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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-27

February 12, 2002

Hamish T. Rose, General Manager
MacKnight Smoked Foods, Incorporated
550 Northeast 185th Street
Miami, Florida 33179

Dear Mr. Rose:

We inspected your seafood processing plant, located at the above address, on April 17-19, 2001. We regret the delay in our review and evaluation of the inspectional findings. The inspection revealed that you continue to have serious deviations from the Seafood HACCP Regulations (21 CFR Part 123). These deviations cause your vacuum packed cold smoked salmon to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for vacuum packed cold smoked salmon lists a critical limit of [redacted] to [redacted] for water phase salt at the curing critical control point that is inadequate to control the food safety hazard of *C. botulinum*. The recognized minimum water phase salt level for vacuum packed cold smoked salmon without the addition of sodium nitrite is 3.5%. A water phase salt level of 3.0% would be acceptable with no less than 100 ppm sodium nitrite. Your HACCP plan fails to list a critical limit for sodium nitrite and fails to specify sufficient drying time designed to achieve adequate water phase salt levels in your finished product. In addition, the critical limit for salting should address various curing times based on the size of salmon fillets being processed or based on the largest salmon fillet processed by your firm.

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.9(c). However, your firm did not record monitoring observations at the curing and blast chill critical control points to control the food safety hazards of *C. botulinum* and pathogen growth and toxin formation.

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). However, your corrective action plan for vacuum packed cold smoked salmon at the curing critical control point to control the food safety hazard of *C. botulinum* is not appropriate in that it fails to include the addition of more salt and curing for an additional period of time prior to conversion to hot smoked product and evaluation.

Chapter 13 of the FDA Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition, June 2001*, provides examples and guidelines to assist your firm in establishing controls for the food safety hazard of *C. botulinum* toxin formation.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice (GMP) Regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

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 copies of your revised HACCP plan, 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.

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Please send your reply to the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

A handwritten signature in cursive script that reads "Emma R. Singleton". The signature is written in black ink and is positioned above the typed name.

Emma R. Singleton
Director, Florida District