, which were previously prepared for the next day's production.
  - Fifteen beetles were observed inside one tray filled with white flour that was stored uncovered on a shelf in the baking production area. Seven beetles were walking over the flour.
  - Approximately twenty-five dead cockroaches were observed on the floor below the counters in the production area.
  - Four dead cockroaches were observed in the baking and filling area.
  - Five dead cockroaches were observed on the floor of the pastry cooling, frosting and cutting area.
  - Fifteen dead cockroaches were observed on the floor of the wine and beverage storage area.

- Failure to hold foods that support the growth of undesirable microorganisms in a manner that prevents the foods from becoming adulterated [21 CFR 110.80(b)(3)]. Specifically:
  - The refrigerator located in the production area had an internal temperature reading of 50°F. This refrigerator is used to store finished products such as rolls filled with any of the following: Bavarian Crème, cream cheese, pineapple, or any fruit filling combined with cream cheese. Refrigerators holding these particular foods should be kept at or below 45 degrees [21 CFR 110.80(b)(3)(i)] .

- Failure to store and dispose of rubbish to minimize the potential for waste becoming an attractant and harborage or breeding place for pests [21 CFR 110.37(f)]. Specifically:
  - An uncovered garbage disposal area containing garbage bags, boxes, and old plastic, wooden, or metal containers, was observed in the plant storage area.
  - Approximately four dozen empty and uncovered pails with old encrusted raw filling material were stored in a wooden closet without a roof located between two storage freezers.

- Failure to provide adequate screening or other protection against pests [21 CFR 110.20(b)(7)]. Specifically:
  - The two doors in the baking and filling areas that open to an unscreened exterior patio have a gap between them of approximately two inches.
  - The windows located in the storage area and leading to the street do not have screens.

- The door in the storage area that leads to the street had a gap between the door and the floor of approximately 5 feet wide and 4 inches high
- The door in the storage area that leads to the street was found open during the first day of inspection

- Failure to store raw materials under conditions that will protect against contamination and minimize deterioration [21 CFR 110.80(a)(1)]. Specifically:
  - On April 19, 2004, one kettle containing guava filling, for use as an ingredient on April 20, 2004, was observed partially uncovered in the baking and filling area.
  - On April 19, 2004, two brown paper bags, each containing approximately 20 lbs of white flour used as an ingredient on April 20, 2004, were observed unlabeled and uncovered in the baking and filling area.

- Failure to design and use equipment so as to preclude the adulteration of food with lubricants and contaminants [21 CFR 110.40(a)]. Specifically:
  - Tubes, a pulley, and the seams of the mixer equipment were covered with a lubricant and were located directly above an uncovered kettle containing guava ingredient. The lubricant used is not food grade.

- Failure to take necessary precautions to ensure persons working in direct contact with food, food contact surfaces, and food packaging materials conform to hygienic practices to protect against contamination of food [21 CFR 110.10(b)]. Specifically:
  - [redacted] were observed wearing jewelry, such as earrings and/or neck chains in the production area.
  - None of the employees in the production area were wearing hair nets.

Color Additives

- Your Brazo Gitano with guava filling that is made with a vanilla flavored batter is adulterated under section 402(c) of the Act because the lemon emulsion concentrate used in the batter contains the ingredient FD&C Yellow No. 5, which is not declared on the finished product label. You must specifically declare the presence of FD&C Yellow No. 5 in the ingredient declaration on your product labels to comply with Title 21 Code of Federal Regulations (21 CFR) section 74.705(d)(2). In addition, the specific declaration of FD&C Yellow No. 5 is a condition for safe use of the color additives in food products.

- Your Brazo Gitano with guava filling is also misbranded under section 403(i)(2) because certified color additives must be individually declared in the ingredient statement by their common or usual names (e.g., FD&C Yellow No. 5, which is in the batter, and FD&C No. 40, which is in the guava filling) (see 21 CFR 101.22(k)(1)).

Food Labeling

- Your Brazo Gitano with guava filling is further misbranded under section 403(i)(2) of the Act, in that the package fails to list the common or usual name of each ingredient. These ingredients must be listed in descending order of predominance by weight on either the principal display panel or the information panel as required by 21 CFR 101.4(a)(1). Specifically, none of the ingredients contained in the filling are listed in the ingredient statement and not all of the ingredients in the batter (e.g., the white vanilla flavor, lemon emulsion concentrate, vegetable lard, butter and honey ingredients) are listed in the ingredient statement. In addition, ingredients which themselves contain two or more ingredients must also be declared in the ingredient statement, in accordance with 21 CFR 101.4(b)(2). For example, all of the sub-ingredients in the enriched flour, butter, baking powder, and lemon emulsion concentrate must be listed in the ingredient statement.

We also note that the ingredient statement on the package lists as ingredients mantequilla, manteca vegetal and Amarillo vegetal (translated by FDA into English as margarine, vegetable butter and yellow vegetable, respectively) ; however, these ingredients are not described in the product formulation

- Your Brazo Gitano with guava filling is misbranded under section 403(k) of the Act in that the label fails to declare the presence of the preservatives potassium benzoate and potassium sorbate.

We note that you informed the investigator who inspected your facility that the nutrition information is only provided on your Brazo Gitano with guava filling rolls that are sold to [redacted] You should be advised that all of your products that are intended for human consumption and offered for sale must bear nutrition information in accordance with section 403(q)(1) of the Act, unless an exemption is provided for the products (see 21 CFR 101.9(j)). Nutrition information must be presented on the label in one of the formats described in 21 CFR 101.9(d).

We do not object to your method of indicating the flavor and filling type of your Brazo Gitano rolls by marking a box(es) on the side panels. However, please note that the ingredients contained in each of the flavors of your Brazo Gitano rolls should also be clearly indicated on the product label.

[See section 505.100 of FDA's Compliance Policy Guide 7102.01, which can be found at http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg505-100.html]

For example, FDA considers it misleading to use the same ingredient statement on your Brazo Gitano vanilla flavor with guava filling and on your Brazo Gitano chocolate flavor with coconut filling. You may wish to consider an alternative means of compliance with

the ingredient labeling requirements, such as the use of a sticker label that bears the ingredient statement that corresponds to the roll flavor and filling type that is indicated on the side panels of your product package. If you choose this course of action, we remind you that the sticker label should adhere to the package and be placed on the principal display panel or the information panel.

Please note that we have only reviewed the labels for the Brazo Gitano rolls with guava filling. You must ensure that the labels for all of your products meet the applicable labeling requirements.

Failure to promptly correct these violations and prevent future violations may result in regulatory action without further notice, such as seizure or injunction. As a food manufacturer, it is your responsibility to ensure that your products meet all of the requirements of the Act and the regulations.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violations listed above, including an explanation of each step being taken to prevent the recurrence of the violations. Your written reply should be addressed to the Food and Drug Administration, Attention: Carlos I. Medina, Compliance Officer, 466 Fernandez Juncos Avenue, San Juan, and Puerto Rico 00901.

Sincerely,

for DJV

Donald J. Voeller
District Director
San Juan District

Enclosures