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Tierney Tully, M.S.O.M., Dipl.Ac.(NCCAOM)
Executive Director

An alliance of individuals and organizations
who use acupuncture and Oriental medicine
principles in their work and lives.

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
April 4, 2003

RE: Docket No. 95N - 0304

I am writing to you on behalf of the Acupuncture and Oriental Medicine Alliance to support continued access to ephedra (*ma huang*) by acupuncturist/herbalists who have been trained in its correct traditional use. The Acupuncture and Oriental Medicine Alliance has an active membership of 1,600 health care providers and consumers, as well as students, colleges, and vendors who support acupuncture and Oriental medicine. The Alliance is a 501(c) (4) public welfare organization committed to putting patients first by allowing access to appropriate healthcare, and is dedicated to assuring freedom to practice, based on standards of competency.

Ma huang (the stems of the plant *Ephedra sinca*) has been effectively employed in Chinese medicine for at least 2,000 years. Early in the twentieth century chemists identified the herb's ephedrine alkaloids, and in the 1920's pharmaceutical companies began marketing new products for allergies and colds based on these discoveries. Today the herbal preparation of ephedra is still used responsibly by practitioners of Chinese medicine. Acupuncturists who study Chinese herbal medicine are trained to use ephedra in small doses, in combination with other herbs to treat certain conditions. If used according to the guidelines of traditional Chinese herbal medicine, ephedra is safe and effective for those conditions in which it is traditionally prescribed.

Forty states and the District of Columbia license acupuncturists. A majority of those states require graduation from a program accredited by the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM). ACAOM is the only accrediting agency recognized by the US Department of Education in the field of acupuncture and Oriental medicine. ACAOM has specific requirements for inclusion of Oriental medical theory, diagnosis and treatment techniques in acupuncture, clinical training, and biomedical clinical sciences in all programs. For the study of Chinese herbal medicine, an additional 450 hours is required which must include Chinese herbal materia medica, formulas, indications and contraindications, and clinical hours. The National Commission for Certification of Acupuncture and Oriental Medicine (NCCAOM) has administered the Comprehensive Written Examination (CWE) in Acupuncture since March 1985 and the Examination in Chinese Herbology since April 1995. Passing this examination confers the status of Diplomate in Acupuncture and Diplomate in Chinese Herbology, respectively.

95N-0304

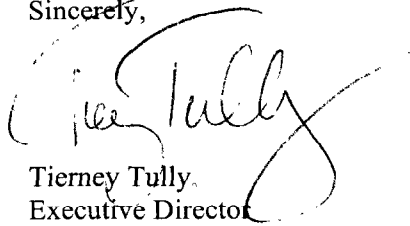
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Our profession has a strong record of safety regarding the use of ephedra and we encourage the FDA to take this into consideration when ruling on this issue. Trained practitioners know the functions as well as the side effects of ephedra. It is safe for use in specific dosage over a short period of time for certain conditions.

In order to maintain access to ephedra, manufacturers and distributors must be able to continue to sell their products which contain ephedra for use by health professionals who are trained in its use. Clearly, the Chinese herbal products industry requires freedom to supply products containing ephedra to practitioners.

Thank you for your consideration of the specific use of ephedra by acupuncture and Oriental medicine practitioners. The Acupuncture and Oriental Medicine Alliance continues to support access to ephedra by qualified health care professionals.

Sincerely,

A handwritten signature in black ink, appearing to read "Tierney Tully". The signature is fluid and cursive, with a large loop at the end.

Tierney Tully
Executive Director