

4 April 2003

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Via Fax: 301-827-6870 Re: Docket No. 95N-0304

Madam or Sir:

As a grower of Chinese medicinal herbs and a leader in the effort to develop domestic agricultural production of a number of these plants, I wish to make a recommendation concerning the regulation of Ephedra, as follows.

The stems and branches of the plant Ephedra sinica Stapf. (and closely related species) have been used for at least two millennia in Asia, and today throughout the world, as the medicinal herb ma huang. It has an important utility in traditional medicine serving, for example, as a primary ingredient in an herbal formula to address the common cold. Ma huang is used in small amounts, for acute symptoms and for a short period of time. Further, traditional herbal practitioners are trained to recognize symptoms of side effects.

An important principle to be recognized in the controversy over Ephedra is that appropriate use of such efficacious herbs by trained and licensed health professionals is beneficial to human health, and has been for thousands of years. However, misuse of ma huang, whether by untrained hands, for the wrong purposes, in concentrated form or over a long period of time, can indeed cause damage. Therefore, it is critical that regulators clearly distinguish between appropriate use, misuse and abuse.

One way to address the problem is to make certain that herbalists who are certified and licensed by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) are specifically exempted from restrictions upon the use of *ma huang*. Two existing pieces of legislation already make this kind of distinction. They are: California Senate Bill No.1884 (passed in August 2002) and Suffolk County, New York bill RE 1954 (passed in February 2003). I urge you to follow these examples.

The trained, certified and licensed practitioners of Oriental herbal medicine in the United States deserve recognition as a valuable addition to our health care professions. They are also the prime market for our cultivated medicinal herbs. Please protect the health of the public through intelligent regulation.

Sincerely,

Jean Giblette Director

Willette

cc: US

US Senator Charles Schumer NY Assemblyman Patrick Manning

95N-0304

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Telecopier No.		Date:	April 4, 2003
Company:	FDA Dockets Management Branch		
City:	Rockville MD		
Attention:	Docket No. 95N-0304		
Fax Number:	301-827-6870		
No. of pages (incl. cover):	2		
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Message:			