



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service  
Food and Drug Administration  
Los Angeles District

19701 Fairchild  
Irvine, California 92612-250  
Telephone (949) 608-2900

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

August 18, 2003

Mr. Kim, Director  
Hanmi, Inc.  
3345 E. Slauson Ave.  
Vernon, CA 90058

W/L 48-03

Dear Mr. Kim:

On June 11, 2003, the Food & Drug Administration (FDA) conducted an inspection of your facility located at 3345 E. Slauson Ave., Vernon, CA 90058. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulations, Title 21 of the Code of Federal Regulations Part 123 (21 CFR §123), "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products", and the Good Manufacturing Practices (GMP) requirements for foods, 21 CFR Part 110. The Seafood HACCP Regulations were issued pursuant to Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Seafood that is processed in violation of the HACCP regulations is adulterated, according to the Act, because it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find this Act and the Seafood HACCP Regulations through links in FDA's home page at <http://www.fda.gov>.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as HACCP. HACCP involves:

- (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and
- (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Prudent processors already take these kinds of measures. HACCP provides a systematic way of taking those measures that demonstrate to FDA, to your customers, and to consumers, that you

Letter to Mr. Kim, Director, Hanmi Inc.

Page 2

are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During our inspection, the FDA investigator observed that your firm did not comply with importer verification requirements. This serious deviation has caused the frozen salted mackerel imported by your firm to be adulterated within the meaning of Section 402 (a)(4) of the Food,

Drug, and Cosmetic Act (the Act) in that you failed to provide verification per 21 CFR 123.12 (d) that your fish and fishery products have been processed under conditions that comply with requirements of 21 CFR 123. The FDA investigator provided you with an FDA 483 listing the serious deviation:

- (1) You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for frozen salted mackerel imported from [REDACTED]

The above identified deviation is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter of specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply relating to these concerns should be directed to:

U.S. Food & Drug Administration  
Attn: Director, Import Operations Branch  
Los Angeles District  
222 West 6<sup>th</sup> Street, Suite 700  
San Pedro, CA 90731

Letter to Mr. Kim, Director, Hanmi Inc.

Page 3

If you have questions regarding the implementation of the HACCP Regulations, you may contact Ruth P. Dixon, Compliance Officer, at (310) 831-6123 extension #155 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,

  
Alonza Cruse  
District Director

cc: California Department of Health Services, Food & Drug Branch  
601 N. 7<sup>th</sup> Street  
Sacramento, California 94234-7320  
Attn: Stuart Richardson, Jr., Chief