



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g 2095d

December 27, 2001

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Kum Kim, President
B.N.S. Uni, Inc.
14405 South Vermont Avenue
Gardena, CA 90247

WL-20-02

Dear Ms. Kim:

We inspected your seafood processing facility, located at 14405 South Vermont Ave., Gardena, CA 90247 on November 13, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your sea urchin roe fishery products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for sea urchin roe ("Uni") to control the food safety hazard of environmental chemical contaminants.
2. You must monitor sanitation conditions and practices as required in 21 CFR 123.11(b), and document those findings with sanitation control records as required in 21 CFR 123.11(c). However, we found during our inspection that you had not implemented this monitoring.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You may wish to include in your response documentation such as HACCP plans, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections.

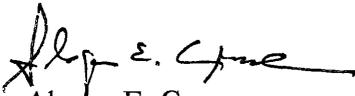
Letter to Ms. Kim, B.N.S. Uni, Inc. - Page 2

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 Part 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.

If you have any questions relating to this letter you should contact Robert B. McNab, Compliance Officer, at (949) 798-7709. Your written reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch
U. S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

Sincerely,


Alortza E. Cruse
District Director
Los Angeles District