



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

g1059d

Telephone: 425-486-8788
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March 27, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-41

James W. Beattie, President
Cucina Fresca, Inc.
5605 Martin Luther King Way South
Seattle, Washington 98118

WARNING LETTER

Dear Mr. Beattie:

We inspected your firm located at 5605 Martin Luther King Way South, Seattle, Washington, on January 29 and February 7, 2001, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your seafood products, including smoked salmon ravioli and ginger/shrimp ravioli, to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations of concern were as follows:

1. 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(b). Your firm does not have a HACCP plan for smoked salmon ravioli and ginger/shrimp ravioli to control the food safety hazard of allergens in the labeling of these seafood products. Our investigators noted that these products contain numerous allergens including: dairy (cheeses), eggs, seafood, and wheat ingredients. The lack of a HACCP plan was brought to your attention during our last inspection on October 18 and 23, 2000, and in a letter to you from the FDA dated December 13, 2000.

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2. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records for all eight areas of sanitation. This violation has also been ongoing since your last inspection and documented in the December 13, 2000 letter to you. You could not provide our investigators with monitoring records for the following eight areas of sanitation:
 - a. Safety of water;
 - b. Condition and cleanliness of food contact surfaces;
 - c. Prevention of cross-contamination;
 - d. Maintenance of hand washing, hand sanitizing, and toilet facilities;
 - e. Protection from adulterants;
 - f. Proper labeling, storage, and use of toxic compounds;
 - g. Control of employees with adverse health conditions; and
 - h. Control of pests.

3. In accordance with 21 CFR 110, our investigators noted six (6) sanitation deficiencies occurring on one and/or both days of the inspection. These deficiencies included: (1) missing end caps from tube light covers; (2) flaking product/paint residues on hood over stove; (3) lack of towels in employee restrooms; (4) employee handling unclean objects while making product, without proper hand sanitizing; (5) open soda can stored in cooler near open containers of ingredients; and, (6) old product residues under processing equipment. A similar sanitation hand-washing deficiency, was observed during the previous inspection and addressed in the December 13, 2000 letter to you.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. 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.

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For your information, our investigators collected labels from your bulk-packed and retail-sized packages. We have reviewed these labels and find that your bulk-packed pasta labels do not collectively contain: firm name, location, product, ingredients, and weight. These labels must be designed in regulation with 21 CFR 101.4, 101.5, and 101.105. In addition, your retail-sized labels fail to list sub-ingredients in accordance with 21 CFR 101.4 and net contents in accordance with 21 CFR 101.105. The FDA also maintains a list of small businesses requesting exemptions from nutritional labeling requirements of conventional foods. As of March 5, 2001, we observed that your firm is not on that list. In accordance with 21 CFR 101.9, nutrition information relating to food shall be provided for on all products intended for human consumption and offered for sale, unless an exemption is provided for the product as specified in 21 CFR 101.9(j).

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

Sincerely,

for 
Charles M. Breen
District Director

Enclosures:
Form FDA 483
21 CFR Parts 101.4, 101.5, 101.9, 101.105, 110, and 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with Disclosure Statement