



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

July 22, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 29

Larry D'Amico
President
D'Amico & Partners, Inc.
211 North First Street
Minneapolis, Minnesota 55401

Dear Mr. D'Amico:

On April 1, 2, and 3, 2003, the Food and Drug Administration (FDA) inspected your facility, D'Amico and Sons, Inc., located at 2210 Hennepin Avenue South, Minneapolis, MN. During the inspection our investigator collected samples of product labels for your Tuna sandwich, Chicken sandwich, Roast Turkey sandwich, Turkey and Pesto sandwich, Roast Beef sandwich, Vegetable sandwich, Low Fat Mediterranean Vegetable Wrap, Low Fat Portobello Mushroom and White Bean Wrap, Cheese Tortellini salad, Turkey and Dried Cherries salad, Smoked Chicken and Roasted Peppers salad, and Fresh Fruit Cup, all of which you manufacture for retail sale by . A copy of the label for Prep Tuna Salad Base, which you manufacture and sell to was also collected.

Our review of these labels reveals that the products are misbranded pursuant to Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and the Food Labeling regulations through links in FDA's homepage at www.fda.gov.

The above named products, except for Fresh Fruit Cup, are misbranded under Section 403(i)(2) of the Act in that the labels fail to list all of the ingredients by their common or usual names. Each of these products, except for Fresh Fruit Cup, contains at least one ingredient that is composed of two or more ingredients that must be declared. For example, the mayonnaise (used in the Tuna Sandwich) and

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the tortellini (used in the Cheese Tortellini salad) each contain two or more ingredients that must be declared as required by 21 CFR 101.4(b)(2).

Undeclared ingredients in your products include wheat flour, eggs, milk, and soy, which are known allergens. Undeclared ingredients that are known allergens are of particular concern to the agency. FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans, and derivatives of these products.

These products are also misbranded under Sections 403(e)(1) and 403(e)(2) of the Act. The product labels (except for that on the Prep Tuna Salad Base) fail to declare the name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5); the Prep Tuna Salad Base label declares the name of the manufacturer, but not the place of business. These products (except for the Prep Tuna Salad Base) also fail to declare an accurate statement of the quantity of contents in terms of weight, measure, or numerical count (21 CFR 101.105).

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the misbranding violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and a reasonable time within which the corrections will be completed.

Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure or injunction.

ADDITIONAL COMMENTS

During the label review, we found that your Low Fat Mediterranean Vegetable Wrap and Low Fat Portobello Mushroom and White Bean Wrap bear the nutrient content claim "Low Fat." This claim is defined by regulation and requires, in part, that the food contain 3 grams or less fat per Reference Amount Customarily Consumed (RACC) (21 CFR 101.62). The RACC for sandwiches is 140 grams (21 CFR 101.12(b)). In accordance with 21 CFR 101.13(q)(5)(ii), we request your basis for a "low fat" claim on these foods.

Since you process foods containing tuna, the inspection was also conducted to determine your compliance with the Food and Drug Administration's fish and fishery products regulations (21 CFR 123) and the current good manufacturing practice (CGMP) regulations for foods (21 CFR 110).

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The fish and fishery products regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Points (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. Prudent processors already take these kinds of measures. HACCP provides a systematic way of taking those measures that demonstrate to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety-oriented workforce, less product waste, and fewer problems generally.

During our inspection we found shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. At the conclusion of the inspection, Investigator Sedzielarz issued you a copy of the Domestic Seafood HACCP Report (form FDA-3501) and the form FDA-483 which presents his evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The observations of concern to us are as follows:

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (b). However, your firm does not have a HACCP plan for Tuna Salad and Tuna Salad Sandwiches to control the food safety hazards of Histamine Formation and Pathogen Growth and Toxin Formation. Both of these hazards are linked to the product you process. In addition, if your sandwiches are packaged in modified atmosphere packaging or reduced oxygen packaging, you must also address the hazard of *Clostridium botulinum* in your HACCP plan. Chapters 7 and 12 of the Fish and Fisheries Products Hazards and Controls Guidance can help you determine the best methods for controlling these hazards.

You must maintain sanitation control records that, at a minimum, document your monitoring and corrections, to comply with 21 CFR 123.11(c). However, for the processing of Tuna Salad or Tuna Salad Sandwiches, your firm did not maintain sanitation monitoring records for the eight key areas of sanitation listed in 21 CFR 123.11 (b).

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with our preliminary assessment of deviations from the seafood HACCP regulations, you should explain how your system identifies hazards and implements controls in a manner that complies with the regulations. We

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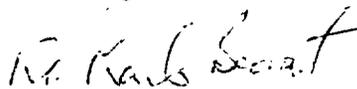
understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards.

If you respond to the HACCP deficiencies listed in this letter, you may include that response with your response to the misbranding issues, or you may respond separately. After we receive your response, we will work with you to resolve any outstanding issues associated with your HACCP system.

This letter does not represent a comprehensive review of all of the products distributed by your firm, nor does it represent a complete review of all product labeling. As president, you are responsible for ensuring that all products distributed by your firm are in compliance with the Act and its implementing regulations.

Please forward your response to the attention of Compliance Officer Brian D. Garthwaite, Ph.D., at the address in the letterhead. If you have any questions, you may contact Dr. Garthwaite at (612) 758-7132.

Sincerely,



W. Charles Becoat
Director
Minneapolis District

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