



Herbal Alternatives USA

"We bring you *Herbal Solutions*™"

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July 20, 1999

Dockets Management Branch (HFA-305)
Docket Number 96N-0417
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

I am writing to express my concerns to CFSAN regarding the negative economic impacts that any proposal to establish "good manufacturing practice regulations" for dietary supplements would have on my small business, as well as other small businesses in the industry.

Increased regulations, quite simply, will increase costs. Small companies may be forced out of business if they cannot bear the costs necessary to comply with the new regulations. These regulations will hurt small businesses, and would not necessarily improve quality for consumers. There is something to be said for small, "homemade" style of manufacturing. Consider your local mom & pop bakery. Their cookies may not be as uniform as Keebler's, but their customers are not expecting them to be—and that certainly does not mean the quality is not equal, if not better, to the large, national brands. If you try to regulate the local small bakery on the same scale as you do the large national brands like Nabisco or Keebler, you will undoubtedly kill the small, local stores. The same holds true for small manufacturers of herbal supplements.

The small company that manufactures the products that I distribute has been making the products since 1992. The company makes the herbal supplements in the traditional Native American preparation process that has been used for hundreds of years. To suggest that they need to be regulated insults both the company and its customers.

To continue to protect the consumer, I recommend continuing to evaluate the kinds of claims that can be made on product labels. A customer then knows what they are purchasing, including whether the goods inside are standardized or not, or meet some kind of quality control. Let us allow companies to provide the information to consumers, and allow consumers to make educated decisions. Increased regulations will destroy many small businesses (the lifeblood of our economy), and will destroy choice for consumers as well.

Thank you for taking my thoughts into consideration.

Best regards,

Brenda Busch
President

96N-0417

CSJ



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