



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M37521

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

Telephone: 425-486-8788
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May 10, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-43

James Shefler, President
South Bend Packers, Inc.
808 Marine Drive
Port Angeles, Washington 98362

WARNING LETTER

Dear Mr. Shefler:

We inspected your firm located at 237 West Robert Bush Drive, South Bend, Washington, on August 17-18, 1999, and found that you have serious deviations from Title 21 of the Code of Federal Regulations Part 123 (21 CFR 123) - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy enclosed) listing the deviations was presented to Diane Raymond, Vice President, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your fresh tuna, frozen breaded salmon, cooked ready to eat, and cooked frozen Dungeness crab processed by your firm 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 were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for:
 - Fresh tuna to control the food safety hazard of *Scambrotoxin* (*histamine formation*), and
 - Frozen breaded salmon tenders to control the food safety hazards of *Staphylococcus aureus* toxin formation in hydrated batter mixes and food additives (Allergens-Wheat, Soy products, etc.).

During the previous inspection, on September 4, 1998, and in a letter from the FDA, dated April 13, 1999, you were notified of the same deficiencies described in point number one of this letter. During the inspection, and in the letter, the FDA explained that you would

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need to take steps to correct this deficiency. The FDA is concerned that in eleven months time your firm has not taken action to correct this deficiency.

2. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(2). Your firm's HACCP plan for Dungeness Crab (cooked, frozen/cooked, ready-to-eat) does not list the critical control points of:
 - Receiving for controlling the food safety hazard of *Natural toxins (PSP)* for your unviserated product.
 - Picking for controlling the food safety hazard of *Pathogen growth and toxin formation* for your picked crab meat; and
 - Cooler Storage for controlling the food safety hazard of *Pathogen growth and toxin formation* for Cooked, Ready-to-eat products.
3. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records. Of the [REDACTED] processing days identified in 1999, only 17 days of sanitation monitoring records have been completed.
4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor exclusion of pests with sufficient frequency to ensure control as evidenced by:
 - Live flies, too numerous to count, directly above the cooked crab product in the processing area, and
 - Insectecutors located in the processing rooms not having catch traps and located directly above the processing table.
5. When a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection that person has with the product, such as "Manufactured for____" "Distributed by____", in order to comply with 21 CFR 101.5(c). Specifically, your frozen breaded salmon tenders are misbranded because the labels state, "GOLD RIVER FOODS, INC.", but do not include a phrase to reveal the connection that Gold River Foods, Inc. has with the salmon tenders.

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 Good Manufacturing Practice regulations (21 CFR Part 110). We may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide

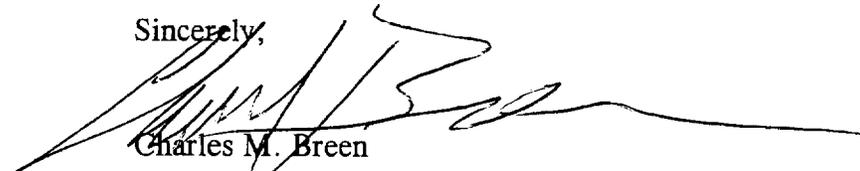
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certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations. Pertinent sections of the Act and regulations are enclosed for your review.

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 the delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 1000 2nd Avenue, Suite 2400, Seattle, Washington 98104. If you have questions regarding any issue in this letter, please contact Mr. Wesley at 206/553-7001, extension 57.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483

21 CFR PART 123

Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement