



Essentially Pure Ingredients Laci Le Beau™ Prolab Nutrition™

March 10, 2003

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

PROTECT DSHEA—NO CHANGE IN LEGISLATIVE AUTHORITY FOR FDA

Dear Food and Drug Administration:

My company has been manufacturing dietary supplements for more than 20 years. When the Dietary Supplement Health and Education Act was passed, we appreciated how it improved consumer access to dietary supplements and information about them while increasing consumer protection against unsafe products and false and misleading claims.

DSHEA works so well, I believe there's no need to change it.

- The FDA already has enough legislative authority to regulate supplements. In fact, former FDA commissioner Dr. Jane Henney testified before Congress that "DSHEA provides FDA with the necessary legal authority to protect the public health."
- The FDA already can seize dietary supplements that pose an "unreasonable or significant risk of illness or injury." The Department of Health and Human Services can also stop the sale of an entire class of dietary supplements if they pose an imminent public health hazard.
- The FDA has finally started to fully implement the law by taking aggressive action against unsubstantiated dietary supplement claims. It has also said that good manufacturing practices for supplements are imminent. Give these efforts a chance to work.

Amending DSHEA could mean that new dietary supplement products would need to go through a lengthy approval process before being sold. This would mean fewer products, reduced innovation and less variety. It would also result in a less competitive marketplace. Finally, it could mean that products could be pulled from shelves with little evidence that they might do harm. Both the consumer and our industry would be hurt.

I agree with Dr. Henney, I strongly support DSHEA, and I do not think any additional legislative authority is necessary.

Sincerely,

Elliott Balbert
President/CEO, Natrol, Inc.

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