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October 7, 2004

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

Re: Chinese Herbal Products Committee of the American Herbal  
Products Association Petition Regarding Pinelia and Sida Cordifolia  
and the Final Rule on Ephedrine Alkaloids; Docket No. 95N-0304.

Dear Sir/Madam:

Please file the attached letter in the above-referenced docket.

Thank you for your assistance.

Sincerely,

  
Anthony L. Young

Enclosure:

95N-0304

LET 49

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Mr. Charles W. Prettyman  
Office of the Center Director  
Center for Food Safety and Nutrition  
Food and Drug Administration  
HFS-001, Room 4B071  
5100 Paint Branch Parkway  
College Park, MD 20740

Re: Chinese Herbal Products Committee of the American Herbal  
Products Association Petition Regarding *Pinellia* and *Sida*  
*cordifolia* and the Final Rule on Ephedrine Alkaloids; Docket  
No. 95N-0304.

Dear Mr. Prettyman:

As we discussed several weeks ago, the Chinese Herbal Products Committee of the American Herbal Products Association (AHPA) was at that time considering whether to withdraw its revised Petition for Reconsideration and Petition for Stay of Action, filed on August 20, 2004, regarding *pinellia* and *Sida cordifolia* in the matter of the Final Rule on Ephedrine Alkaloids in the above-captioned docket. Based on the information you provided in our conversation and recorded below, the Committee has determined to do so and is doing so with this letter. A copy of this letter is being filed with the Dockets Management Branch.

In our discussion, we agreed that the Final Rule applies only to dietary supplements containing ephedrine alkaloids. It does not apply to dietary supplements that contain *pinellia* or *Sida cordifolia*, which were mentioned in the preamble to the final rule as possible sources of naturally-occurring ephedrine alkaloids, so long as dietary supplements that contain either of these herbal ingredients do not contain ephedrine alkaloids. In addition, the Final Rule does not apply to traditional Asian medicines that contain ephedrine alkaloids.

KLEINFELD, KAPLAN AND BECKER, LLP

Mr. Charles W. Prettyman  
October 7, 2004  
Page 2 of 2

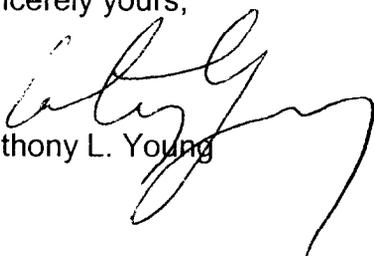
You advised that the Agency is now testing and will continue to test dietary supplements that contain either pinellia or *Sida cordifolia* for the presence of ephedrine alkaloids. In so doing, the Agency will use the AOAC official method No. 2003.13 for ephedrine alkaloids that was published in the *Journal of AOAC International*, 2004 Jan-Feb 87(1): 1-14. If a dietary supplement tested with this analytical method is shown to contain ephedrine alkaloids, that dietary supplement will be deemed to be adulterated subject to the Final Rule.

The Chinese Herbal Products Committee and AHPA have previously advised the Agency that several AHPA members manufacture in the United States traditional Asian medicines that contain botanical ingredients that are known to contain or possibly contain naturally-occurring ephedrine alkaloids, including pinellia and *Sida cordifolia*. Since these ingredients are not grown or harvested in the United States, all such ingredients must be imported. AHPA will advise companies that import raw materials or products that are known to contain or that possibly contain naturally-occurring ephedrine alkaloids as ingredients in traditional Asian medicines that will be manufactured and/or sold in the United States to ensure that all such ingredients or products be labeled in a manner that clearly identifies their intended use as ingredients in traditional Asian medicines only.

As you are also aware, a number of AHPA's members are testing dietary supplements containing pinellia or *Sida cordifolia* for the presence of ephedrine alkaloids and they are now using the AOAC method. AHPA may share these data with FDA in the future and ask FDA to provide results of any similar analyses that are conducted by the Agency. If the results of such testing are consistently negative, AHPA may ask FDA to look again at whether an active testing program should be continued to be expected for dietary supplements that contain either of these two botanicals.

On behalf of the Chinese Herbal Products Committee of AHPA, and on behalf of AHPA, we want to thank you for the open line of communication that has resolved this matter.

Sincerely yours,

  
Anthony L. Young