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

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

COPY

July 28, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-30

Greg Favretto, President & Owner
Favco, Inc.
1205 West 29th Place
Anchorage, Alaska 99503

WARNING LETTER

Dear Mr. Favretto:

On May 6, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 1205 West 29th Place, Anchorage, Alaska. At the conclusion of the inspection, Randy C. Rau, Plant Manager, was 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 fresh tuna processed by your firm is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

1. Failure to identify a critical control point (CCP) at the receiving step in your HACCP plan for fresh tuna. 21 CFR Part 123.6(c)(2)(ii) requires you to list critical control points designed to control food safety hazards introduced even outside the processing plant environment. A combination of controls needs to be present at the receiving critical control point in order to control for the food safety hazard of histamine. This can be accomplished by checking for the presence of ice or gel packs, or obtaining a record from the transporter that shows the fish were held at 40 degrees Fahrenheit or lower.

2. Failure to list adequate monitoring procedures in your HACCP plan for fresh tuna as required under 21 CFR Part 123.6(c)(4). Once a day is not adequate monitoring of fresh tuna, which is a scombrotoxin forming species. At a minimum, this species of fish needs to be monitored two times per day if stored in a cooler under ice whereby you could check for the presence of sufficient ice. If the fish are not stored under ice, then even more frequent temperature monitoring would be needed to ensure their safety.

3. Failure to verify the adequacy of your HACCP plan to control the hazard of histamine that is reasonably likely to occur at the chill storage step, per 21 CFR Part 123.8(a). The HACCP plan for fresh finfish with histamine potential states that the cooler temperature will be checked once per day. This critical limit is not adequate as defined by 21 CFR 123.3(c).

4. Failure to list the records that will be kept to monitor the "chill storage" critical control point as required under 21 CFR 123.6(c)(7).

During the previous inspection, on February 20, 1998, and in a letter from the FDA, dated June 18, 1998, you were notified of similar deficiencies described in this letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in 11 months time your firm still has similar deficiencies.

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.

ADDITIONAL COMMENTS:

1. The HACCP plan does not list the verification steps that will be taken as required under 21 CFR 123.6(c)(6).

2. The monitoring log that is kept to monitor the coolers (and freezers) does not list the time the check is made as required under 21 CFR 123.9(a)(2).

3. Management has not routinely reviewed the cooler (and freezer) monitoring log at least every seven days as required under 21 CFR 123.8(a)(3)(I).

4. There was no HACCP plan for fresh, cooked crab, stored and sometimes repackaged at your facility. 21 CFR Part 123.6(b) requires you to have and implement a HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. Pathogen growth and toxin formation are considered significant hazards in this ready-to-eat product.

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: Janelle K. Main, Compliance Officer, 22201 23rd Drive S.E., Bothell, Washington 98021-4421.

Sincerely,

Roger L. Lowell
District Director

Enclosures:
FORM FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: <u>With Disclosure Statement</u>
ADEC