

Dockets Management Branch  
Federal Drug Administration  
12420 Parklawn Drive, Room 1-2577  
Rockville, MD. 20857

Desert Bloom Herbs  
506 N. Bullard  
Silver City, NM. 88061

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Dear Sirs,

Sorry for the last minute letter, but I want to respond to your request for comments regarding the proposed Good Manufacturing practices regulations you are considering implementing.

I am a clinical Herbalist here in New Mexico, trained by one of the most knowledgeable herbalists in this country, Mr. Michael Moore. Since graduating six years ago from the Southwest School of Botanical Medicine, I have been operating a small herb store here in Silver City..... (I now have six years of experience, being a practicing herbalist)... and I can tell you from a business-owners point of view, as well as from the point of view of a trained clinical herbalist, that the proposed "testing".. of raw materials, as well as too much more paperwork, would not only drive up the prices of all of herbal medicine across the board, but would effectively put lots of companies out of business..... (those who are too small to afford to have on-staff technicians to perform these tests.)

What is the point anyway? Herbs, as we prepare them, have NEVER been harmfully imparted by any qualified herbalist to any client or customer, and have a sterling record of effectiveness and gentleness. Plant medicines are also the most widely-used form of medicines in the world today, as they always have been. They are used by fully 90% of the entire world's population today to maintain health... (usually as herbal teas).

If we as a nation are truly seeking less-expensive alternatives to conventional allopathic medicine, (as is the intent of most folks who enter my store ...) then what needs to happen is that we need to work from the **opposite** end of the spectrum. Instead of testing the herbs... which have already passed the test of time, there needs to be some recognition of the role of the clinical herbalist. The existing schools for herbal training need to become accredited, just as schools for any other health care professionals are. Also, licensing... (similar to that required for the fields of Chinese Medicine, and Chiropractic forms of medical treatment), need to be put into place for herbalists. It is only by **OPENING**, rather than restricting these alternative practices, that we will EVER bring down the costs of medical treatment in this country. Also, if there were standardized training and licensing procedures for us herbalists and manufacturers, then unnecessary concerns in the matter of proper, competent preparation would also be taken care of in the process. (Although these very basic extraction methods which are involved in making simple plant extracts require little or no technical knowledge, and minimal math skills). Organizations which already exist, (like the American Herbalist's Guild) would undoubtedly be happy to sit with you to act as a **partner** in the formation of practical as well as academic standards which would need to be met by herbalists and manufacturers of products.

Most of **my** herbal preparations are fresh plant extracts, made from freshly harvested wild or cultivated herbs, which I identify and collect myself. I am careful to keep herbs separate.. and then to properly label the raw extracts for later decanting.

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I do not collect any plants which can not be positively identified, using botanical keys, or which are not included in my present repertoire of herbal knowledge.

I process some dried herbs... sometimes using a percolation extraction method, using specifications from late 1800's materia medica, or herbal formulary, since these texts come from the time of the peak of herbal medical practice in this country, and contain the most accurate methodology for extraction, or in other ways, preparation of these herbs, for use as remedies.

These new proposed regulations might be appropriate for extremely large manufacturers, who employ hundreds of workers, purchase herbs by the ton, (usually in a form no longer visually recognizable... ie., cut and sifted, or powdered), and who supply these herbal products to large numbers of consumers, but in my own case, for example, the types of regulations you are referring to... requiring testing of dried herb material, or thin layer liquid chromatography of extracts, would represent an extreme, and **unacceptable burden**, which would force me out of business and prevent me from providing the service of making herbal products for my local community.

In small stores, such as mine, which are administrated by trained clinical herbalists, the highest quality control and care is maintained in the processes of making herbal products. This is control which extends even to the gathering of the raw plant materials used in the process, and so in these respects, We can NEVER be matched for quality control.

In other matters, regarding the manufacture of herbal products, Perhaps the facility in which these products are produced, (which is more closely related to the concern of cleanliness, than efficacy), may be more closely monitored, but again, If the F.D.A implements burdensome regulations which would require a manufacturer to invest hundreds of thousands of dollars for clean rooms, and such, we small herb stores will again be forced out of business, and in addition, the cost of herbal products produced by the large manufacturers will rise across the board. (An effect which I'm sure will not endear you to the huge numbers of voters who are users of herbal products).

By imposing these proposed regulations, you would drive smaller manufacturers out of business, thus forcing the public to buy products from large companies who cannot possibly match the quality standards of small stores.. who use fresh herbs. The proposed action would also have the effect of taking herbal medicine out of the hands of the common people once again. This is **NOT** what you intend, I **believe**, and so, in my opinion, some alternative strategies need to be addressed.

Perhaps some of these regulations could apply to larger companies... if they produced over a certain amount of product each year, or if they employed over 10 people, or something...and especially if they produce standardized extracts, using highly technical equipment, or are isolating and concentrating herb constituents; but for the small businessman, struggling to stay in business, and acting as a necessary service to their community, these burdens would be not only restrictive to the point of putting us out of business, but are hardly representative of the wishes of the public at large, (although they may be representative of certain special interest lobbies).

I wholeheartedly **oppose** any moves on the part of The F.D.A. to further restrict or in other ways, regulate herbal products made by small companies, unless a company has been shown to have produced and sold defective or dangerous

products to the public, and then, in those theoretical cases, they should be dealt with on an individual basis, using current laws. There are already enough laws in existence to protect those who might be adversely affected, and hold responsible those who ARE responsible.

**I see these proposed new regulations as mostly just another angle of attack upon the herbal industry by the forces of (probably) allopathic medicine, or other large-scale producers of herbal products who see the small herbalist as a threat to their market shares, and in reality, have nothing to do with the safety of herbs in regards to use by the general public. I also have had not a single case brought to my attention... (an herbalist dispensing tainted or ineffective herbal products), which would give you any legitimate reason to actually adopt these types of intrusive regulations. Let herbalists be responsible for herbs. We know them well.**

I ask that you respond to this letter, and keep me informed of any changes to your current policies in these matters.

With kind regards,

Richard McDonald, C.H.

P.S. — do you have an e-mail address?  
if so, please send it to me at  
desertbloom@zianet.com (my e-mail)