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update*

Backpedaling on NDI

FDA statements on the subject are encouraging—but may be a smokescreen.

It appears that the overwhelming public outcry against the New Dietary Ingredient (NDI) Draft Guidance may finally be getting through to the Food and Drug Administration. At a recent herbal products conference, the director of the FDA's Division of Dietary Supplement Programs addressed the FDA's current attitude towards the agency's NDI guidelines. Surprisingly, the director revealed that the FDA is "not currently preparing to enforce" the proposed NDI Draft Guidance. Further, the director went out of his way to assure the audience that the proposed NDI rules are "just a draft guidance."

With that, it appears as if the FDA is suddenly backpedaling on its own proposed guidelines for new dietary ingredients. In the blink of an eye, the agency has gone from demanding reams of paperwork for new supplement ingredients and threatening to pull thousands of nutritional supplement products off store shelves to standing down on the whole matter and meekly explaining the guidelines were "just a draft." What could explain this abrupt reversal?

Our Voices Count

The FDA may be realizing that it simply cannot force NDI on an American public that has clearly and powerfully voiced its support for the nutritional supplement industry and for the Dietary Supplement Health and Education Act (DSHEA), the law that defines supplements as foods instead of drugs, as it stands.

More than 150,000 comments were submitted to the FDA on this topic, a number that reflects the passionate involvement of the American public in the future of health freedom. Senators Tom Harkin (D-IA) and Orrin Hatch (R-UT) publicly decried the NDI Draft



Guidance and called for protection of DSHEA. In addition, 14 members of Congress wrote the FDA to protest against NDI Draft Guidance and voice support for the efforts of the supplement industry.

What's more, the public seems to have been highly motivated by recent estimates that revealed NDI guidelines could potentially pull over half of all supplements from store shelves (up to 30,000 different products), costing nutritional supplement manufacturers close to \$15 billion annually—a figure that would likely trigger the downfall of the entire industry.

As the full destructive potential of the NDI Draft Guidance came to light,

the American public responded accordingly, unifying as a force to defend health freedom. Opposition from House members, supplement manufacturers and millions of American consumers has apparently cowed the FDA into submission.

FDA Plays Possum?

It would be nice if we could take the FDA's most recent comments at face value. But unfortunately, the agency has a track record of capitalizing on complacency, lulling consumers into a false sense of security and then attacking DSHEA and health freedom under the cloak of night. So even though the FDA director's comments may indicate that the agency is backing down from its NDI Draft Guidance, we must, in fact, be extra vigilant and increase our efforts to reject the NDI Draft Guidance once and for all.

The NDI Draft Guidance threat is still very real, despite what the FDA may lead you to believe. It is imperative that we not rest. We must actively protect DSHEA, now more than ever. Don't be distracted, and don't let the FDA's New Dietary Ingredient Draft Guidance quietly advance!

Continue faxing and calling your elected officials, and remind them that DSHEA is a top priority. Continue to express your support for the elected officials who are representing health freedom and fighting against the FDA's NDI Draft Guidance. And stay tuned for more news: The supplement industry is joining forces for a major call-to-arms against NDI Draft Guidance soon. Visit www.NHA2012.com for more information! ♦

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