



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
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April 14, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-39

Reed Cory, President  
Stone Mill Foods, Inc.  
22613 76<sup>th</sup> Avenue South  
Kent, Washington 98032

WARNING LETTER

Dear Mr. Cory:

We inspected your firm located at 22613 76<sup>th</sup> Avenue South, Kent, Washington, on March 2 and 3, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form (copy-enclosed) listing the deviations was presented to Greg M. Chrones, Vice President of Operations at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your imitation crab seafood salads 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 homepage at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). Your firm's HACCP plan for imitation crab seafood salads does not list the food safety hazard of *Clostridium botulinum*. This deviation was previously brought to your attention in our letter of January 5, 2000.
2. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for imitation crab seafood salads does not list the critical control point of receiving for controlling the food safety hazard of *Clostridium botulinum*, nor does it list finished product storage for control of pathogen growth. These deviations were previously brought to your attention in our letter of January 5, 2000.

Reed Cory, President  
Stone Mill Foods, Inc., Kent, WA  
Re: Warning Letter SEA 00-39  
Page 2

3. You must have a HACCP plan that lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for imitation crab seafood salads lists a critical limit, "held under proper temperature," at the storage of raw materials critical control point that is not adequate to control *Clostridium botulinum* growth and toxin formation. This deviation was previously brought to your attention in our letter of January 5, 2000.
4. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, in order to comply with 21 CFR 123.7(b). Your corrective action plan for imitation crab seafood salads at the storage, preparation and processing critical control points to control microbiological, chemical and physical hazards does not include corrections for both the product and process.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating. Pertinent sections of the Act and regulations are enclosed for your review.

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. You may wish to include in your response documentation such as your revised HACCP plan and copies of your 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.

Please send your reply to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 1000 2<sup>nd</sup> Avenue, Suite 2400, Seattle, WA 98104. If you have questions regarding any issue in this letter, please contact Robert Wesley at 206/553-7001, extension 57.

Sincerely,



Charles M. Breen  
District Director