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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
Facsimile: 504-253-4520

April 1, 2004

WARNING LETTER NO. 2004-NOL-18

Mr. Frank J. Spalitta, President
S & W Wholesale Foods, Inc.
d.b.a. Frosty Cold Storage
18120 Old Covington Highway
Hammond, Louisiana 70403-0652

Dear Mr. Spalitta:

We inspected your firm, located at 18120 Old Covington Highway, Hammond, Louisiana, on December 10 & 12, 2003, and found that you have serious deviations from the Seafood Hazard Analysis Critical Control Point (HACCP) regulation, 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 refrigerated, pasteurized, ready-to-eat crabmeat has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You can find the Act and the Seafood HACCP regulation through links in FDA's home page at <http://www.fda.gov>.

The deviations were as follows:

1. 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 the monitoring observations at the _____ and _____ critical control points as listed in your HACCP plan for seafood products. Your "Frosty SEAFOOD HACCP Plan" and "S&W SEAFOOD HACCP Plan" (Plan/s) both include a description that you will take temperatures to control pathogen growth at the _____ stage.
 - Your firm failed to record the temperatures of the refrigerated, pasteurized, ready-to-eat crabmeat you receive. The invoice collected by our investigator dated November 25, 2003, indicates that you received _____ types of products that day, including _____ and _____. The corresponding shipping record for November indicates that you recorded the temperature of the frozen _____ at receiving. However, the item that should have been monitored was the refrigerated, pasteurized, ready-to-eat crabmeat, which is associated with the hazard of pathogen growth and toxin formation, as listed in your Plan. We

expect you to implement the Plans for products where hazards exist due to time and temperature abuse.

Your Plans also include a description that you will take temperatures to control pathogen growth at the _____ stage.

- Your firm failed to record the monitoring observations at the _____ critical control point.
 - 1) You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your Plans do not list monitoring procedures at the _____ critical control point that are adequate to control for pathogen growth and toxin formation in the refrigerated, pasteurized, ready-to-eat crabmeat during refrigerated storage. FDA recommends the installation of a temperature-recording device that provides a continuous monitoring record of the temperature with a visual check of the equipment once per day. Periodic temperature checks do not provide the same safety assurances.
 - 2) You must retain records at the processing facility for at least one year after the date they were prepared in the case of refrigerated products to comply with 21 CFR 123.9(b)(1). However, your firm only was able to provide the most recent two months' (November and December) records for receiving (labeled Shipping Record) refrigerated, pasteurized, ready-to-eat crabmeat that was received and stored by your firm.

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

We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. Please respond in writing, within fifteen days 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 copies of 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 you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

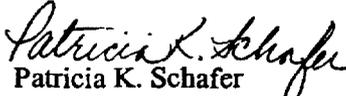
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation and the Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Page 3 – S & W Wholesale Foods, Inc.
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Please send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253 -4519.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483