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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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November 20, 2001

WARNING LETTER NO. 2002-NOL-14

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Eric F. Skrmetta, CEO
Anglo American Limited
501 Destrehan Avenue
Harvey, Louisiana 70058

Dear Mr. Skrmetta:

We inspected your firm, located at 501 Destrehan Avenue, Harvey, Louisiana, during September 25 - 26, 2001, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your ready-to-eat, 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 this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). However, your firm did not verify the adequacy of the critical limits for ready-to-eat, cold smoked salmon at the "SALMON FILLETS," "CURE," "DRYING & COLD SMOKING," and "COLD STORAGE" critical control points to control for the food safety hazards of pathogen growth and toxin formation, including *Clostridium botulinum*.

In addition, your HACCP plan for ready-to-eat, cold smoked salmon at the "CURE," "DRYING & COLD SMOKING," "SKINNING MACHINE," "SLICING MACHINE," and "COLD STORAGE" critical control points does not list any verification procedures.

- You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at any of the critical control points to control for the food safety hazards of pathogen growth and toxin formation, including *Clostridium botulinum*, listed in your HACCP plan for ready-to-eat, cold smoked salmon.

In addition, your firm does not have calibration records for the salometer used to measure the salinity of ready-to-eat, cold smoked salmon during the “CURE” critical control point operation to control for the food safety hazards of pathogen growth and toxin formation including *Clostridium botulinum*.

- 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 HACCP plan for ready-to-eat, cold smoked salmon does not list the monitoring procedure or frequency at the “SALMON FILLETS” critical control point to control for the food safety hazards of pathogen growth and toxin formation including *Clostridium botulinum*.

Your firm’s HACCP plan for ready-to-eat, cold smoked salmon does not list the monitoring records at the “CURE,” “DRYING & COLD SMOKING,” “SKINNING MACHINE,” or “SLICING MACHINE” critical control points to control for the food safety hazards of pathogen growth and toxin formation including *Clostridium botulinum*.

- 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 ready-to-eat, cold smoked salmon does not list a critical limit(s) during [REDACTED] at the “CURE” critical control point to control for the food safety hazards of pathogen growth and toxin formation including *Clostridium botulinum*.

In addition, your firm’s HACCP plan for ready-to-eat, cold smoked salmon does not list a critical limit(s) during receiving at the “SALMON FILLETS” critical control point to control the food safety hazards of pathogen growth and toxin formation including *Clostridium botulinum*.

- 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 ready-to-eat, cold smoked salmon at the “CURE” critical control point to control “C. BOTULINUM” is not appropriate. The corrective action merely states “RE-SALT FILLETS.” The corrective action does not state the salt level will be readjusted to a specific level or range.
- You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2). However, your firm’s HACCP plan for ready-to-eat, cold smoked salmon does not list the critical control point of repackaging for controlling the food safety hazard(s) of pathogen growth and toxin formation including *Clostridium botulinum*.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating.

We are aware that during our inspection Mr. Jon S. Bard, President, made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as HACCP plans, verification documentation, 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 you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations and the CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483