

# THE SHELTON GROUP

Public Relations Consulting

March 18, 2003



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

Dear Sir/Madam,

I own for a small public relations firm in Skokie, Il and have been in the natural products industry for 15 years.

The passage of the Dietary Supplement Health and Education Act of 1994 improved consumer access to dietary supplements and information about them, while increasing consumer protection against unsafe products and false and misleading claims. However, for several years I have been concerned that the FDA has shown a lack of commitment to that law's enforcement.

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. Shouldn't you first give these recent efforts a chance to work, and perhaps even issue the good manufacturing practices for supplements that were mandated by the law passed NINE years ago, before calling for new laws? The current law is adequate. New laws would only confuse the situation and given the FDA's track record of slow enforcement, certainly would not lead to better public safety.

The agency has ample authority to regulate ephedra without dismantling DSHEA. It is 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 an imminent public health hazard. The former FDA commissioner, Dr. Jane Henney, has even stated before Congress that she believes that DSHEA provides FDA with the necessary legal authority to protect the public health. I agree with Dr. Henney, strongly support DSHEA, and do not believe any additional legislative authority is necessary.

Sincerely,

  
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