



DEPARTMENT OF HEALTH AND HUMAN SERVICES

COPY

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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

January 6, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter 00-26

Thomas M. Hickey, President
Hickey Foods, Inc.
309 ½ South Main Street
Hailey, Idaho 83333

WARNING LETTER

Dear Mr. Hickey:

On May 20, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 309 ½ South Main Street, Hailey, Idaho. 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 (21 CFR) Part 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 vacuum packaged, smoked fish products processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR 123.

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). However, your firm does not have a HACCP plan for vacuum packaged, hot smoked salmon to control the food safety hazard of toxin formation by *Clostridium botulinum*. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for smoked trout does not list the critical control point of finished product storage for controlling the food safety hazard of pathogen growth. .
2. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, your firm does not have sanitation control records for safety of water, prevention of cross

Thomas M. Hickey, President
Hickey Foods, Inc., Hailey, ID
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contamination, protection from adulterants, proper labeling, storage, and use of toxic compounds, control of employees with adverse health conditions, and exclusion of pests.

During the previous inspection, on May 20, 1998, and in a letter from the FDA, dated October 7, 1998, you were notified of the same deficiency described in point number two of this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct this deficiency. The FDA is concerned that in seven months time your firm has not taken action to correct this deficiency.

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.

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: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,


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

Enclosures:

Form FDA 483

21 CFR Part 123

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

cc: IDHW With Disclosure Statement