



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to FEI: 3001549123

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Food and Drug Administration
Baltimore District Office
Central Region
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454
FAX: (410) 779-5705

03-BLT-05

December 11, 2002

WARNING LETTER

VIA CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Mr. Robert L. Williamson, Owner/Partner
Virginia Seafood, LLC (dba) Outer Banks Seafood
11179 Hopson Road, Unit #4
Ashland, Virginia 23005

Dear Mr. Williamson:

The Food and Drug Administration (FDA) inspected your firm, located at 11179 Hopson Road Unit #4, Ashland, Virginia 23005, on September 3 and 11, 2002. During the inspection, samples of three (3) product labels were collected. Review of the labels found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Part 101, Food Labeling (21 CFR Part 101), as follows:

HATTERAS ISLAND CRAB DIP AND SPICY CRAB DIP

These products are misbranded within the meaning of Section 403(c) of the Act, in that they are an imitation of another food and their labels failed to include, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated as set forth in 21 CFR 101.3(e). Specifically, your "crab dip" products actually contain imitation crabmeat as the main ingredient. Thus, examples of lawful product names would be "Hatteras Island Imitation Crab Dip" and "Spicy Imitation Crab Dip."

Your Hatteras Island Crab Dip and Spicy Crab Dip products are also misbranded within the meaning of section 403(i)(2) of the Act because their labels fail to declare the component ingredients of all of the products' compound ingredients as required by 21 CFR 101.4(b)(2). For example, your Hatteras Island Crab Dip product contains cream cheese, mayonnaise, and imitation mozzarella cheese, but the label does not declare the component ingredients from which cream cheese, mayonnaise, and imitation mozzarella cheese are made. Your Spicy Crab Dip product also does not declare the component ingredients of its cream cheese, imitation cheddar cheese, and mayonnaise ingredients, such as milk and eggs. Declaration of the milk and egg components in the cheese and mayonnaise ingredients is of particular concern because they are allergenic substances. 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 allergenic responses are milk, eggs, fish, crustacea, tree nuts, wheat, peanuts, soybeans and derivatives of these products.

Further, these products are misbranded within the meaning of Section 403(e) of the Act, in that they do not list the place of business of the manufacturer, packer, or distributor, as set forth in 21 CFR 101.5(a).

SMOKED SHRIMP SPREAD

Your Outer Banks Seafood Shrimp Spread product is misbranded within the meaning of Section 403(i)(1) of the Act because the product does not bear the common or usual name of the food. The statement of identity, “Smoked Shrimp Spread,” is not an appropriate common or usual name for this product because it implies that the product is made of smoked shrimp (see 21 CFR 101.22(h)(6)). The recipe for this product indicates that the product is actually made of shrimp and liquid smoke flavoring.

This product is also misbranded within the meaning of section 403(i)(2) of the Act because the label fails to declare the component ingredients of all of its compound ingredients as required by 21 CFR 101.4(b)(2). For example, the product contains cream cheese and mayonnaise, but the label does not declare the component ingredients from which cream cheese and mayonnaise are made, such as milk and eggs. Declaration of the milk and egg components in the cheese and mayonnaise ingredients is of particular concern because they are allergenic substances, as discussed above. For sensitive individuals, the presence of allergens in food is potentially life threatening. In addition, the liquid smoke flavoring that you use to flavor the product is not declared in the ingredient statement as required by 21 CFR 101.4 and 21 CFR 101.22(h)(6).

This product is also misbranded within the meaning of Section 403(e) of the Act, in that it does not list the place of business of the manufacturer, packer, or distributor, as set forth in 21 CFR 101.5(a).

The above violations concern certain labeling requirements and are not meant to be an all-inclusive list of deficiencies of your labels. For example, during review of the labels, it was noted that the value expressed in grams, in parenthesis, following the net weight of 6 ounces is incorrect. Your labels declared a value of 227 grams when in fact the correct gram value for 6 ounces is 170 grams. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration (FDA).

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such regulatory action may include seizure and/or injunction.

You should 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. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

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Your reply should be directed to Jose R. Hernandez, Compliance Officer, 10710 Midlothian Turnpike, Suite 424, Richmond, VA 23235. If you have any questions concerning the violations noted please contact Mr. Hernandez at (804)379-1627, extension 15.

Sincerely,



LB Lee Bowers,
Director, Baltimore District

cc. Virginia Department of Agriculture
and Consumer Services
Division of Consumer Protection
Office of Dairy and Food
1100 Bank Street, Suite 510
Richmond, Virginia 23219