



JAN 14 2005

Mr. Miles Sledd  
Research Director  
Eastern Wisdom Herb Company  
2724 Vassar Place NE  
Albuquerque, New Mexico 87107

Dear Mr. Sledd:

This is in response to your letter of December 26, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Eastern Wisdom Herb Company is making the following claim, among others, for the product **Yin Chiao Formula**:

“[T]o treat inflammation and to mitigate cold symptoms.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely the common cold. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

975-0163

LET 803

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Denver District Office, Office of Compliance, HFR-SW240

NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA and 21 C.F.R. § 101.93

Rec'd  
JAN 7 2005

This notification is being filed on behalf of Eastern Wisdom Herb Company which is the producer of the product which bears the statements identified in this notification. Its business address is: 2724 Vassar Pl. NE; Albuquerque, NM 87107. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is Yin Chiao.

A. The text of each structure/function statement or claim for which notification is now being given is:

(Statement 1): Yin Chiao™ is a famous formula developed in China, where forsythia fruit compounds have been traditionally used for centuries to treat inflammation and to mitigate cold symptoms.

(Statement 2): Our proprietary blend of herbs is designed to support a healthy immune system during periods of temporary stress associated with seasonal changes.\*

B. The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement that is the Subject of the Statement</u>
1.	Yin Chiao Formula
2.	Yin Chiao Formula

I, Miles Sledd, am authorized to certify this Notification on behalf of Eastern Wisdom Herb Company. I certify that the information presented and contained in this Notification is complete and accurate, and that Eastern Wisdom Herb Company has substantiation that each structure/function statement above is truthful and not misleading.

Date Signed: 12/26/2004

By: Miles Sledd  
Miles Sledd  
Research Director, Eastern Wisdom Herbs

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