



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94394d

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 13, 2003

Mr. Peter Chen, President
Golden Luck Inc.
6000 Peachtree Street
Commerce, CA 90040

WL 08-04

Dear Mr. Chen,

On June 16, 2003, the Food and Drug Administration (FDA) detained an import shipment of Red Pepper Powder ([REDACTED] cartons/48 bottles/1.4 oz.) pursuant to Sections 402(a)(1) and 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 342(a)(1) and 381(a)(3). FDA sampled the red pepper powder and found *Salmonella*, a poisonous and deleterious substance which causes the product to be adulterated within the meaning of Section 402(a)(1) of the Act, 21 U.S.C. § 342(a)(1). On August 11, 2003 your firm initiated a voluntary recall of this red pepper powder shipment, imported under entry number [REDACTED] because it had been sold and distributed into U.S. Commerce. Your firm was able to recall and destroy, under FDA supervision, [REDACTED] returned bottles out of the [REDACTED] sold bottles on August 26, 2003. In addition, on September 4, 2003, your firm submitted to us a Standard Operating Procedure (SOP) for handling FDA regulated commodities which outlined your firm's intent to follow a procedure for holding merchandise under FDA hold/detention pending an FDA release.

On August 21, 2003, FDA refused a shipment of Leek Flower Sauce ([REDACTED] cartons/48 jars/7.4 oz.), imported under entry number [REDACTED] for failure to file information regarding its process as required by Title 21, Code of Federal Regulations (C.F.R.), sections 108.25(c) (2) and/or 108.35(c) (2). FDA lab findings of a pH greater than 4.6 and a water activity greater than 0.85 confirmed the applicability of 21 C.F.R. 108.35(c)(2) for this product. Acidified and low-acid foods that lack filed processes may be denied entry into the United States under section 801 of the Act, 21 U.S.C. § 381.

On September 23, 2003, an FDA investigator attempted to examine the leek flower sauce shipment, but it had been distributed. On October 1, 2003 you acknowledged that [REDACTED] of the [REDACTED] cartons were sold and distributed into U.S. commerce. Your firm initiated a voluntary recall of the leek flower sauce by issuing a recall letter to your customers on October 2, 2003.

On October 9, 2003, an FDA investigator also found your firm had distributed [REDACTED] cartons of various tea products which made entry as [REDACTED] on April 21, 2003 and have never been made available for FDA examination. In addition, on October 9, 2003, a recommendation for redelivery was submitted to the Customs and Border Protection (CBP).

On February 25, 2003 a shipment of Chinese Prickly Ash Oil ([REDACTED] cartons/40 bottles/4.06 fl.oz.) was detained under entry # [REDACTED] for failure to declare, in English, the common name of the product, ingredients, net weight, firm name and address, and directions for use as required by 21 C.F.R. 101.15. Failure to include such required information on the label in such terms as to render it likely to be read and understood by the ordinary consumer causes the product to be misbranded within the meaning of Section 403(f) of the Act, 21 U.S.C. § 343(f). On September 11, 2003, FDA approved a revised reconditioning proposal. On October 7, 2003 your firm submitted a signed Importer's Certificate to FDA, certifying the completion of the reconditioning and informing FDA that the relabeled product was ready for examination. On October 10, 2003, an FDA investigator visited your firm and found that [REDACTED] cartons of the Chinese Prickly Ash Oil had not been relabeled and were, therefore, still misbranded.

Failure to promptly correct these violations 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 CBP, such as in a bonded warehouse. You will be responsible for all costs incurred at secured storage.

To date your firm has distributed a significant number of FDA regulated products that have been found adulterated. In addition, you have failed to bring misbranded products into compliance even after you submitted a certificate of completion to recondition to FDA. As the importer of record, it is your responsibility to ensure that imported product meets all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder and hold the product intact until it is released. Your firm has an ongoing responsibility to ensure that all import brokers, consignees and others working in your behalf hold the imported product intact unless and until it is released or destroyed. We remind you that introduction into or receipt in interstate commerce of any article that is adulterated or misbranded is a violation of the Federal Food, Drug and Cosmetic Act, and may result in domestic seizure or other sanctions, including injunction or prosecution.

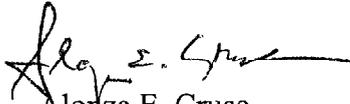
Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of such violations. In addition, please submit recall results for the red pepper powder and leek flower sauce. This letter, and your response, except for any confidential, personal, or commercial information contained in either document, will be available to the public no earlier than fifteen days after transmittal and receipt.

Warning Letter to Mr. Peter Chen, Golden Luck, Inc.

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Please send your reply to Food and Drug Administration, Attention: Dr. James Lin, Compliance Officer, 222 West 6th Street, Suite 700, San Pedro, CA 90731. If you have questions regarding any issue in this letter, please contact Dr. Lin at (310) 971-2312.

Sincerely,

A handwritten signature in black ink, appearing to read "Alonza E. Cruse". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Alonza E. Cruse
District Director