

NHA/WASHINGTON

update*

NDI Redraft Coming Soon?

The FDA's revised New Dietary Ingredient Guidance document is due in 2014.

This year, health freedom advocates celebrate the 20th anniversary of the Dietary Supplement Health and Education Act (DSHEA) that secured and protected our right to take nutritional supplements. July 2014 marks another anniversary: It has now been three years since the FDA unveiled its New Dietary Ingredient (NDI) Draft Guidance for supplements—which, some have suggested, may be an instrument to destroy all that DSHEA has accomplished.

NDI Threat Still Lurks

In 2011, the FDA's original incarnation of NDI was met with resistance from both Americans who take supplements and the elected officials who represent them. From the outset, it seemed clear that NDI was an inefficient and overly burdensome document.

Instead of protecting health, the draft appeared to block promising new health-promoting natural compounds—such as krill oil, astaxanthin and ubiquinol—from ever reaching the market. NDI's first draft also seemed to empower the agency to recall products that had been used safely for many years, potentially denying Americans' access to some of their favorite supplements.

Perhaps most significantly, the first NDI draft seemed capable of undoing DSHEA by apparently suggesting dramatic changes to the act that had defended Americans' health freedom since its inception 17 years earlier.

Nearly 150,000 citizen comments

and 14 letters from members of Congress sent the FDA's original NDI draft guidance back to the drawing board. As many called for the NDI draft guidance to be deleted entirely, the FDA appeared to partially acquiesce. With a suspiciously gracious soft-



ening of its stance, the FDA retreated to "re-work" its original draft. Since that time, health freedom advocates have anxiously waited to see what the new NDI will look like.

A Significant Anniversary?

Earlier this year, the FDA reported that the NDI revision would be finalized sometime in 2014. Since the original NDI draft guidance was issued in July of 2011, it has been suggested that July 2014—the draft's three-year anniversary—might be the perfect time for FDA to finally emerge from hiding and reveal its long-awaited revision of this critical document. Anyone who takes nutritional supplements to

support their health should be ready to respond to this looming event.

While the FDA initially appeared to be receptive to overhauling NDI, later reports suggested the agency was only willing to slightly modify its original draft guidance. That change of tempo seems to suggest the FDA's NDI revision may be equally as destructive—or even more destructive—as the original. If this is the case, advocates of health freedom are urged to fight, not for another revision or re-working, but for a complete scrapping of the NDI and all it stands for.

How to Respond

If the FDA's forthcoming NDI revision appears to restrict health freedom, it may be interpreted as direct defiance of the American public's clearly voiced support of DSHEA and nutritional supplementation. The agency has been given abundant time to fix its flawed Draft Guidance. If the FDA chooses to waste the opportunity offered by the American public to make their Draft Guidance reasonable, functional and beneficial, they should not be given another chance.

Please remain vigilant for news on the FDA's NDI revision. If the new NDI Draft Guidance displays even the slightest threat to DSHEA, be prepared to act.

The FDA will likely overstep its bounds again, opening the door for a swift, coordinated retaliation from health-conscious Americans that may shred the Draft Guidance once and for all. Visit www.nha2014.com for more details on NDI and the fight to keep supplements in our lives! ❖

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