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

COPY

June 7, 1999

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

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-21

Lisa May, Owner & President  
Smoki Foods, Inc.  
19002 13<sup>th</sup> Place South, Building #3  
Seattle, Washington 98148

WARNING LETTER

Dear Mrs. May:

On February 22, 1999, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 19002 13<sup>th</sup> Place South, Seattle, Washington. At the conclusion of the inspection, Chris Tief, Assistant General 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 vacuum packaged, cold smoked salmon 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. Your HACCP plan for vacuum packaged, refrigerated, cold smoked salmon, did not identify how you are controlling the food safety hazard associated with the formation of toxin by *Clostridium botulinum* for at least as long as the shelf life of the product under normal and moderate abuse conditions. Therefore, the HACCP plan does not meet the requirement of 21 CFR Part 123.16.

Your HACCP plan for vacuum packaged, refrigerated, cold smoked salmon, did not identify appropriate critical control points for the food safety hazard of bacterial pathogen growth and toxin formation, including *Clostridium botulinum* toxin formation. Your HACCP plan must identify critical control points at the brining, drying, smoking and final product storage of refrigerated product process steps for the hazard of bacterial pathogen growth and toxin formation, including *Clostridium botulinum*. Therefore, the HACCP plan does not meet the requirement of 21 CFR Part 123.6(c)(2).

Lisa May, Owner & President  
Smoki Foods, Inc., Seattle, WA  
Re: WarningLetter SEA 99-21  
Page 2

2. Your firm was not maintaining sanitation monitoring records for the following four (of eight) areas of sanitation:
  - a. prevention of cross contamination;
  - b. protection from adulterants;
  - c. control of employees with adverse health conditions; and
  - d. exclusion of pests.

21 CFR Part 123.11(c) requires you to maintain records of sanitation monitoring and any corrections made as a result of that monitoring.

3. Your firm was not adequately monitoring, or was not taking corrective action when sanitation deficiencies were found, in the areas of prevention of cross-contamination and protection from adulterants. This was evidenced by deficiencies listed below.
  - a. Water was dripping from a PVC pipe directly into a bucket of brining fillets.
  - b. An insect light, without a catch tray, was suspended directly above a processing table in the fillet room.
  - c. End caps were missing from lights suspended over processing tables in the fillet room.

21 CFR Part 123.11(b) requires that eight areas of sanitation be monitored and corrective action be taken whenever a sanitation problem is found. These observations demonstrate to the FDA that your firm is not adequately monitoring for prevention of cross contamination, protection from adulterants, or exclusion of pests, or is not taking corrective action when sanitation deficiencies are found.

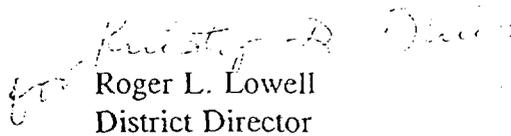
The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt 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

Lisa May, Owner & President  
Smoki Foods, Inc., Seattle, WA  
Re: WarningLetter SEA 99-21  
Page 3

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 23<sup>rd</sup> Dr. SE, 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: With Disclosure Statement  
WSDA