
*Owners:*
**RAY & ANTONIA KOEHN**
1642 State Route 121 North
Murray, Kentucky 42071
(270) 767-0486 • Fax: (270) 753-7993

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March 20, 2003

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madam,

I am the owner of a health food store in Murray, Kentucky, and have been in business nearly eight years. We here in Murray appreciate how the passage of the Dietary Supplement Health and Education Act of 1994 improved our access to dietary supplements and the information about them. We were able to help our customers make informed choices and also to advise them on unsafe products and false and misleading claims. It made our job easier and the customers feel more assured they are getting reliable information.

I am concerned that the FDA has only just begun to initiate aggressive enforcement actions under DSHEA, yet is calling for suggestions for increased legislative authority in order to better regulate the supplement industry. I feel you should first give these recent efforts a chance to work, and perhaps even issue good manufacturing practices for supplements before calling for new laws. According to the *Journal of the American Medical Association* in a recent issue there have been over 100,000 deaths caused by drug reactions when the drug was properly prescribed, properly filled, and properly taken. That was only in the year of the study which I believe was in 1998. That is over 270 persons per day! If the airline industry had a problem like that, they would ground every plane in the world. Why does the FDA concern itself with 40 or so deaths that may attributed to abuse of some herbal preparations, when the pharmaceutical industry has a problem of such magnitude with its products? I know a death is serious, but let's put things in their proper perspective and not succumb to a knee-jerk reaction and call for new laws. Simply put, I believe the agency can regulate ephedra without dismantling DSHEA.

It is also my understanding that DSHEA *increased* FDA's enforcement powers and that FDA can seize a dietary supplement if it presents an unreasonable or significant risk of illness or injury. Furthermore, the government can stop the sale of an entire class of dietary supplements if they pose in imminent public health hazard. With those regulatory powers, I believe that the FDA has enough tools to work with without further laws or changes in existing ones. In fact the former FDA commissioner, Dr. Jane Henney, has stated before Congress that she believes the DSHEA provides the FDA with the necessary legal authority to protect the public health. I agree with Dr. Henney, strongly support DSHEA, and do not think any additional legislation is necessary.

Sincerely,

Ray Allan Koehn
Der Dutch Merchant
1642 St. Rte. 121 N.
Murray, KY 42071

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