# News Release

## DSPA - NHF's Pre-emptive Strike on the FDA Draft Guidance The FDA's Attack on Supplements Can be Stopped

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In an end-run worthy of an NFL halfback, the National Health Federation is spearheading the introduction of legislation to counter the FDA's infamous new Draft Guidance on New Dietary Ingredients (NDIs). The Guidance, if finalized and acted upon, would result in the loss of access to countless safe natural health products Americans consume daily. The Guidance would require perfectly safe dietary-supplement ingredients to undergo very expensive, burdensome, and unnecessary testing and FDA approval or else be removed from the market.

Since the passage of the Dietary Supplement Health and Education Act of 1994, the United States has enjoyed excellent access to essential nutrients, but more recently we have watched as the FDA increasingly squeezes the life out of that law with new and onerous rules and regulations. Now, the FDA wants to enforce even more rigorous "safety" standards on products that have never caused harm, but which entered the marketplace after the year DSHEA became law, 1994.

The Dietary Supplement Protection Act (DSPA), which has not yet been issued a bill number, is the brainchild of the Federation and is being introduced by health-freedom advocate Rep. Dan Burton (R-IN). (For more information on Rep. Burton, visit the website http://indianadan.com.) Simply but powerfully, DSPA amends DSHEA by moving forward the grandfathering date to 2007, from 1994, thereby putting many thousands of safe, time-tested products immediately out of range of the NDI Draft Guidance.

The logic of the DSPA is clear, given that the safety standards of the entire industry have undergone an overhaul since DSHEA, with much more stringent manufacturing practice standards in place; the current regulatory environment is vastly different from what it was 17 years ago. As a consequence, the innovative formulators and manufacturers of some 26,000 products added since 1994 have jumped through increasingly smaller flaming hoops to bring their products to market, meeting tougher and tougher standards.

To provide a perspective of just how many of our products the NDI guidance could ultimately affect, consider that prior to DSHEA, there were only 4,000 products on the market, and now there are 30,000: that's a staggering 87% of our supplements that might be considered "novel" under the existing grandfathering date, and hence potentially "unsafe." The FDA calls this "Subject to evaluation," the NHF calls it a strip search.

Scott Tips, president of the National Health Federation, asks, "*Where are the dead bodies from these new dietary ingredients? There are none, and the FDA knows this simple fact yet wants to push these safe supplements off the market or price them beyond the reach of most consumers through expensive and useless regulations camouflaged as 'protecting the public.' We must preempt the FDA, to push the goal posts far enough forward as is politically feasible so as to ensure that no matter the outcome of the Draft Guidance, the natural health industry, and the millions upon millions of consumers who use its products, are saved from the FDA's immediate*

*stranglehold on health freedom. We are very appreciative of Representative Dan Burton for introducing this bill.*"

The NHF takes very seriously its role as a watchdog over the machinations of the FDA, and has pressed Congress to take a more aggressive stance on the FDA's misinterpretation of the spirit and intent of DSHEA. In fact, the Draft Guidance on NDIs is contemptuous of the intent of Congress when it passed DSHEA, because instead of ensuring access to a full range of products, it obstructs their path to the marketplace.

With the Dietary Supplement Protection Act, the NHF is attempting to establish a bulkhead against further restrictions of the healthy choices of Americans, and in the coming weeks will be pushing hard for its passage. DSPA can score a touchdown for consumers and the industry alike, and NHF will continue to seek support for its earliest possible enactment into law.