



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1135d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

April 12, 2001

Our Reference: 2937270

Mr. Hee Gon Kim, Vice-President
Hanmi, Inc.
3345 East Slausen Avenue
Vernon, California 90058

WARNING LETTER

Dear Mr. Kim:

We inspected your seafood firm located at 2992 Alvarado Street, Unit # M, San Leandro, CA 94577, on March 21, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations, Part 123 (21 CFR 123) and the current Good Manufacturing Practice (cGMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your fish and fishery products, including dried anchovy, frozen mackerel, and frozen amberjack, to be adulterated within the meaning of Section 402(a)(4) of the Federal, Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared packed, or held under insanitary conditions, whereby the foods may be contaminated with filth or rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed with Mr. TaeWon Chong, Branch Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your ready reference. Your serious HACCP violations are as follows:

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 product specifications for:

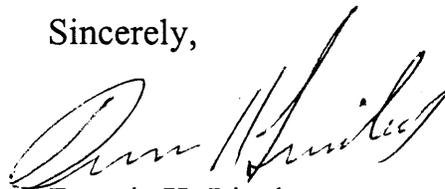
- a) dried anchovy from Korea, to ensure control of the food safety hazard of histamine formation, and potential pathogen growth and toxin formation from inadequate drying of the product;
 - b) frozen mackerel and amberjack from Korea, to ensure control of the food safety hazard of histamine formation as a result of time/temperature abuse.
2. You must implement an affirmative step to ensure that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for the dried anchovy, frozen mackerel, and frozen amberjack from Korea, to verify that the products were processed in accordance with the seafood HACCP regulations.
3. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm failed to maintain sanitation control records that, at a minimum, document the monitoring and corrections that are appropriate to the plant and food being stored, and related to the following:
- a) protection of food, food packaging material and food contact surfaces from adulterants;
 - b) proper labeling, storage, and use of toxic compounds;
 - c) exclusion of pests from the food plant.

The above violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure, injunction, or detention of future shipments without physical examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response, documentation such as copies of product specifications, verification plans, your foreign processors' HACCP plans, or other useful information that would assist us in evaluating your corrections. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 93402-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley". The signature is fluid and cursive, written over a white background.

Dennis K. Linsley
Director
San Francisco District

Enclosure

cc: Mr. Tae Won Chong, Branch Manager
Hanmi, Inc.
2992 Alvarado Street, Unit M
San Leandro, California 94577