



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

W.L. File  
MBZAN

1990 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

**WARNING LETTER**

June 16, 1999

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

Michel G. Blanchet, President  
Michel Cordon Bleu, Inc.  
3625 South Western Avenue  
Los Angeles, California 90018

W/L 33-9

Dear Mr. Blanchet:

On February 18 & 22, 1999, Investigators from the Food and Drug Administration (FDA) conducted an inspection of your firm, located at 3625 South Western Avenue, Los Angeles, California. 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 cold smoked, vacuum-packaged salmon processed at your facility is 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 investigators found the following deficiencies, related to cold smoked, vacuum packaged salmon, stored and sold as refrigerated and/or frozen product:

1. Failure to identify appropriate critical control points as required under 21CFR 123.6(c)(2), e.g., brining, smoking/drying, finished product storage.
2. Failure to establish critical limits as required under 21 CFR 123.6(c)(3), to prevent toxin formation by Clostridium botulinum for at least as long as the shelf life of the product under normal and moderate abuse conditions, as required under 21 CFR 123.16.

Documentation must be provided that critical limits set at the critical control points of brining, smoking, and/or drying steps consistently results in a critical limit of 3.5% water phase salt or more in the finished product in vacuum packages. Water phase salt measurements should be taken until it is documented that the critical limit is consistently achieved over the entire range of the processing

Letter to Mr. Blanchet  
June 16, 1999  
Page 2

conditions (e.g., temperature of brine, thickness of fish, brine to fish ration, smoking/drying and finished product storage).

We acknowledge that your firm has sent samples of your products to a private laboratory to test for water phase salt (WPS) levels in these products. The analytical documents supplied to our investigators by you during the inspection show that the levels vary widely, however, from ██████████ WPS in one sample, to ██████████ in another sample. These results only reinforce our contention that a critical control point is needed at the brining/curing step in your process, to ensure a consistent and proper WPS level. We caution you that finished product testing alone does not meet the requirements of the HACCP regulation. HACCP is designed to build safety into a seafood processing operation through monitoring specific critical limits at critical control points (CCP) during processing. Finished product testing is more useful as a verification tool, to ensure that your procedures allow you to meet your critical limits.

3. Failure to provide an adequate recordkeeping system as required under 21 CFR 123.6(c)(7).
4. Failure to implement appropriate monitoring procedure as required under 21 CFR 123.6(c)(4).
5. Failure to monitor the conditions and practices related to eight elements of sanitation as required by 21 CFR 123.11(b). The areas of sanitation which are not monitored include: a) conditions and cleanliness of food contact surfaces, b) prevention of cross contamination, c) maintenance of hand washing, hand sanitizing, and toilet facilities d) protection from adulterants, e) proper labeling, storage and use of toxic compounds, and f) control of employees with adverse health conditions.

We are particularly concerned with sanitation and food handling practices of your smoked fish products after smoking and prior to packaging. As ready-to-eat products, pathogen introduction at this step may occur without adequate sanitation controls.

6. Failure to document review of monitoring records (i.e. temperatures at receiving) as written in your HACCP plan. A review of your temperature logs for raw material salmon at receiving found that these records were not reviewed. 21 CFR 123.8 (a)(3)(i) requires you document that CCP monitoring records are reviewed within one week of when the record was made in order to verify that the values listed are within critical limits.

You should take prompt action to correct all 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.

Letter to Mr. Blanchet  
June 16, 1999  
Page 3

The above HACCP violations are not meant to be an all-inclusive list of HACCP deficiencies in your firm. It was noted that your firm manufactures smoked seafood items other than cold smoked, vacuum packaged farmed Atlantic Salmon, such as hot smoked, vacuum-packaged trout, tuna & whitefish, etc., and cold smoked, vacuum packaged mussels, swordfish & sturgeon, etc. Each of these products requires a HACCP plan with appropriate CCPs, critical limits and monitoring, etc. It is your responsibility to assure that all of your products are manufactured in compliance with applicable statutes enforced by FDA.

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. Your response should include a copy of the revised HACCP plans, SSOP (if applicable) and sanitation monitoring forms or procedures. 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.

We acknowledge your response dated 8/10/99<sup>98</sup> to the letter sent to your firm covering the initial inspection of 6/11-16/98. Your response, however, does not address all HACCP deficiencies and other deficiencies found during that inspection, and as evidenced by the aforementioned items.

It should be noted that we do not agree with your significant hazard of "pathogens" at receiving, and do not feel that this is a safety issue. However, if you choose to include this in your HACCP plan with defined critical limits, then you must follow your plan, i.e. monitoring and review.

Your written reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Thomas L. Sawyer, Compliance Branch Director, 19900 MacArthur Boulevard, Suite 300, Irvine, CA 92612-2445. Any questions that you may have regarding this letter can be directed to Robert B. McNab, Compliance Officer, at (949) 798-7709.

Sincerely,



Thomas Allison  
Acting District Director

Enclosures: FORM FDA 483

cc: California Department of Health Services, Food & Drug Branch  
601 North 7<sup>th</sup> Street, Sacramento, CA 95814  
Attn.: Stuart E. Richardson, Jr., Chief