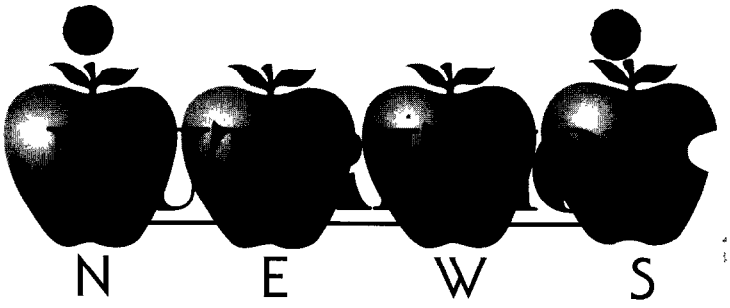


March 25, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madam,

I own a publishing company in Riverside, CA. We have been in the natural products industry for 27 years. Both my customers and I appreciate the significance of the Dietary Supplement Health and Education Act of 1994 with regard to protecting our right to choose how we care for ourselves.

I am concerned that FDA has only just begun to implement key sections of DSHEA. For instance, the agency recently released its proposed good manufacturing practices for the industry, and yet is immediately calling for suggestions for increased legislative authority in order to better regulate the supplement industry. Shouldn't you first give DSHEA a chance to work as it was intended to before calling for new laws?

Please also don't overlook that DSHEA actually increased FDA's enforcement powers. FDA can seize a dietary supplement if it presents an unreasonable or significant risk of illness or injury. In addition, the government can stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard.

I have also been reading the news lately and am concerned about the increasing litigation regarding drug companies mis-deeds. $100 million against Bayer for disregarding their own research which showed the cholesterol drug Baycol had a serious side effect - rhabdomyolysis which can cause the kidney to clog with disintegrating muscle tissue, resulting in failure and death.

Bristol-Meyers recently settled charges that it blocked the sale of cheaper generic versions of three of its drugs, allegedly costing cancer patients hundreds of millions of dollars. By the way, haven't we had a way on cancer for well over 20 years? There doesn't seem to be an less cancer around but we certainly seem to have lots of drug companies selling lots of drugs and not one has been shown to cure cancer.

Warner-Lambert managed to get their diabetes drug Rezulin approved *with* FDA help in spite of the fact that patients who took the drug in clinical studies had suffered life threatening liver damage. Company officials assured the FDA that the risk was trivial.

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It seems to me that the FDA has far bigger problems before it than regulating the supplement industry - an industry born out of time tested natural substances that offer

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few if any side effects. Certainly not anywhere near the catastrophic numbers of prescription drug related deaths each year.

In sum, I agree with the former FDA commissioner, Dr. Jane Henney, that DSHEA provides FDA with the necessary legal authority to protect public health.

DSHEA improved consumer access to dietary supplements and information about them, while increasing consumer protection against unsafe products and false and misleading claims. I strongly support DSHEA and do not think any additional legislative authority is necessary for FDA to regulate ephedra or any other dietary supplement.

Please consider, that the growth of the supplement industry has been largely fueled by the marketplace. Consumers are voting with their dollars. Many prefer a more self-directed approach to health care. With the costs of care and prescription drugs rising well out of the budgets of most citizens *and* most companies who provide insurance, perhaps its time to consider a more natural, supplement based program of health management. This is a highly leveraged solution. It's low cost, effective and far safer than the alternative offered by the institutional sickness and drug delivery model. Consumers simply will not continue to pay for diminishing returns on their health care dollar. If a supplement or an herb works for them, they will continue to buy them and fight for their rights to free access to them.

Sincerely,

Gurumantra S. Khalsa
Publisher