



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

July 14, 2000

VIA FEDERAL EXPRESS

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

In reply refer to Warning Letter SEA 00-57

John G. Roberts, Owner
Mr. Robert's Seafoods
15416 Produce Lane
Mt. Vernon, Washington 98273

WARNING LETTER

Dear Mr. Roberts:

We inspected your firm located at 15416 Produce Lane, Mt. Vernon, Washington, on April 11, 12, and 17, 2000, and May 5, 2000, 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 April inspection. These deviations, some of which were previously brought to your attention, cause your smoked seafood products 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, to comply with 21 CFR 123.6(b). Your firm does not have a HACCP plan for your vacuum packed smoked salmon, smoked oysters, and smoked shrimp products to control the food safety hazards of *Clostridium botulinum* growth and toxin formation.

A sample of vacuum packed smoked oysters was collected during the inspection on April 11 and 12, 17, 2000. Analysis of the sample found the percent water phase salt of ten subsamples ranged from 2.31 to 2.49 which is below the recommended amount of 3.5%. It is your responsibility to assure your brining process will produce 3.5% water phase salt in your finished product.

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 food contact surfaces, prevention of cross

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contamination, maintenance of toilet and handwash facilities, protection from adulterants, proper labeling and storage of toxic compounds, control of employee health, and exclusion of pests.

Labeling

The labels for your smoked seafood products lack nutrition information. 21 CFR Part 101.9(a) requires that nutrition information relating to food be provided for all products intended for human consumption and offered for sale, unless an exemption applies. A copy of A Food Labeling Guide, which contains applicable sections of the food labeling regulations, is enclosed for your review and information. Some small businesses are exempt from the nutritional labeling requirements and file an exemption notice. A Small Business Food Labeling Exemption Notice, which includes exemption criteria and instructions on filing an exemption notice, is enclosed.

The above HACCP and labeling 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.

In addition, the FDA reviewed your labels collected by our investigator during the April 11, 12, and 17, 2000, and May 5, 2000, inspections and have the following comments:

1. You must list in your ingredient statement all the ingredients by common or usual name in descending order of predominance by weight (21 CFR 101.4(a)(1)). The labels for your "Indian Style" smoked oysters, smoked shrimp, and smoked salmon (in one inch strips) do not declare "lemon pepper" as an ingredient. Your label for "Indian Style" smoked salmon in one inch strips does not include olive oil in the ingredient statement. Your labels do not list oysters, shrimp, or salmon as an ingredient.
3. The labels for you "Indian Style" smoked oysters, smoked shrimp, and smoked salmon (in one inch strips) do not list the sub ingredients of lemon pepper (21 CFR 101.4(b)(2)). One way to achieve this is to declare the common name of the ingredient e.g., lemon pepper followed by a parenthetical listing of all of its ingredients in descending order of predominance.

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During the May 10, 2000, inspection, our investigator found you had inventory of these products in your freezer which did not have correct labels. Specifically, these labels did not declare the ingredient "lemon pepper" which contains an allergen called "FD&C Yellow 5 Lake". This inventory represented all that remained of the lots. Please inform us in your response to this letter what you did with this product. Our investigator informed you of our labeling requirements and that you have an undeclared allergen on these three product labels.

4. You must list the correct address of your place of business on your label (21 CFR 101.5(a)). Your product labels list your previous address and not your current one.

For your information, our investigator also noted during the April 11-12, 17, 2000, inspection that you did not have a HACCP plan to control for the food safety hazard of allergens (FD&C Yellow 5 Lake) in three seafood products produced by your firm. In order to achieve this, you would list label review as a critical control point in your plan(s). Our Center for Food Safety and Applied Nutrition (CFSAN) and Office of Seafoods is currently in the process of clarifying their position on this issue and a formal policy has not been issued.

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.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand at 425-483-4913.

Sincerely,


Charles M. Breen
District Director