



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1194d

18900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

March 29, 2001

Mr. Roger Lee, Owner  
Chiu-Chou Lee CHB  
440 Hindry Ave. #H  
Inglewood, CA 90301-2016

WL-I-02-01

Dear Mr. Lee,

On October 4, 2000, entries [REDACTED] and [REDACTED] were Detained Without Physical Examination (DWPE) for the appearance of *Staphylococcal Enterotoxin* adulteration covered within Import Alert 25-11, "Detention Without Physical Examination of Canned and Brined Mushrooms From the Peoples Republic of China" and Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, in that this article appeared to contain a poisonous or deleterious substance which may render it injurious to health.

<u>Product</u>	<u>Entry Number</u>	<u>Quantity</u>
Canned Mushrooms Pieces and Stems	[REDACTED]	[REDACTED] cartons
Canned Mushrooms Sliced	[REDACTED]	[REDACTED] cartons

After receiving location information that the above shipments (consisting of a total of three containers) were transported to [REDACTED] in [REDACTED] arrangements were made with our New York District Office to have these containers examined. On November 29, 2000 an FDA investigator from our New York District attempted to examine the containers, but according to the consignee, the product had already been sold and distributed. At your request, the consignee then initiated a recall of the products involved by issuing a recall letter entitled "Urgent Food Recall". A U.S. Customs Notice to Redeliver was issued on 12/18/00.

Based on the Customs Form 3461 filed for Entry Number [REDACTED] and your own statement to our investigator, formalized in an affidavit you signed on December 6, 2000, your

firm is the Importer of Record and as such is responsible for the bond for this merchandise and the violation which occurred.

These events are in violation of Title 21 Code of Federal Regulations (CFR), Part 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA. We have issued a Notice of Refusal of Admission and have notified U.S. Customs of the distribution.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice, such as seizure, injunction, or detention without physical examination of future shipments. It is your responsibility, as the importer, to ensure that imported product meets all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

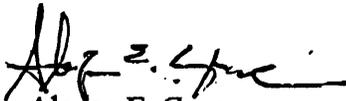
Within 15 working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, we also wish to be advised of the results of the voluntary recall undertaken by your consignee.

Please send your reply to:

Irene Gomez  
Director Import Operations Branch  
U.S. Food and Drug Administration  
222 West 6<sup>th</sup> Street, Suite 700  
San Pedro, CA 90731.

If you have questions or a need for clarification regarding any issue in this letter, you may contact Compliance Officer Ruth Dixon at (310) 831-6123, ext. 155.

Sincerely,

  
Alonza E. Cruse  
District Director