



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

San Juan District Office  
466 Fernandez Juncos Avenue  
San Juan, Puerto Rico, 00901

Telephone: 787-474-9510  
FAX: 787-729-6658

April 17, 2007

**WARNING LETTER**  
**SJN-07-05**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Won Young Kim  
President  
STM Trading Corporation  
3<sup>rd</sup> Street Lots #10, 11, 12, 13  
Hato Tejas Industrial Park  
Bayamon, PR 00961

Dear Mr. Kim:

We inspected your seafood processing facility, located at 3<sup>rd</sup> St. Lots# 10, 11, 12, and 13 Hato Tejas Industrial Park Bayamon PR on December 4-8, 2006. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a) (4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a) (4). Accordingly, your sushi and surimi products are adulterated, in that they have been prepared, packed, or held under unsanitary conditions whereby they may have been rendered injurious to health.

In addition, after careful review of your product labels, we found your products to be misbranded and in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act). You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

Your significant violations were as follows:

**Seafood HACCP:**

You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur, and you must have and implement 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(s) for the preparation of your ready-to-eat seafood products, such as sushi and surimi based products, to control the food safety hazards of pathogen growth and toxin formation.

**Labeling Deviations:**

**Ingredient Listing**

- Your [ ] and [ ] are misbranded under sections 403(i)(2) and 403(k) of the Act [21 U.S.C. 343(i)(2) and 343(k)] because they contain artificial colors that are not declared on the product label. Under 21 CFR 101.22(k)(1), certified color additives must be individually declared in the ingredient statement by the name specified in the listing regulation for the color additive (e.g., 21 CFR 74.340 for FD&C Red No. 40). The name may be abbreviated to omit the "FD&C" prefix and the abbreviation "No." (e.g., "Red 40" instead of "FD&C Red No. 40"). Specifically, the ingredient statement for your [ ] does not list Yellow 6 and Red 40, which are listed as ingredients of the smoked salmon used in the [ ]. Under 21 CFR 101.22(k)(2), noncertified color additives may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as "Colored with \_\_\_\_" or "\_\_\_\_ color", the blank to be filled with the name of the color additive listed in the applicable regulation in 21 CFR Part 73. Specifically, the ingredient statement for your [ ] does not declared the presence of annatto, paprika and carmine. We note that, under 101.22(a)(2), paprika and other spices which are also colors shall be declared as "spice and coloring" unless declared by their common or usual name.
- Your [ ] is further misbranded under section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)] in that the label contains the statement "No added MSG." The "fish cake" ingredient contains MSG, making your labeling false.
- Your [ ] and [ ] are misbranded under section 403(i)(2) of the Act [21 USC 343(i)(2)] because they are formulated with two or more ingredients, but their labels fail to bear the common or usual name of each ingredient as required by 21 CFR 101.4.

- Your [ ] ingredient statement declares "imitation crab" and your [ ] ingredient statement declares "smoked salmon." The imitation crab and smoked salmon are multi-component ingredients, which themselves contain two or more ingredients; however, the ingredient statement on your products does not declare the component ingredients of the salmon or imitation crab, as required by 21 CFR 101.4(b)(2). This requirement may be met by either parenthetically listing the component ingredients after the common or usual name of the multi-component ingredient (in this case, the imitation crab and smoked salmon), or by listing the component ingredients without listing the multi-component ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the multi-component ingredient; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food.

For example, according to information provided during the inspection, the ingredient label for the imitation crab (Fish Cake) lists in part Pollack, water, egg white, wheat starch, sugar, sorbitol, and salt. According to the smoked salmon label, it contains in part salmon, salt, sugar, and natural smoke.

- Cream cheese is listed as a single ingredient in your [ ] however, it is a food for which a definition and standard of identity has been prescribed by regulation (21 CFR 133.133) and it is an ingredient which contains two or more component ingredients.
- During the inspection the investigator noted that dried seaweed is used in your [ ] and [ ] however, it is not declared in the ingredient statement of either product. [21 CFR 101.4(a)(1)]

#### Allergen labeling

Your [ ] and [ ] are misbranded within the meaning of section 403(w) of the Act [21 U.S.C. 343(w)] in that the labels fail to declare all major food allergens present in those products, as required by section 403(w)(1). Section 201(qq) of the Act [21 U.S.C. 321(qq)] defines a major food allergen as milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils. A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

1. The word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredient, [section 403(w)(1)(A) of the Act, 21 U.S.C. 343(w)(1)(A)],

or

2. The common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list

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appears as part of the name of an ingredient that is not a major food allergen) [section 403(w)(1)(B) of the Act, 21 U.S.C. 343(w)(1)(B)].

For tree nuts, fish, or crustacean shellfish, the term, "name of the food sources from which the major food allergen is derived," means the name of the specific type of nut or species of fish or crustacean shellfish. [Section 403(w)(2), 21 U.S.C. 343(w)(2)].

Guidance on the allergen labeling requirements in section 403(w) may be found on FDA's website at [www.fda.gov](http://www.fda.gov).

Your food labels fail to declare the following major food allergens as specified by the Act:

- Egg: Your  contains egg white, which is a sub-component of the fish cake.
- Pollack: Your  contains Pollack which is the species of fish.
- Milk: Your  contains milk, which is a subcomponent of the cream cheese.

#### Product Identification

Your products are further misbranded under section 403(e)(2) of the Act [21U.S.C. 343(e)(2)] in that your products fail to declare an accurate statement of the quantity of contents in terms of weight, measure, or numerical count. [21 CFR 101.105]

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

You should 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 violations. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation (21 CFR Part 123) and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

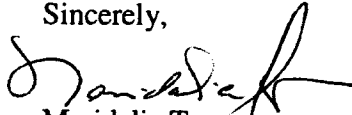
We note that section 403(q) of the Act [21 USC 343(q)] requires a packaged food to bear nutrition labeling unless it qualifies for an exemption. Your products currently do not bear nutrition labeling. The exemptions to nutrition labeling are described in 21 CFR 101.9(j). We recommend that you review those exemptions to ensure that your products qualify for an exemption.

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We also note that the ingredient statement for both products declares the presence of several multi-component ingredients as follows: "Includes Soy Sauce, Wasabi, and Ginger." The component ingredients of each of these multi-component ingredients must be declared as part of the ingredient statement.

Please send your reply to the Food and Drug Administration, Attention: Margarita Santiago, Compliance Officer, 466 Fernandez Juncos Avenue, San Juan, Puerto Rico, 00901-3226. If you have questions regarding any issues in this letter, please contact Ms. Santiago at 787-474-4789.

Sincerely,

A handwritten signature in black ink, appearing to read "Maridalia Torres", with a long horizontal flourish extending to the right.

Maridalia Torres  
District Director  
San Juan District

Enclosure: FDA 483