



March 6, 2003

2003 03 06 13:13:13

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

Dear Sir/Madam,

I own a dietary supplement manufacturing facility in Fairfield, California, and have been in the natural products industry for many years. Both my customers and I appreciate how 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.

I am concerned that 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 good manufacturing practices for supplements, before calling 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 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 think any additional legislative authority is necessary.

Sincerely,

A handwritten signature in black ink, appearing to read "Allen Baroff".

Allen Baroff
President

AB:cmb:allen/fda.ephedra

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ABC Laboratories, Inc.

2450 S. Watney Way (Solano Business Park) • Fairfield, California 94533 • (707) 432-2200 Fax (707) 432-2225

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