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December 2, 1999

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

Telephone: 425-486-8788
FAX: 425-483-4996

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-22

Marian I. Puariea, Co-Owner
Marian's Kitchen
1763-A Center Street
Tacoma, Washington 98409

WARNING LETTER

Dear Mrs. Puariea:

On October 14 and 15, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1763-A Center Street, Tacoma, Washington. At the conclusion of the inspection, you were presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations Part 123 (21 CFR 123) - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the clam chowder processed by your firm is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR 123.

1. There is no HACCP plan for clam chowder produced at your firm. Our investigator conducted a hazard analysis and identified pathogens as a food safety hazard that is reasonably likely to occur. 21 CFR 123.6(b) requires processors to have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. The HACCP plan must at a minimum:
 - a. list the food safety hazards that are reasonably likely to occur;
 - b. list the critical control points for each of the identified food safety hazards;
 - c. list the critical limits that must be met at each of the critical control points;
 - d. list the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
 - e. include any corrective action plans to be followed in response to deviations from the critical limits at critical control points;
 - f. list the verification procedures, and frequency thereof, that will be followed to verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur; and

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- g. provide for a record keeping system that documents the monitoring of the critical control points.

2. No one at your facility has received HACCP training or has an equivalent knowledge of the HACCP principles presented at the HACCP training. 21 CFR 123.10 requires that the following functions be performed by an individual who has successfully completed training in the application of HACCP principles or who is otherwise qualified through job experience to perform these functions:
 - a. developing a HACCP plan;
 - b. reassessing and modifying the HACCP plan; and
 - c. performing the HACCP monitoring record review.

3. Your firm does not have a program that adequately monitors the sanitation procedures in your plant. There were no records to show monitoring in the following areas:
 - a. safety of the water that comes into contact with food or food contact surfaces;
 - b. condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
 - c. prevention of cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces;
 - d. maintenance of hand washing, hand sanitizing, and toilet facilities;
 - e. protection of food, food packaging material, and food contact surfaces from adulterants;
 - f. proper labeling, storage, and use of toxic compounds;
 - g. control of employees with adverse health conditions which could result in the contamination of food, food packaging materials, and food contact surfaces; and
 - h. exclusion of pests from the food plant.

21 CFR 123.11(b) and (c) require you to monitor eight areas of sanitation listed above and to maintain records of that monitoring and any corrections made as a result of that monitoring. 21 CFR 110 lists the current good manufacturing practices (GMP's) that you are required to follow.

During the previous inspection, on March 29 and 31, 1999, and in a letter from the FDA, dated April 30, 1999, you were notified of the same deficiencies described in points numbered 1 through 3 of this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in seven months time your firm has not taken action to correct these deficiencies.

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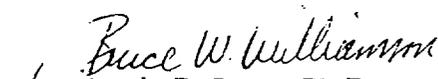
The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

During the March 29 and 31, 1999, inspection by the FDA of Marian's Kitchen, a sample of the labeling for "Marian's Classic Clam Chowder", which is distributed by your firm, was collected for review. Our review found the label had a number of deficiencies. A subsequent inspection by FDA on October 14 and 15, 1999, found continuing labeling deficiencies.

The labeling deficiencies observed concern the statement of ingredients for "Marian's Clam Chowder". It was noted that the label fails to declare each ingredient by its common or usual name in descending order of predominance by weight, as required by regulations. Adequate declaration of ingredients, which themselves contain two or more ingredients, either provides a parenthetical listing of all components by common or usual name, or incorporates into the ingredient statement the common or usual name of the components without listing the ingredient itself. The ingredients of "Marian's Clam Chowder" that are not adequately declared are the ingredients of the "chowder base" to include the following: Partially Hydrogenated Vegetable Oil (may contain one or more of the following oils: Soybean, Coconut and Cottonseed), Lowfat Milk, Natural and Artificial Flavorings, Butter, Salt, Sodium Caseinate, Sugar, Textured Soy Protein, Maltodextrin, and Dehydrated Vegetables (Carrots, Celery, Onions, Tomatoes, and Parsley).

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 1000 2nd Avenue, Suite 2400, Seattle, Washington 98104.

Sincerely,


for Austin R. Long, Ph.D.
Acting District Director

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Enclosures:

Form FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
WSDA