

NHA/WASHINGTON

update*

NDI Guidelines to be Finalized

Changes on the horizon may destroy health freedom forever, unless you act now.

Can you believe it has been three years since the FDA's New Dietary Ingredient (NDI) Guidelines for dietary supplements were first introduced? Way back in 2011, the initial draft of these guidelines was met with a firestorm of controversy and criticism. One main concern: The FDA's NDI draft appeared to contradict the Dietary Supplement Health and Education Act (DSHEA), the crucial law that protects our freedom to take supplements.

The DSHEA-defying NDI draft guidance hinted at changes whereby supplements with new ingredients might be treated as food additives—potentially requiring pre-market approval before being sold to consumers. These changes were puzzling because 17 years earlier, backed by one of the largest letter-writing campaigns in American legislative history, DSHEA had established that supplements would be treated as foods, which don't require pre-approval.

Complicating matters, the FDA's draft guidelines proposed that supplements which changed their formulations even slightly would be regarded as NDIs. Plus, each formulation change would require a new NDI notification be sent to the FDA, creating countless hours of redundant bureaucratic paperwork. Consumers and industry leaders voiced concern that the guidelines as drafted might destroy the nutritional supplement industry—and with it, our freedom to take vitamins.

We Fought Back

With NDI placing both DSHEA and

nutritional supplements squarely in the FDA's crosshairs, 150,000 health-conscious consumers fought back—contacting the FDA to protest the ill-conceived guidelines. Senators and members of Congress soon followed, submitting their own letters of protest



to the FDA while voicing support for DSHEA. As objections gained steam, the original NDI draft guidelines were exposed as confusing, inefficient, anti-innovation and destructive to nutritional health. The FDA seemed to grudgingly back down—admitting they were not prepared to enforce the guidelines as drafted.

The FDA then quietly retreated to rework its guidelines for greater “clarity.” At first, the agency appeared willing to concede to public demands and completely overhaul the guidelines. Later, the FDA seemed to suggest the NDI draft revision would only be modified slightly from its original incarnation. NDI progress screeched to a halt, with the FDA seemingly paralyzed by indecision. A House of Representatives

Committee even reprimanded the FDA over its slow progress in mid-2013, demanding they pick up the pace on the NDI revision.

Now, at long last, the revision is almost here: The FDA has committed to finalizing its NDI guidelines sometime in 2014. But what the NDI revision will bring is anybody's guess.

What Will 2014 Bring?

The timing of the FDA's self-imposed NDI deadline is disturbing, since 2014 is also the 20th anniversary of the passage of DSHEA—the very act the original NDI appeared to undermine in the first place. Are we now approaching a showdown? Will the revised NDI strike down DSHEA just as it turns 20?

If you want to preserve DSHEA and continue taking dietary supplements that are affordable and accessible, it is vitally important that you contact your elected officials right *now* about the forthcoming NDI revision. NDI may have fallen off the radar for some. Please remind your elected officials that NDI holds tremendous destructive potential. Depending on how the guidelines are finalized, NDI may dismantle DSHEA, block supplement innovation or send supplement prices skyrocketing.

The supplement industry will be with you, watching and waiting for the FDA's finalized NDI guidelines. Visit NHA2014.com to stay updated on the latest NDI developments, along with information on how you can keep safe, natural nutritional supplements in your life. For the sake of health freedom, join the NHA today! ❖

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