

FROM :  
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PHONE NO. :

Jun. 29 1996 04:04AM P1



中國醫藥發展公司  
**Sinomedical Development Inc.**



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Jeanne E. Latham, R.D., M.S., L.D.  
Consumer Safety Officer  
Regulatory Branch  
Division of programs and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Washington, DC 20204

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**RE : Asking for comments on nutritional  
statements of 7 dietary supplements.**

Dear Ms. Jeanne E. Latham:

My company, Sinomedical Development Inc., is a California corporation. Recently we plan to import some herbal products from China and market them in the States. On our requirement, the manufacturers in China labeled their products as dietary supplements according to the related US labeling regulations about food and dietary supplement. On the labels of 7 products, there are nutritional support statements. Those statements are as follows:

**THE NUTRITIONAL SUPPORT STATEMENT ON THE LABEL OF  
Longstand:**

**"Longstand**, as a product, is more convenient to use, while it's original formula's benefits to human health is enhanced, i.e., help promote blood circulation and maintain a well-being."

**THE NUTRITIONAL SUPPORT STATEMENT ON THE LABEL OF XL™  
Seabuckthorn Seed Oil:**

**"Seabuckthorn Seed Oil** is extracted by CO<sub>2</sub> supercritical fluid. This advanced process makes no use of organic solvent, while preserves seabuckthorn seed's natural active components and its health promoting properties: it may help boost immunity, soften blood vessel and maintain a healthy heart."

**THE NUTRITIONAL SUPPORT STATEMENT ON THE LABEL OF Gu Kang  
Ye:**

975-0162

LET 745-53694

"Researches in lab and clinic have shown that consumption of this product can improve blood circulation and bone growth of human."

**THE NUTRITIONAL SUPPORT STATEMENT ON THE LABEL OF Hua Ai:**

"Based on a proved formula, **Hua Ai** has well received by consumers for its benefits to human body: it may help boost immunity and maintain a well-being."

**THE NUTRITIONAL SUPPORT STATEMENT ON THE LABEL OF Xiao's Herbs™ Wei An:**

"Studies indicate that consumption of this product may help maintain a healthy, calm stomach."

**THE NUTRITIONAL SUPPORT STATEMENT ON THE LABEL OF Longshine:**

"Studies indicate that consumption of this product may boost human immunity and maintain a well-being."

**THE NUTRITIONAL SUPPORT STATEMENT ON THE LABEL OF Lee's Herbs™ Chang An:**

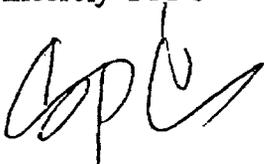
"Studies indicate that consumption of this product may help improve function of the colon."

Of course, there is such a disclaim after those nutritional support statements on the labels:" This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

I would like to take the liberty to ask you for comments on those nutritional support statements. Are those statements allowed to be used as nutritional support statements of dietary supplements? Or are they proper nutritional support statements of dietary supplements? May they be regarded as medical claims? If we import them into US, will they be detained by FDA due to those statements?

I will be very grateful to you for your kind consideration and reply.

Sincerely Yours.



Liang Yan M.D.  
President of Sinomedical Development Inc.