



DEPARTMENT OF HEALTH & HUMAN SERVICES

942332
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Martin D. Reilly, President
Reilly Brothers Seafood, Inc.
12773 State Route 38
P.O. Box 162
Berkshire, NY 13736

August 15, 2003

Ref: NYK-2003-34

Dear Mr. Reilly:

On July 9 and 10, 2003, we inspected your seafood processing facility, located at the above address. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly your scombroid species fish and pasteurized canned crabmeat are adulterated, in that they have has been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may 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 implement the record keeping system that you listed in your HACCP plans, to comply with 21 CFR 123.6(b). However, your firm did not always record monitoring observations at the receiving critical control point to control scombrototoxin (histamine) formation listed in your HACCP plan for scombroid species of fish. Further, your firm did not record monitoring observations at the receiving critical control point to control *Clostridium botulinum* toxin formation listed in your HACCP plan for pasteurized canned crabmeat.

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

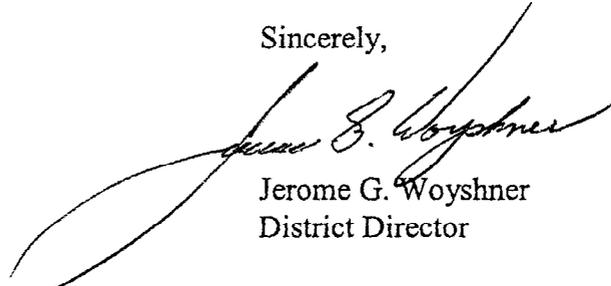
Reilly Brothers Seafood, Inc.
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Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as copies of receiving/temperature 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.

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 Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, please contact Mr. Goldwitz at 718-340-7000 ext. 5582.

Sincerely,



Jerome G. Woyshner
District Director

Enclosure: Form FDA 483 dated July 10, 2003