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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

RE: Docket No 1996N -- 0417

28 July 2003

The Acupuncture and Oriental Medicine Alliance requests that herbs prepared for individual sale to a specific patient be exempted from the proposed Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements. Although the proposed rule is intended for manufacturers, as it is currently written it may inappropriately apply to Licensed Acupuncturists who include herbal medicine in their practice when preparing individualized herbal formulas for specific patients on a case-by-case basis.

There is no evidence of harm from herbs prepared by Licensed Acupuncturists. No adverse events related to trained herbalists, including Licensed Acupuncturists, were reported in the documentation for the proposed rule. As public interest in the use of herbal medicine has grown, Licensed Acupuncturists with clinical training are able to provide guidance in the safe and appropriate use of herbs. Public health is safeguarded by access to trained herbalists. Failure of the FDA to provide an exemption for trained herbalists preparing individualized herbs for their patients would negatively impact our ability to deliver this important part of health care services.

Recently enacted Canadian legislation for Natural Health Care Products exempted health care practitioners in the following definition of manufacturer:

*" 'manufacturer' means a person who fabricates or processes a natural health care product for the purpose of sale, but does not include a pharmacist or other health care practitioner who at the request of a patient compounds a natural health care product for the purpose of sale to that patient (fabricant) "*

Public health would be well served by exemption from the Current Good Manufacturing Practices for Dietary Ingredients and Dietary Supplements of herbs prepared by a trained herb practitioner for individual sale to a specific patient.

The Acupuncture and Oriental Medicine Alliance has an active membership of 1600 health care providers and consumers, as well as the students, colleges, and vendors who support acupuncture and Oriental medicine practice. The Alliance is a 501(c)(4) public welfare organization committed to putting the patients first by allowing access to appropriate healthcare, and dedicated to assuring freedom to practice, based on standards of competency. Acupuncturists are currently licensed in 40 states and

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the District of Columbia. The Council on Colleges of Acupuncture and Oriental Medicine (CCAOM) ensures that the skills and knowledge of a practitioner of acupuncture and Oriental medicine include a comprehensive graduate education, on a par with other professional programs acknowledged by the community of American higher education. Graduates must complete a formal, full-time acupuncture program with a minimum of 93 semester credits or 1725 hours. The Accreditation Commission for 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. Acupuncturists who go on to study Chinese herbal medicine must complete an additional 450 hours which must include materia medica, formulas, indications and contraindications of Chinese herbology, 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. Practitioners who hold these designations are prepared to safely serve the public as health professionals.

Clearly this regulation, which requires testing and storage of each finished batch, is not intended for a small dispensary where a trained herbalist prepares several modified herbal formulas each day. Therefore, we request that the FDA provide clear language in this regulation that will preserve the liberty of trained herb practitioners to prepare herbal formulas on a case by case basis in small herbal dispensaries for sale to a specific patient.

Thank you for your consideration

Sincerely,



Tierney Tully  
Executive Director