



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

August 11, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-85

William H. Kendall, Owner
Ike's Fish Company
20829 Pugh Road
Poulsbo, Washington 98370

WARNING LETTER

Dear Mr. Kendall:

We inspected your firm located at 20829 Pugh Road, Poulsbo, Washington, on June 26 and 30, 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). An 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 Hot Smoked Salmon 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 HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Hot Smoked Salmon does not include the "what", "how", "frequency" and "who" for quantity of fish, time, temperature or thickness of fish critical limits listed under your monitoring procedures for the brining critical control point.

As a result, the sample collected by FDA found that your product failed to achieve the desired 3.5% water phased salt required to control the hazard of Clostridium botulinum growth and toxin formation. Our sample found the Water Phase salt as low as 3.02% in the sample collected on June 27, 2000.

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

William H. Kendall, Owner
Ike's Fish Company
Poulsbo, Washington 98370
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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. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

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: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Williamson, at (425) 483-4976.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

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