DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Public Health Service

Memorandum

Date DEC 18 1998

From Senior Regulatory Scientist, Regulatory Branch, Division of Programs & Enforcement Policy (DPEP), Office of Special Nutritionals, HFS-456

Subject 75-day Premarket Notification for New Dietary Ingredient

To Dockets Management Branch, HFA-305

New Dietary Ingredient:	Danshen Root (*Salvia miltiorrhiza Bge.*)
Firm:	XILI, U.S.A.
Date Received by FDA:	November 13, 1998
90-day Date:	February 10, 1999

In accordance with the requirements of section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 after February 10, 1999.

Robert J. Moore, Ph.D.

95S-0316

RPT36

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 18 1998

2065 '99 JAN -4 P2:57

Mr. David Chen
President
XILI, U.S.A.
1057 SE 17th Street
Fort Lauderdale, Florida 33316

Dear Mr. Chen:

This letter is in response to your submission to the Food and Drug Administration (FDA) dated November 4, 1998 and received by FDA on November 13, 1998 making a submission for a new dietary ingredient pursuant to 21 U.S.C. 350b(a)(2). Your letter notified FDA of your intent to market a product containing danshen root (*Salvia miltiorrhiza Bge.*).

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing danshen root, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. First, although your submission provides the amount of active ingredient (i.e., tanshinone) in the product, information on the amount of the dietary supplement itself to be consumed per day is not provided. Furthermore, the information provided in the Chinese herbal medicine reference included in your submission refers to pharmacological, clinical, and toxicological

findings on danshen root from various studies. However, the exact dose exposures associated with these effects are, for the most part, not provided. Additionally, relevant information about the species of test animals exposed and the route of administration of the test material is not provided in all cases.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that danshen root, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Please contact us if you have any questions concerning this matter.

Sincerely,

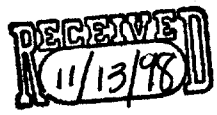
Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

62260

XILI U.S.A.

November 4, 1998

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Aministration
200 C Street, S.W.
Washington, DC 20204



Dear Sir or Madam:

Enclosed is the information required by the FDA for Premarket Notification of a new dietary ingredient.

Please notify me if any additional documentation is necessary.

Thank you.

Sincerely,

David Chen
President

1057 SE 17th Street, Fort Lauderdale, FL 33316
Phone: (954)524-7881 FAX: (954)463-3878

XI LI USA

PREMARKET NOTIFICATION FOR DANSHENGTONG

Manufacturer:	Hebei Xinlong Xi Li Pharmaceutical Company Xiguan, Xinlong County Hebei Province, China
U.S. Distributor:	Xi Li USA 1057 S.E. 17th Street Fort Lauderdale, FL 33316
Trade Name of Supplement:	Danshengtong
Herb Name of Supplement:	Danshen Root
Active Ingredient:	Tanshinone
Latin Name:	Salvia Miltiorrhiza Bge.
Level of Active Ingredient in Supplement:	150mg per capsule
Labeling Information:	Danshengtong, a dietary herbal supplement, is used for cosmetic purposes.
History of Use and Evidence of Safety:	Please see enclosed references: 1. Bensky, Dan and Gamble, Andrew, Chinese Herbal Medicine: Materia Medica, Eastland Press, Inc., 1993, pp. 267-268. 2. Hsu, Hong-Yen and Associates, Oriental Materia Medica: A Concise Guide, Oriental Healing Arts Institute, 1986, pp. 480-481. 3. Yen Kun-Ying, The Illustrated Chinese Materia Medica: Crude and Prepared, SMC Publishing, Inc., Taiwan, Republic of China, 1992, p. 60. 4. Quian, Xinzhong, editor, Color Illustrated Chinese Herbs, People Medical Publishing House, Beijing, China, May 1996, p. 74.