



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Minneapolis District Office  
Central Region  
250 Marquette Avenue, Suite  
600  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
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May 13, 2011

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**Refer to MIN 11 - 29**

Paul C. Hsu  
President  
Hsu's Ginseng Enterprises, Inc.  
T6819 County Highway W, P.O. Box 509  
Wausau, Wisconsin 54402

Dear Mr. Hsu:

During an inspection of your facility on November 30-December 3, 2010, located at T6819 County Highway W, Wausau, Wisconsin, we collected a sample (number 501236) that was analyzed by the Food and Drug Administration for pesticides. The sample was labeled "Root to Health, American Ginseng, Herbal Supplement, 500 Veggie Capsules 500 mg. each, Net Wt. 250 g. (8.82 oz.), Hsu's Ginseng Enterprises, Inc., P.O. Box 509, Wausau, WI 54402-0509, Lot#022109-1170, EXP:03/13."

Our analysis revealed that the above product is adulterated within the meaning of the section 402(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(2)(B), in that it bears and contains a pesticide chemical residue, namely Chlorpyrifos and Pentachlorobenzonitrile, that is unsafe within the meaning of 21 U.S.C. § 346a, because no tolerance or exemption from the requirement of a tolerance is in effect for the pesticide chemical residue on the article of food.

The above identification of a violation is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the federal regulations. Moreover, it is your responsibility to produce safe

products. You should take prompt action to prevent further violation of the Act. Further violation of the Act may result in regulatory action without additional notice, which can include seizure of your products and/or injunction of your firm.

We note, during the inspection, the investigator also found a number of deficiencies from Current Good Manufacturing Practice regulations for Dietary Supplements, Title 21, Code of Federal Regulations, Part 111 (21 CFR 111). For example:

- Finished product release specifications for ginseng encapsulated products do not include that finished products meet identity, strength, purity, composition, or contamination limits, 21 CFR 111.70(e).
- A review of the training records and procedure PH13 Personnel Training Program Rev A. DCO12345 (effective date 6/5/09) revealed that your firm's training records do not include such items as who was trained, training topics covered, who provided the training, course length, and if training objectives were successfully met, 21 CFR 111.12(c).
- An attempt was made to review the firm's copies of the batch records for both the American Ginseng 500 Veggie Capsules Herbal Supplement and the Bee Pollen & American Ginseng 100 Capsules Herbal Supplement; however, the documentation was not available, 21 CFR 111.610(a) and (b).

We note that there is an expiration dating placed on product labels of 500 Veggie capsules manufactured in your facility. Any expiration date you place on a product label should be supported by data. (See 72 FR 34752 at 34856, June 25, 2007). You should continue to work with your customers to provide supporting data for the expiration dates placed on the products you manufacture.

Please notify this office in writing, within 15 working days from receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent recurrence. You should include in your response, documentation such as copies of correspondence submitted to FDA, and other useful information to assist us in evaluating your corrections. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Please address your reply to Jane E. Nelson, Compliance Officer, at the address above. If you have questions regarding the contents of this letter, please contact Ms. Nelson at (612) 758-7119.

Sincerely,

/s/

Gerald J. Berg  
Director  
Minneapolis District