



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

November 21, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref. # DEN-02-06

Mr. William Hamil, President
Steamboat Meat & Seafood Company, Inc.
1030 Yampa Street
Steamboat Springs, Colorado 80477

Dear Mr. Hamil:

We inspected your firm, located at the above address, on October 22-23, 2001 and found that you have serious deviations from the Seafood HACCP regulations [Title 21 Code of Federal Regulations, Part 21 (21 CFR Part 123)]. The deviations we found cause your smoked, vacuum packed fish and seafood pasta products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control pathogen growth when your process for smoked marlin deviated from your critical limit at the smoking/cooking critical control point. For example, your firm manufactured smoked marlin, and the data recording chart showed the fish was smoked for less than the required 30 minutes at 145°F.

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(c)(7). However, your firm did not record monitoring observations at the smoking/cooking critical control point to control pathogen growth listed in your HACCP plan for smoked fish. For example, you have not maintained records showing

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the time and temperature products have been smoked. In addition, smoking records maintained by your firm do not identify the product smoked, to assure the smoking time and temperature reached appropriate values.

You must retain records at the processing facility for at least 1 year after the date they were prepared in the case of refrigerated products, and 2 years in the case of frozen products, to comply with 21 CFR 123.9(b)(1). Your records are not maintained for any specified period of time.

You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the safety of the water that comes into contact with food or food contact surfaces (21 CFR 123.11(b)(1)); the proper labeling and storage of toxic compounds (21 CFR 123.11(b)(6)); the control of employee health conditions that could result in the microbial contamination of food, food packaging materials, and food contact surfaces (21 CFR 123.11(b)(7)); and the exclusion of pests from the food plant (21 CFR 123.11(b)(8)) as evidenced by the fact that your sanitation records do not provide for monitoring the above conditions.

You must correct sanitation deficiencies detected during monitoring in a timely manner, to comply with 21 CFR 123.11(b). However, your firm did not correct the sanitation deficiencies of:

Water dripping from the evaporator unit in the catering cooler onto products stored below; the shelves in the same vicinity were rusty; the fish cutting board was scarred and no longer cleanable; and the sprayer over the two compartment sink was encrusted with grime and fish scales. In addition, we found that the sanitation log showed the pasta room and all equipment were cleaned, when in fact this was not true, and the equipment was soiled with dough and flour.

Finally, be advised that we do not believe it is appropriate to freeze dead or dying lobsters for later use in soup stock.

We may take further action if you do not promptly correct these violations. For instance, we may seize your 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 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 Federal Food, Drug, and Cosmetic 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.

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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.

Please direct your response to the Food and Drug Administration, Denver District, Attention: Ms. Shelly L. Maifarth, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Maifarth at (303) 236-3046.

Sincerely,


Thomas A. Allison
District Director

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