

NHA/WASHINGTON

update*

Another Try to Block DSHEA

The FDA's NDI draft guidance attacks the very essence of Health Freedom!

Once again, the stronghold of Health Freedom—the Dietary Supplement Health and Education Act (DSHEA)—is under attack. The latest weapon: The FDA's New Dietary Ingredient Draft Guidance (NDI). NDI appears custom-designed to revoke Americans' access to supplements and derail supplement innovations. Without an immediate intervention by the people, NDI will undo DSHEA and take your vitamins away!

In 1994, the passage of DSHEA preserved our right to nutritional supplements by classifying them as foods that do not need FDA approval. DSHEA was designed to help Americans achieve good health by making supplements abundant and affordable. But NDI is poised to change all that by rewriting DSHEA—which would destroy our Health Freedom forever.

FDA's NDI Draft Guidance proposes a "notification process" that would drain supplement manufacturers' resources to the point of bankruptcy. FDA's NDI Draft Guidance proposes a narrow definition of "dietary ingredient" while taking a broad view of what makes an ingredient new. The narrow view restricts innovation, while the broad view buries manufacturers under NDI paperwork. This one-two punch is a devastating combination that represents the most dangerous threat our Health Freedom has ever faced.

Full-On Assault

NDI Draft Guidance proposes that bioidentical nutrients, such as synthe-

sized vitamins and amino acids, cannot be used in dietary supplements—unless they were used prior to 1994. Newly discovered probiotics and nutrients such as zeaxanthin, astaxanthin and ubiquinol would also require NDI notification—even though these life-giving supernutrients were in the food supply prior to 1994.

This position directly contradicts DSHEA and would severely limit manufacturers' ability to create breakthrough formulations. Plus, under these guidelines, if science discovers a nutrient that could supercharge health and well-being, the public would never know about it—no company would be willing to deal with NDI's regulatory red tape and spend millions of dollars.

In addition to crippling manufacturers' ability to formulate new supplements, NDI discourages manufacturers from improving existing formulations. Under NDI Draft Guidance, any change related to manufacturing, extraction or NDI levels in a product will trigger an NDI notification—even if these changes make a supplement even better. If a manufacturer added a single NDI to its 40 multivitamin products, for example, that would trigger 40 NDI notifications. Any change in manufacturing or formulation would guarantee huge losses for supplement manufacturers, due to time, money and paperwork demands of countless NDI notifications.

NDI notifications would punish any manufacturer who even attempted to create a "New & Improved" product. The tremendous forward progress of the Natural Health Industry would come to a screeching halt, as nutri-

tional innovation would give way to fear of FDA reprisal and reams of meaningless paperwork.

The real victims of NDI's tyrannical DSHEA-rewrite would be the millions of Americans who support their health and well-being with safe and beneficial supplements. Health-promoting nutritional advancements would suddenly die off. Many nutritional supplements that are available now would disappear under NDI—driving health food stores out of business. And once DSHEA has been rewritten, the precedent will be set for the FDA to take away all of our health-promoting vitamins forever.

Make Your Voice Heard!

This is your wake-up call. Since the FDA is introducing a "Draft Guidance" and not a regulation, the NDI rules will bypass all the scrutiny, checks and balances of normal regulation. It's a classic from the FDA's playbook: Sneaking destructive legislation under the cloak of night without the public's knowledge. So remain vigilant: We may have only one chance to stop the FDA from taking our vitamins away.

Go to NHA2011.com to write your elected officials today. Tell them you vehemently disagree with the FDA's NDI Draft Guidance. Remind them that it's your God-given right to decide which nutritional ingredients you consume! Tell them you want more innovative and improved nutritional supplements—and that NDI works against this. The supplement industry is joining forces for a major call-to-arms against NDI guidance, so stay tuned ... visit NHA2011.com for up-to-the-minute news! ❖

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