

Be Prepared

Marilyn Allen, Editor at Large

In March 2003, the U.S. Food and Drug Administration (FDA) approved new guidelines for which acupuncturists dispensing dietary supplements across the nation will be accountable. According to the FDA, Chinese herbs are classified as dietary supplements. The [current Good Manufacturing Practice](#) (cGMP) guidelines final ruling will require compliance from companies with fewer than 20 employees by the [summer of 2010](#). This will, of course, affect small private clinic-sized facilities. The cGMP can be difficult for the average acupuncturist to understand since the basic practices and procedures are complicated by legal terminology. You can access the guidelines online by [clicking here](#).

We are living and practicing in times when many people are losing faith in Western medicine and are searching for other health care options. It is imperative that practitioners of Oriental medicine take advantage of this opportunity to demonstrate the legitimacy and professionalism of the services offered and delivered by acupuncturist throughout the United States. To secure the respect of government and health agencies across the nation, it is essential that practitioners of Oriental medicine are not only informed of the latest regulations and guidelines but are also implementing and following such procedures. The best way to do that is to follow that old Boy Scout motto: Be prepared.

The Consortium for Oriental Medicine Research and Education (COMRE) has been formed and approved as a 501C by the Internal Revenue Service. This entity, along with the American Acupuncture Council are presenting a series of courses for continuing education credit in California and National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) professional development activity credit nationwide. This course is designed to help ensure that private practices are following the cGMP guidelines.

David Kailan, LAc, who has studied regulations and compliance issues, figured that full regulatory compliance would cost each acupuncturist somewhere in the neighborhood of \$65,000. This amount of money is out of reach for most practitioners. So in order to follow compliance and ensure safety for public health and welfare, a course on dispensary and compounding guidelines Procedures has been designed for practitioners.

This course, however, has a much broader scope and importance than simply explaining terminology to practitioners across the United States. The repercussions of the information disseminated through this course are significant. As acupuncturists consistently demonstrate their understanding of and compliance with cGMP guidelines and procedures, Oriental medicine will not only gain wider acceptance but also an increased level of respect among both government and health care leaders, as well as the general public. This can only serve to further the success of practitioners throughout the field of Oriental medicine.

This course will be offered throughout the United States at various Oriental medicine schools. The course will include: A glossary of terms used in the cGMP guidelines; how to establish written procedures for record-keeping; correct labeling; how to care for and maintain the physical

facilities; sanitation and hygiene; proper handling and storage of herbs; how to handle complaints; how to handle returns; information on the adverse reaction database; and much more. Each attendee will be given a downloadable CD with forms for record-keeping, a section for the office policies and procedures notebook and a certificate to display in the office.

The piece of the process about which I am most excited is that the money raised from these seminars is going back into the profession to support research and both national and state legislation. The schools have generously provided the places to present the seminars, and the entire profession will benefit in both knowledge and gaining the ability to properly follow the cGMP guidelines. I sincerely hope you will support this nationwide endeavor to be properly prepared for the advancement of the profession.

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