



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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August 22, 2002

WARNING LETTER
CHI-24-02

Food and Drug Administration
Chicago District Office
Suite 1600
550 W. Jackson Street
Chicago, IL 60661
Telephone: (312) 353-6863
FAX: (312) 596-4195

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael Gorton
Chairman & CEO
Slade Gorton & Co. Inc.
225 Southampton St.
Boston, MA 02118-2724

Dear Mr. Gorton:

On April 29-30, and May 2, 7, 2002, the Food and Drug Administration (FDA) conducted an inspection of your facility, located at 4433 W. 42nd Place, Chicago, Illinois. The inspection found that you have serious deviations from the seafood hazard analysis and critical control point (HACCP) regulations set forth in Title 21, Code of Federal Regulations (21 CFR), Part 123. These deviations, some of which were previously brought to your attention, cause seafood products being manufactured and distributed by your facility to be adulterated within the meaning 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 <http://www.fda.gov>.

Our determinations and your deviations are as follows:

In regard to your import seafood operation:

- You must have product specifications, which are designed to ensure that the fish and fishery products you import are not adulterated under Section 402 of the Act because they may be injurious to health or have not been processed under insanitary conditions, to comply with 21 CFR Part 123.12(a)(2)(i). However, your firm does not have written product specifications for pike perch imported from Turkey, and sander imported from Estonia. This deviation was cited in our letter of October 5, 1999, which was sent to the Chicago, IL location of Slade Gorton & Co., Inc. Please also note that a similar deviation was cited in an April 2001 Warning Letter sent to the Boston, MA location of your firm.

In regard to your domestic seafood operation:

- You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and to identify the preventative measures that you can apply to control those hazards, to comply with 21 CFR 123.6(a). In addition, you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have HACCP plans for: vacuum-packed mahi-mahi; vacuum-packed smoked salmon; vacuum-packed red snapper; and canned, pasteurized crabmeat, to control the food safety hazard of *Clostridium botulinum* toxin formation which FDA believes is reasonably likely to occur.
- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as “the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.” However, your firm’s HACCP plan for scombrototoxin (histamine) producing fish lists a critical limit at the receiving critical control point that is not adequate to control histamine formation.

As a secondary processor receiving refrigerated histamine-producing fish which are delivered refrigerated and unfrozen, your receiving critical limits should assure that the fish are held at safe temperatures throughout transport. Two suggested methods of control are:

- Lots received are accompanied by transportation records that show that the fish were held at or below 40 F throughout transport; or
 - For fish held under ice or chemical cooling media, that there is an adequate quantity of ice or other cooling media at the time of delivery to completely surround the product.
- 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 scombrototoxin (histamine) forming species lists a monitoring frequency at the storage critical control point that is not adequate to control scombrototoxin (histamine) formation. Monitoring should be continuous for both coolers.

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The above is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection, you were issued a Form FDA-483 (copy enclosed), which is a list of our investigators' observations of deviations noted during the inspection. It is your responsibility to assure that all of your fishery products are processed in compliance with the requirements of the Act, the seafood HACCP regulations (21 CFR Part 123), and the Good Manufacturing Practice regulations (21 CFR Part 110), as appropriate.

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.

We are aware that you made a verbal commitment at the close of the inspection to correct the observed deficiencies. Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of steps taken to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be sent to Patrick J. Brown, Compliance Officer, at the above address.

Sincerely,

\s\
Arlyn H. Baumgarten
District Director

cc: Mr. Thomas P. Elliot
Vice President and Division Manager
Slade Gorton & Co., Inc.
4433 West 42nd Place
Chicago, IL 60632