



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1977d

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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

November 13, 2001

Yen K. Trieu, Owner  
New Japan International Inc.  
4560 Worth Street  
Los Angeles, CA 90063

**WARNING LETTER WL-I02-02**

Dear Ms. Trieu,

The Food and Drug Administration (FDA) has information which shows your firm violated the Federal Food, Drug, and Cosmetic Act and referenced provisions of the United States Code (U.S.C).

<u>Entry Number</u>	<u>Product</u>	<u>Invoiced Quantity</u>	<u>Arrival Date</u>
T76-0123268-1/3/1	Frozen Spring Roll	cartons	4/28/01

Frozen Spring Roll offered for import into the United States by your firm was sampled by FDA and detained on June 1, 2001 since the article was found to be adulterated with *Salmonella*, a poisonous and deleterious substance which may render it injurious to health, within the meaning of the Food, Drug & Cosmetic Act 402(a)(1).

This article was Refused Admission on July 2, 2001. Arrangements were made to destroy the product under FDA supervision at [REDACTED] on October 11, 2001. During the destruction our investigation revealed significant discrepancies:

- Five additional variations of the retail unit label. These variations included an altered ingredient, net weight and firm statement and label format modifications.
- Original master carton label, identified by the sampling FDA investigator, consisted of red lettering and a white box. During the destruction the first top three rows of the pallet were identified as the mentioned original master carton label, and the remainder was not. The remaining master carton labels consisted of an adhesive label with black lettering placed on a white box originally labeled as "\*\*\*FROZEN STEAMED MACKEREL FISH\*\*\*".

Your actions of commingling an entry found to be violative for the presence of *Salmonella*, a poisonous and deleterious substance, with other product has caused this entry to be adulterated, within the meaning of 21USC342(b)(2).

The following are previous entries whereby product was presented for destruction under FDA supervision and found adulterated within the meaning of 21USC 342(b)(2) , and annotated on the Customs Form 3499 (Application and Approval to Manipulate, Examine, Sample or Transfer Goods):

<u>Entry Number</u>	<u>Product</u>	<u>Invoiced Quantity</u>
880-0025673-0/3/1	Black Pepper	2 cartons
880-0026223-3/7/1	Dried Bamboo Shoot	2 cartons

In addition both entries listed were FDA sampled, detained and Refused Admission since the products were found to be adulterated in whole or in part of a filthy, putrid, or decomposed substance or otherwise unfit for food, within the meaning of the Food, Drug & Cosmetic Act 402(a)(3).

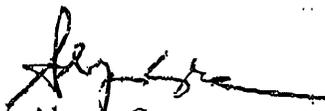
Failure to promptly correct this violation and prevent future violations may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U.S. Customs, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage as well as to ensure that imported product meets all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Within 15 working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal, or commercial information purged.

Please send your reply to Food and Drug Administration, Attention: Ruth P. Dixon, Compliance Officer, 222 West 6<sup>th</sup> Street, Suite 700, San Pedro, CA 90731. If you have questions regarding any issue in this letter, please contact Ms. Dixon at (310)831-6123, ext. 155.

Sincerely,



Alonza Cruse  
District Director