



19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

January 7, 1999

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Patrick A. Martin, Owner  
The Cambridge House  
133 East De La Guerra  
Santa Barbara, CA 93101

WL 17-9

Dear Mr. Martin,

On September 15-17, 1998, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of The Cambridge House, located at 1030 B Cindy Lane, Carpinteria, CA 93101. At the conclusion of the inspection Damon E. Watkins, General Manager, was presented with FORM FDA 483 listing significant 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 products processed at your facility are adulterated within the meaning of Section 402 (a) (4) of the Food, Drug and Cosmetic Act (the Act) and 21 CFR Part 123.

Specifically, our investigator found the following deficiencies, related to cold smoked, vacuum packaged salmon, stored and sold as refrigerated product:

1. You did not have any documentation such as a scientific study showing that your firm's smoked salmon process will control the hazard of *Clostridium botulinum* (C. bot) growth and toxin formation. A study which may include analytical testing of a representative number of finished products is needed to show that process parameters (Critical Control Points) that you have set up in your firm's HACCP plan are sufficient to prevent C. bot growth and toxin formation on a consistent basis. Part 123.8 (a) requires you to verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur.
2. You did not take corrective action as prescribed in your HACCP plan at the salting CCP on two occasions, 9/8/98 & 9/11/98, when your critical limit of salting time was not met. The salting CCP lists your critical limit (in part) as "MINIMUM [REDACTED] HOURS

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SALTING TIME". The daily monitoring record for lot #97/98 dated 9/8/98 shows the "DURATION IN SALT" of [REDACTED] HRS". The daily monitoring record dated 9/11/98 does not show any salting time. Although neither of these records meet your critical limit of [REDACTED] hours, there are no corrective action reports or other information suggesting that you had followed the corrective action described in your written HACCP plan. This corrective action is "1. HOLD LONGER IN SALT".

3. Your firm is not implementing your HACCP plan as written. During the inspection, our investigator noted that your firm was not monitoring your critical limits of: 1. Salt Concentration; 2. Ratio of Salt to Fish (during salting); 3. Label checks during the "Vacuum Packaging & Labeling" step.

For your information, your critical limit at the cold smoking step should address the maximum temperature allowed (i.e. [REDACTED]), instead of your current limit of a minimum temperature of [REDACTED].

Failure to achieve prompt correction may result in enforcement actions without further notice. These include seizure and injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. 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 directed to the Food & Drug Administration, Los Angeles District, Attention: Robert B. McNab, Consumer Safety Officer, 19900 MacArthur Blvd, Ste. 300, Irvine, CA 92612-2445.

Sincerely,

*Tom Allison / Sr.*  
Elaine C. Messa

Los Angeles District Director

Enclosures:

FORM FDA 483

Section 402 of the Act 21 CFR Part 123