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JUN 13 2002

WARNING LETTER

SJN-02-10

Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

Certified Mail
Return Receipt Requested

Mr. Plinio Alfaro
General Manager
Dulces de Aqui
P.O. Box 6238
Caguas, PR 00726

Dear Mr. Alfaro:

During our inspection of your firm from February 26 to March 5, 2002, we evaluated your manufacturing and labeling of Queso del Pais and Antipasto De Aqui containing tuna. During this inspection, our Investigator documented violations from the Federal Food, Drug, and Cosmetic Act (the Act), the Public Health Service Act (PHS Act), and federal regulations promulgated under both laws. The violations concerning your firm's Queso del Pais soft cheese and Antipasto De Aqui containing tuna are as follows:

Queso del Pais soft cheese:

We observed significant deviations during manufacturing that cause your soft cheese to be adulterated within the meaning of section 402(a)(4) of the Act and the federal regulation promulgated thereunder at Title 21, Code of Federal Regulations (CFR), Part 110 – “Current Good Manufacturing Practice for Manufacturing, Packing or Holding Human Food”, and section 361 of the PHS Act and the federal regulation promulgated thereunder at Title 21 CFR Part 1240 - “Control of Communicable Diseases.”

You must heat every particle of milk used to manufacture soft cheese, a milk product as defined under 21 CFR 1240.3(j), to assure pasteurization as described and required by 21 CFR 1240.61 - “Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.” Also, 21 CFR 110.80(a)(2) requires that your raw materials, such as raw milk, must not contain levels of microorganisms that may produce food poisoning or other diseases in humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated. However, during our inspection, you stated that your firm's standard practice is to receive 55 gal. containers of raw milk and manually transfer a portion (approximately 50% of each container) into heating equipment. The heat-treated portion is then mixed with the other 50% of the raw milk remaining in the container, which is not heat-treated. This milk is subsequently used to manufacture your firm's soft cheese. Furthermore, the inspection revealed that the processing equipment

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used to heat half of the milk did not have temperature recording or indicating devices, and you stated that you do not manually check the processing temperatures during heat processing of the raw milk.

During the inspection, our investigator collected in-line and finished product samples of the product El Criollito® Queso del Pais. FDA's Southeast Regional Laboratory examined these samples for microbiological contamination and the results were sent to your firm by letter dated April 18, 2002 (copy attached). The finished product sample (FDA sample 165313) contained alkaline phosphatase in two sub samples at 1106.358 ug/g and 933.576 ug/g phenol equivalents. The presence of phosphatase at these levels in your soft cheese demonstrates inadequate pasteurization of milk.

1. Water that your firm uses which contacts food or food-contact surfaces must be safe and of adequate sanitary quality, to comply with 21 CFR 110.37(a). In addition, your firm's plumbing must be of adequate design and adequately installed and maintained to avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition, to comply with 21 CFR 110.37(b)(3). However, during the inspection, the nozzle of a water hose used for cleaning equipment and work areas was submerged in a metal pot filled with water and neither the hose nor the faucet attached to the hose was equipped with a back-flow prevention device. Further, none of the three faucets supplying water to the manufacturing were equipped with back-flow prevention devices.

We also observed significant labeling violations for your firm's El Criollito® Queso del Pais soft cheese that cause your product to be misbranded under section 403 of the Act:

- 1. The label fails to bear the name and place of business of the manufacturer, packer, or distributor as required by section 403(e)(1) and 21 CFR 101.5.
- 2. The label fails to bear the common or usual name of each of the ingredients in the food as required by section 403(i)(2) and 21 CFR 101.4. For example, liquid coagulant is added to the milk; however, liquid coagulant is not listed in the ingredient statement by its common or usual name.

Antipasto De Aqui containing tuna

We also found that your firm has a serious seafood HACCP deficiency that causes your ready-to-eat antipasto product containing tuna, a scombrototoxin-forming fish, to be adulterated within the meaning of section 402(a)(4) of the Act and the federal regulation promulgated thereunder at 21 CFR 123.11(c) as follows:

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1. You must have sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records.

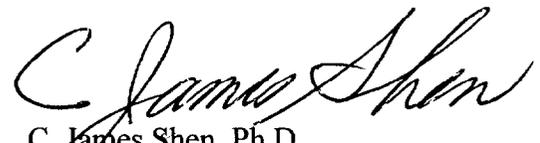
Moreover, your firm's Antipasto De Aqui product is misbranded under section 403(i)(2) of the Act because it fails to bear the common or usual name of each ingredient in the food. Each ingredient used in the product must be listed in the ingredient statement by its common or usual name and in descending order of predominance by weight to comply with 21 CFR 101.4(a)(1). In addition, the label for the Antipasto product lists tomato sauces in the ingredient statement. According to the EIR, the sauces are the standardized food ketchup and the ingredient with the common or usual name of tomato sauce. Both of these foods (ketchup and tomato sauce) are fabricated from two or more ingredients. However, the ingredient statement for this product fails to bear the common or usual name of each ingredient in the ketchup and tomato sauce as required by 21 CFR 101.4(b)(2).

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,



C. James Shen, Ph.D.
Acting District Director