

FDA: Reclassifying Supplements?

A “Redbook Attack” defies DSHEA and may destroy Americans’ health freedom.

In early December 2014, the Food and Drug Administration (FDA) held an open meeting to listen to public opinions on their Guidance for Industry “Toxicological Principles for the Safety Assessment of Food Ingredients,” also known as the “Redbook.” In existence since 1982, the Redbook focuses on how food additives are evaluated for safety and approved for proper use.

In advance of this public meeting, however, the FDA announced that it is considering expanding the scope of the Redbook to include not just food additives, but dietary supplement ingredients as well—a move that could have catastrophic implications for the Dietary Supplement Health and Education Act (DSHEA) that protects our right to take nutritional supplements.

Supplements Are Not Additives

When DSHEA was passed in 1994, partly thanks to 2.5 million citizens who wrote letters to Congress urging its approval, it established that dietary supplements are to be treated as foods. But DSHEA also contains language that explicitly states dietary supplements should not be treated as food *additives*.

An entirely separate category, food additives includes things like food dyes, trans fats, artificial sweeteners and preservatives—a far cry from the safe, natural supplements taken by 60% of all Americans. When the FDA suggested it might include supplements among these food additives in its Redbook, it dramatically

overstepped its bounds—apparently presuming to categorize supplements where they don’t belong, and in doing so, change DSHEA.

Senators Step In

Senators Orrin Hatch and Tom Harkin— key DSHEA architects and



defenders—quickly responded to the FDA’s brazen power grab with a letter that explains exactly why including supplements in the Redbook would undermine DSHEA. In their letter, the Senators point out that DSHEA already establishes that supplements are not food additives; that the Redbook was created to help regulate food additives only; and that if the FDA changed the Redbook to include supplements, they may even violate the Administrative Procedures Act (APA) that governs federal agencies.

Hatch and Harkin closed their letter by reminding the FDA that supplement safety is already regulated under DSHEA, and urged the FDA to cease

including supplements in their Redbook discussions, stating, “...dietary ingredients are not an appropriate or relevant topic in your meeting about the Redbook.”

Attorney Marc Ullman of the New York-based law firm Ullman, Shapiro & Ullman also weighed in, pointing out that the FDA’s efforts to redefine supplements as food additives appears to be wasteful and unproductive, especially since the FDA is late on delivering its revised draft guidance for new dietary ingredients (NDI) in supplements.

An Urgent Call to Action!

Washington Update readers were warned that another FDA assault on DSHEA was looming, and the “Redbook Attack” appears to fit the bill. The good news: FDA presented its Redbook plans in a hearing designed to collect public opinions, and it is easy to share yours: Visit www.regulations.gov and enter “FDA-2014-N-1497” in the search box. Click the blue “Comment Now!” box on the right, and enter your message. Please tell the FDA to keep supplements out of their Redbook, and to stop attacking DSHEA!

In addition to sharing your opinion with the FDA, please consider sending a fax to Senators Tom Harkin at 202-224-9369 and Orrin Hatch at 202-224-6331 to say thank you for protecting DSHEA. Just as they have done, we must rise up and actively defend DSHEA! Finally, Visit NHA2015.com for ongoing updates on the Redbook Attack. For the sake of health freedom, join the NHA today. ❖

*This editorial is a public service announcement sponsored by the Nutritional Health Alliance (NHA).