



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94590d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

March 22, 2004

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-21

Akram Joudi, President
Dreamland, Inc.
1125 North 152nd Street
Shoreline, Washington 98133

WARNING LETTER

Dear Mr. Joudi:

The Food and Drug Administration (FDA) conducted an inspection of your firm located at 1125 North 152nd Street, Shoreline, Washington, on December 11, 2003. During that inspection, our investigator collected labels for various products and found them to be in violation of Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21 of the Code of Federal Regulations 21 CFR Part 101- Food Labeling. You can find this Act and the food labeling regulations through links in FDA's homepage at <http://www.fda.gov>.

The deviations are as follows:

1. Your Hummos and Baba Ghannouj products are misbranded within the meaning of section 403(q)(1) of the Act in that the labels bear nutrition information that is not in the formats specified in 21 CFR 101.9. The labels for your Hummos products and your Baba Ghannouj contain nutrition information but it is not in one of the formats specified by current regulations. Furthermore, the small business exemptions under 21 CFR 101.9(j)(1) and 101.9(j)(18) do not extend to products with labels that bear nutrition information or nutrition claims. Therefore, if you voluntarily provide nutrition information on your Hummos and Baba Ghannouj products, it must be in one of the formats specified in 21 CFR 101.9.
2. Your Falafel Sandwich and Spinach Pie are misbranded within the meaning of section 403(i)(2) of the Act in that they are fabricated from two or more ingredients, but the labels fail to bear the common or usual name of each ingredient in the products as specified in 21 CFR 101.4. Your Falafel Sandwich label does not declare pita bread, the pita bread sub-ingredients, or the oil that is used for the deep fried ground garbanzo beans. Your spinach pie label does not declare the ingredients that are in the "homemade flour dough" or properly declare the oil ingredients (see 21 CFR 101.4(b)(14)). The ingredients that make up a multi-component ingredient, unless exempt under 21 CFR

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101.100, must also be included in the ingredient statement in one of the manners specified in 21 CFR 101.4(b)(2).

3. Your Baba Ghannouj and Hummos products are misbranded within the meaning of section 403(e) of the Act in that the labels fail to bear the name and place of business of the manufacturer, packer or distributor. The product labels identify "Middle Eastern Specialty Food by Saleh Al Lago." Since Dreamland Incorporated, not Saleh Al Lago, is the manufacturer of this food, the name of the responsible firm declared on the label must either be listed as Dreamland Incorporated, or must be qualified by a phrase that reveals the connection of the named person (in this case, Saleh Al Lago) to the food, e.g., "distributed by" (see 21 CFR 101.5). During the inspection, the investigator determined that Saleh Al Lago restaurant, which is the location where you previously manufactured your products, is no longer in business.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels or in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes and regulations enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. Furthermore, if you have any questions regarding any issue in this letter, please contact Lisa M. Elrand at (425) 483-4913.

Sincerely;



Charles M. Breen
District Director

Enclosures:

Section 403 of the FD&CA Act

cc: WSDA with disclosure statement