

February 3, 2010

New Legislation Poses Threat to DSHEA

At a press conference held earlier today, Sen. John McCain (R-Ariz.) announced that he would be introducing legislation that would amend the Dietary Supplement Health and Education Act (DSHEA) to give the U.S. Food and Drug Administration (FDA) additional powers over retailers and suppliers in the dietary supplements industry. The Natural Products Association is reviewing McCain's bill, which is cosponsored by Sen. Byron Dorgan (D-N.D.), and offers this initial analysis regarding the impact of the legislation on the industry.

NPA will work aggressively to address this threat to the industry. The association will continue to keep its members informed and let them know how they can help protect their businesses.

Brief description of the provisions of the *Dietary Supplement Safety Act of 2010*

New Requirements from Suppliers to Retailers

Suppliers and retailers regardless of size all along the chain of commerce are required to "obtain adequate written evidence" from the seller that the product is registered as required. That evidence must be retained in a file available for inspection.

Adverse Event Reporting (AER)

Requires reporting of all adverse events, not just serious adverse events. In addition, a compilation of non-serious AERs must be submitted annually, and records must be maintained for three years.

"Accepted Dietary Ingredients" List

Mandates creation by the Secretary of a list of "Accepted Dietary Ingredients" to replace the current "in commerce pre-DSHEA" test.

New Dietary Ingredients (NDI)

NDIs are considered adulterated unless there is a history of use or evidence of its safety. Registrants shall maintain a "scientifically reasonable substantiation file" available for inspection by the Secretary of Health and Human Services. Registration required 75 days prior to market.

Recall Authority

Provides immediate recall authority to the Secretary upon determination that a supplement "would cause serious, adverse health consequences or death, or is adulterated or misbranded." Companies subject to a recall have the right to challenge the order in an "informal hearing" within 10 days. At their own expense, retailers must notify customers of such recalls.

Registration of Dietary Supplement Facilities

Dietary supplement facilities shall register with the Secretary (required information includes name, address of all facilities, trade names, list of supplements, their ingredients, and labels). Registration is annual.

[Read the complete bill here.](#)

