Coalition of Consumer Advocacy Groups and the Dietary Supplement and Nonprescription Drug Trade Associations In Support of Adverse Event Reporting for Dietary Supplements and OTCs

American Herbal Products Association, Citizens for Health, Consumer Federation of America, Consumer Healthcare Products Association, Council for Responsible Nutrition, National Consumers League, National Nutritional Foods Association, United Natural Products Alliance

July 17, 2006

United States Senate

RE: Support the Dietary Supplement and Nonprescription Drug Consumer Protection Act (S 3546)

Dear Senator:

On behalf of the consumer advocacy groups and the dietary supplement and nonprescription drug trade associations, we are writing to urge you to support S 3546, the Dietary Supplement and Nonprescription Drug Consumer Protection Act, introduced by Sens. Orrin Hatch (R-UT), Tom Harkin (D-IA), Richard Durbin (D-IL), Mike Enzi (R-WY) and Ted Kennedy (D-MA).

The legislation would amend the Food, Drug and Cosmetic Act (FD&CA) to require that the manufacturer, packer or distributor of a dietary supplement or monographed over-the-counter drug (OTC) notify the Food and Drug Administration (FDA) of any serious adverse events it receives that are associated with one of their dietary supplement or OTC products within 15 business days. A serious adverse event is (a health-related event that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity or a congenital anomaly or birth defect).

Adverse event reports provide early warning signals to FDA of potential product problems, like product contamination or adulteration, tampering, bioterrorism and ingredient safety issues. By providing this information to a single source – FDA – manufacturers increase the likelihood that trends indicating a problem will be identified more quickly and fewer consumers will be affected. Although FDA receives adverse event reports now from consumers, healthcare providers, poison control centers, and even many manufacturers on a voluntary basis, S 3546 will ensure that all serious reports sent to a company are transmitted to FDA.

The nonprescription drug and the dietary supplement trade associations along with the consumer advocacy groups listed on this letter believe that this legislation is just the right thing to do. Consumers should be able to expect that when a serious incident happens the manufacturer will tell the federal agency that regulates these products. Please join us in supporting the Dietary Supplement and Nonprescription Drug Consumer Protection Act by voting for S 3546.

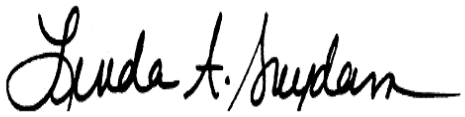
If you have any questions regarding this legislation, please contact any of the following organizations for more information: Michael McGuffin – (301) 588-1171 – American Herbal Products Association; James Gormley – (914) 701-4511 – Citizens for Health; Chris Waldrop – (202) 797-8551 – Consumer Federation of America; Linda Suydam – (202) 429-9260 – Consumer Healthcare Products Association; Steve Mister – (202) 776-7929 – Council for Responsible Nutrition; Linda Golodner – (202) 835-3323 – National Consumers League; David Seckman – (202) 223-0101 – National Nutritional Foods Association; or Loren Israelsen – (801) 474-2572 – United Natural Products Alliance.

Sincerely yours,

American Herbal Products Association

Citizens for Health

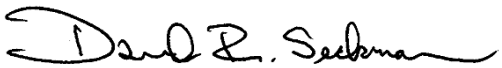
Consumer Federation of America



Consumer Healthcare Products Association

Council for Responsible Nutrition

National Consumers League



National Nutritional Foods Association

United Natural Products Alliance