

September 27, 2006

**Re: *Dietary Supplement and Nonprescription Drug Consumer Protection Act***

Dear Congressman:

As a responsible manufacturer of dietary supplements, we are writing to voice our continued concerns over and opposition to the proposed Dietary Supplement and Nonprescription Drug Consumer Protection Act, S. 3546 (the “Act”). A version of the Act that is identical to the Senate version (S. 3546) was recently introduced to the House and referred to the Health Subcommittee of the House Energy and Commerce Committee (the “Committee”).

We believe the proposed Act is well intentioned but ill-conceived and would only further tax an already under-funded Food and Drug Administration (“FDA”) without any corresponding benefit to the public health. The effect of the proposed Act would be to unjustifiably burden dietary supplement manufacturers and even retailers and dissuade consumers in their use of supplements, a consequence at odds with the clear intent of the Committee when it approved for passage the Dietary Supplement Health and Education Act (“DSHEA”).

As you consider the Act, we ask that you keep in mind the following:

1. **The Act is enormously expensive to the government and the economy.** GAO estimates are that implementation of the Act for FDA alone will be as much as \$50 million by 2011 – imagine what the cost to industry will be and the corresponding increase in the cost of supplements. Since so many parties are involved in receiving, documenting, reporting and creating and keeping records (for 6 years), we believe the costs could be enormous – certainly many multiples of the \$50 million cost to the government.
2. **The Act offers no real public benefit.** The Act is entitled a “consumer protection act,” but offers no real health benefit. FDA already collects and evaluates thousands of adverse event reports for nonprescription drugs and for dietary supplements using a voluntary reporting system.<sup>1</sup> This system has a proven track record of identifying safety issues and protecting the public health. In fact, the large number of reports that FDA received for high potency/dosage ephedra products using this voluntary system proves that underreporting of events is not the problem. Many responsible companies already voluntarily report serious adverse events to the government. Current product liability insurance claims also identify the most serious adverse events.
3. **A better title for the Act would be “The 2006 OTC and Dietary Supplement Recordkeeping Act.”** The Act requires OTC and supplement manufacturers, distributors and packers (even retailers for private label products) to keep records of *all* adverse event reports (medical and consumer complaints) – not just serious reports – for 6 years! This means if someone calls and complains about a stomach-ache and mentions it might have been their multivitamin, suddenly

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<sup>1</sup>If Congress and FDA believe that underreporting is occurring and are truly interested in serving the public, they could require that companies add the 1-800 MedWatch number to their bottles. This would provide the public with more direct access to FDA. FDA could then decide which information is valuable and which is not. In contrast, the Act relies on companies to make this decision. Responsible companies will over-report and irresponsible ones will ignore the rules. A 1-800 number levels the playing field and makes compliance simple for both industry and FDA, which can simply take non-compliant products off the market.

there is a recordkeeping requirement for six years. Most companies will record every phone call, letter and e-mail they get to make sure they are in compliance. This is an expensive and unnecessary requirement. What is the possible benefit to the public health of companies maintaining these records?

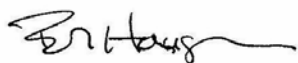
4. **The Act is a boon to plaintiff's lawyers.** With all of these records now being generated and maintained for six years, plaintiff's lawyers who seek to lay blame for their client's woes are going to get an unexpected gift. Imagine the amount of unnecessary and irrelevant paperwork companies will have to produce in litigation, and all the questions and issues that might come up from each complaint. Consider too that in not a single instance is there any proof of causation – these are complaints made almost entirely by consumers. They are not qualified to determine causation and have a conflict of interest in any case!
5. **The Act is a solution in search of a problem.** Supplements are safe – far safer than foods even, and far safer than OTCs or drugs. There is no evidence that they are causing public health issues. FDA, the agency charged with the responsibility for assuring the safety of nonprescription drugs and dietary supplements, has not requested additional authority to require mandatory reporting of adverse events for these products. When product safety issues occur, healthcare professionals and consumers know to report events to FDA. If the Act is passed, the best possible outcome for our country is that FDA will collect a significant amount of data and do little or nothing with it. The worst possible outcome is far worse. In either case, the cost to the government and the economy is significant.

The Act is not needed—there is already an existing reporting system. FDA has not requested the Act nor does it have or will it have the funds to respond to its obligations under the Act. FDA should be spending its time and resources enforcing DSHEA and putting Good Manufacturing Practices (GMPs) in place. Dealing with this unnecessary legislation will only serve to distract them from their existing responsibilities, which they are already struggling with. A case in point are GMPs, for which the public and industry have been waiting 12 years!

We believe that this legislation that is unnecessary, costly and burdensome to the economy and offers to solve no legitimate problem. As a responsible manufacturer of dietary supplements, one who is fully committed to the safety and health of its customers and to the welfare of this industry as a whole, we urge you not to support the Act.

If Congress believes that some legislation is necessary, we would support a version of the Act that required a 1-800 number on all manufacturer labels of foods, supplements and OTC products. Alternatively, we believe there are changes that could be made to the Act that would improve it significantly and would be happy to discuss or provide those at your convenience.

Sincerely,  
NUTRACEUTICAL CORPORATION



Bruce R. Hough  
President