



DEPARTMENT OF HEALTH AND HUMAN SERVICES 95022d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4142

October 4, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 - 01

Dean E. Budde
President
Shang Gardens Inc.
42332 - 520 Street
North Mankato, Minnesota 56003

Dear Mr. Budde:

On July 23, 2004, an Investigator with the United States Food and Drug Administration (FDA) collected a sample of ginseng capsules from your distributor, Grimmer Enterprises. The 50 count bottles of ginseng capsules were labeled, in part, "MFG. SHANG GARDENS" and the lot number was identified as 110154. We subsequently visited you at your residence on August 3, 2004. You stated that your firm received lot 110154 from a contract processor located in Wisconsin under delivery receipt dated November 15, 2001. The ginseng used by the contract processor was produced by your firm. The product label identifies this product as a dietary supplement and as such is a food within the meaning of Sections 201(f) and 201(ff) of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 301-397). You can find the Act on the Internet through links on FDA's web page at www.fda.gov.

The capsules were analyzed to determine compliance with the Act. FDA analysis of these capsules found pesticide chemicals for which no tolerance level has been established.

The article of food was adulterated when introduced into and while in interstate commerce and is adulterated while held for sale after shipment in interstate commerce, within the meaning of Section 402(a)(2)(B) of the Act, in that it bears and contains a pesticide chemical residue, namely Pentachlorobenzene, Quintozene, Pentachloroaniline and Lindane, that is unsafe within the meaning of Section 408a of the Act because no tolerance or exemption from the

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requirements of a tolerance is in effect for the pesticide chemical residue on the article of food.

You are responsible for assuring that the products you distribute are not adulterated and are otherwise in compliance with the law. Failure to do so may result in regulatory action, without further notice, such as seizure and/or injunction.

You should notify this office, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. You should direct your reply to Compliance Officer Jane Nelson at the address on the letterhead. She may be reached at (612) 758-7119 if you have any questions.

Sincerely,



W. Charles Becoat
Director
Minneapolis District


JEN/ccl