



DEPARTMENT OF HEALTH AND HUMAN SERVICES

91094d

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

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

April 3, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-44

Stuart M. Siderman, Owner
Mountain Pride
P.O. Box 6077
Ketchum, Idaho 83340

WARNING LETTER

Dear Mr. Siderman:

We inspected your firm located at 206 Northwood Way, #C, Ketchum, Idaho, on March 8, 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 tuna, mahi mahi, and escolar 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:

You must have a 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 scombrototoxin-forming fish, including tuna, mahi mahi, and escolar, to control the food safety hazard of scombrototoxin formation (histamine formation).

In addition, in order to comply with 21 CFR 123.10, your HACCP plan must be developed by an individual who has successfully completed training in the application of HACCP principles. The training must be at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or through job experience that would also be recognized as meeting at least the standardized curriculum.

These deviations were previously brought to your attention in our letter dated December 13, 2000.

Stuart M. Sideman, Owner
Mountain Pride, Ketchum, Idaho
Re: Warning Letter SEA 01-44
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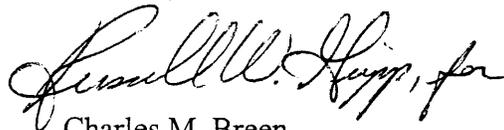
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

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.

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 new HACCP plan and records of HACCP training, 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. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Lisa M. Althar, Compliance Officer, at (425) 483-4940.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charles M. Breen, for".

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: ISDH with disclosure statement