

**Comment on [docket No.  
96n-0417] RIN 0910-  
AA59.**

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Dr., rm. 1-23,  
Rockville, MD 20857

To Whom It May Concern:

This letter should serve as my official comment regarding FDA Docket No 96n-0417, RIN 0910-AA59, Good Manufacturing Practices in Manufacturing, Packing, or Holding Dietary Supplements. I am currently studying natural medicine at Bastyr University in Seattle, Washington.

In review of the document listed above, I was pleased to see that the "natural products industry" is attempting to reach a level of production proficiency and safety that is currently being practiced by Practitioners of Oriental Medicine as well as other healthcare professional across the United States. Dietary supplements that have been routinely prepared for consumers by "qualified" healthcare practitioners, have been prepared safely in our country for many years. Chinese herbal medicine, which is used by thousands of Americans daily, has a history of safe and effective use for over two thousand years. Natural products were used to supplement the American diet long before pharmaceutical drugs replaced them. The use and preparation of natural dietary supplements is an innate part of Native American and Asian American cultures and is rapidly becoming an important part in the general populations life.

The Industry Draft has benefits for the manufacturing industry, but this draft will create unfavorable conditions for the consumer, and for qualified healthcare practitioners. The measures contained in this draft would require qualified healthcare practitioners to implement production controls and standards that are not economically practicable. Furthermore, qualified healthcare practitioners are already producing the end-results that the industry and the FDA are attempting to achieve by implementing this draft. This draft places an unnecessary burden on qualified healthcare practitioners in addition to placing the consumer and small natural products manufactures at an economic disadvantage.

Thousands of Americans will be forced to buy commercial products if this proposed regulation is applied to all parties who manufacture natural dietary supplements. Practitioners would no longer be able to meet their patient's needs due to such heavy regulation. You should note that many Americans choose to use natural medicine as their means of primary healthcare and should not have their quality of professional care decreased by placing needless regulations upon their qualified healthcare practitioner(s).

Secondly, the negative effects that this regulation would have on the health of Americans who choose to use natural medicine would be profound! Chinese herbal medicine depends on the ability of the practitioner to be able to mix herbal/natural product preparations that are specific to the needs of the individual. The ingredients of these preparations are adjusted as required by the healthcare practitioner. Although, the industry has been able to develop some of the basic formulas used in Chinese medicine they have not adequately produced the variety of formulations that are usually required by most consumers who choose this efficient method of promoting wellness. The ability to choose and create formulations as needed by trained healthcare professionals allows for an infinite number of treatment options.

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The production of Chinese herbal preparations requires a thorough knowledge of the animal, plant and other natural substances used. The large number of qualified healthcare practitioners who currently manufacture natural dietary supplements without incident and with positive outcomes for their consumers adequately represents this knowledge. The ability to manufacture and design tinctures, powders, extracts, capsules as well as other safe means for administration of natural products is the foundation of most forms of natural health care and should not be destroyed by placing unnecessary regulations on competent healthcare providers. These regulations will destroy the individual professional practices that have been established by hard-working qualified medical professionals.

I urge you to review my comments and to explore better means of insuring good manufacturing practice in manufacturing, packing, or holding dietary supplements. Ideally, a plan that does not destroy competent forms of healthcare delivery or that places devastating financial burdens on consumers and medical providers,

Sincerely,

Heidi A. Brubaker

I am a student who has worked incredibly, unexpectedly hard for 6 yrs. so that I may call myself a Naturopathic physician. Above all else, devising & inventing formulas in botanical medicine is what I am trained to do. I urge you to ~~not~~ consider this act from the perspective that individual formulations for each person's individual biochemistry is the meaning of the healing arts!