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Shred the Guidelines

FDA hints at NDI revisions while the public demands a complete NDI overhaul.

In a recent presentation, the director of the Food and Drug Administration's Division of Dietary Supplement Programs addressed forthcoming changes to the New Dietary Ingredient (NDI) Draft Guidance for nutritional supplements. The director revealed that the agency's next step in dealing with the much-maligned NDI draft will be to revise the existing guidelines to try making them clearer.

This appears to be a far cry from the complete NDI restructuring and rewrite that health freedom proponents have been demanding for more than a year. The American public's wishes for a thorough NDI overhaul were presented to the FDA in the form of 150,000 public comments, to say nothing of letters from 14 members of Congress. And yet, the FDA's recent comments seem to suggest they may intend to merely "tweak" the existing NDI document.

The FDA Digs In

What's more, the FDA appears to be digging in its heels on some of the more controversial points of NDI, such as their position that bioidentical nutrients, such as synthetic vitamins and amino acids, should not be allowed in nutritional supplements unless they were already included in formulations prior to 1994. This could mean that consumers who wish to promote their health with the more affordable synthetic versions of nutrients will be out of luck—even if those nutrients have been shown to be as safe and effective as the natural forms that have been used for decades.

In other news, the FDA has noted publicly that 50 NDI notifications were received in 2012, a number that was far below what the agency had been expecting. But when the FDA's

proposed guidelines are so unreasonable, what can they possibly expect? In the FDA's world, those 50 NDI notifications in 2012 should probably have been closer to 5,000 notifications, with 95% of the notifications being redundant or meaningless filings.

It seems that if the FDA had their way and received the number of NDI notifications they were expecting, then the nutritional supplement industry would have spent all of 2012 writing up and submitting NDI paperwork instead of focusing on developing life-changing, health-enhancing supplements.

False Sense of Security

What may be most disturbing about these recent FDA updates is that they all seem to be variations on a distressingly familiar theme: The FDA plays possum. After the public uproar that followed release of the initial NDI draft guidance, the FDA responded with a statement reassuring us that the proposed NDI rules were "just a draft guidance." From all appearances, that first NDI draft guidance was going into the trash where it belonged. But then, as we've come to expect from the FDA, that reassuring quote seems to have been a smokescreen. With such deceptions and reversals, how can we trust the FDA's upcoming NDI clarifications?

A "tweaked" NDI Draft Guidance would likely be just as destructive to our health freedom as the original draft guidance was. And, with the FDA's recent comments on modifying NDI, it seems that their earlier conciliatory positions may have been a ruse to appease the public.

It is clear that we must continue faxing and calling our elected officials in Washington. We need to keep reminding them that we don't want the NDI guidelines "revised" or "clarified"—we want the guidelines shredded. We want the FDA sent back to the drawing board to start from scratch in developing a new set of guidelines that are true to the Dietary Supplement Health and Education Act (DSHEA) and respectful of our health freedom.

The nutritional supplement industry is now joining forces to fight against NDI Draft Guidance, so stay tuned. Visit www.NHA2013.com for more information—and for ways you can join the health freedom battle! ❖

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