



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
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December 19, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-11

Charles H. Dorman, Owner
Kodiak Smoking and Processing
P. O. Box 8022
Kodiak, Alaska 99615

WARNING LETTER

Dear Mr. Dorman:

We inspected your firm located at ¼ Mile Sargent Creek Road, Kodiak, Alaska, on July 31 and August 1 through 2, 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 inspection. These deviations, some of which were previously brought to your attention, cause your hot smoked fish 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 HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's Plan of Operation (HACCP plan) for hot smoked vacuum packed salmon and halibut does not list the food safety hazard of color additives. Your Lemon & Pepper Seasoning Salt ingredient contains FD&C Yellow 5 Lake, a known allergen.
2. 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 Plan of Operation (HACCP plan) for vacuum packed hot smoked salmon and halibut does not list who performs the monitoring procedures at the brining, smoking, and final product storage critical control points to control

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pathogen growth and toxin formation (e.g., *Clostridium botulinum*). In addition, your firm's Plan of Operation (HACCP plan) does not list the frequency of monitoring at the brining and final product storage critical control points.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Your corrective action plan for hot smoked vacuum packed salmon and halibut at the brining, drying, and cooling critical control points to control pathogen growth and toxin formation (e.g., *Clostridium botulinum*) is not appropriate. There is no mention to hold and evaluate product when critical limit deviations occur. You must also ensure that no product enters commerce that is either injurious to health or otherwise adulterated as a result of these deviations. In addition, for the smoking critical control point, there is no mention of correcting the process. Pre-determined corrective actions must address both product and process.
4. Your firm did not verify the adequacy of the critical limits for hot smoked vacuum packed salmon and halibut at the brining, drying, and smoking critical control points to control pathogen growth and toxin formation (e.g., *Clostridium botulinum*). Two samples of hot smoked salmon and one sample of hot smoked halibut final product were collected by our investigator and analyzed by our Pacific Regional Laboratory Northwest. The results of the analyses found unacceptable water phase salt levels in each sample. The interplay of the inhibitory effects of salt, temperature, smoke, and nitrite level is complex. Therefore, evaluation of the process steps represented by the aforementioned critical control points is needed to establish processes that can consistently achieve at least 3.5% water phase salt in the final product. If the nitrite level in the finished product is 100-200 parts per million, a 3.0% water phase salt is adequate. Critical factors that are necessary to assure adequate brining and can be used as critical limits may include brine strength (salometer reading), brine time, brine temperature, fish thickness, and brine to fish ratio.
5. 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 six of the eight points of sanitation. These points included: condition and cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand-washing, hand-sanitizing, and toilet facilities; protection from adulterants; labeling, storage, and use of toxic compounds; and employee health conditions. Your firm has failed to keep records of these six points of sanitation since the last inspection on September 29, 1999. These same observations were noted on the Form FDA 483 issued during that inspection.

The above HACCP 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

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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.

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: Diane J. Englund, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have any questions regarding any issue in this letter, please contact Diane J. Englund at (425) 483-4864.

Sincerely,


for Charles M. Breen
District Director

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

cc: ADEC with Disclosure Statement