

NEWS RELEASE

Save Your Supplements

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Write the FDA Now - Here's Why & How

Everyone with even an ounce of common sense has grave concerns about the U.S. Food and Drug Administration's recently released **Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues**. This Agency sprang this trap on both industry and consumers without seeking any prior input from us at all. It had almost 17 years to seek our opinion before coming out with this document, and now they are giving us a miserly 90 days to respond with our comments. Why is this issue so important?

The Erosion of Our Health Rights

When the Dietary Supplement Health and Education Act of 1994 (DSHEA) was passed, contrary to what the mainstream media falsely reports, the law did not remove dietary supplements from the regulatory oversight of the FDA. What it did do is to remove the FDA's *arbitrary* powers of life and death over supplements so that they could be treated more like foods rather than as drugs. The innovative tidal wave that was unleashed as a result of this breakout from regulatory prison resulted in some 1,000 new products a year in this market. What an incredible difference DSHEA made, and we all benefitted from the prison break. Oh, wait, the FDA's drug-industry bosom-buddies did not benefit. And that is something they have never forgotten and have been fuming over ever since.

Not without their cohorts in U.S. Congress, the drug industry's lobbyists have been pushing for years to hamstring DSHEA and its freedoms. For more than a decade, they have failed. But for the last several years, they have succeeded with sausage-slicing tactics that have gradually eroded DSHEA. First, there was the Adverse Event Reporting law, then the law mandating "Good Manufacturing Practices," and after that came the so-called FDA "Modernization" Act – each one designed to ratchet up the pressure on supplements, to drive out the smaller supplement manufacturers who could not keep up with the increasing regulatory costs demanded of them by these laws that were touted as making already-safe supplements "safe," and to gradually eliminate individual supplements. Were these laws ever truly designed to protect consumers? No, these laws had only one purpose in mind: To make supplements more expensive, less available, and to drive the consumer back into the filthy arms of the drug pushers.

This latest nonsense is straight out of the warped minds of the FDA's Berchtesgaden nest of anti-health thugs. They could care less about good health, certainly care less about you or me. This has been proven so many, countless times over the decades of the Agency's existence that there can no longer be even a shred of doubt. The revolving door between the drug industry and the FDA is a never-stopping one. Just witness its recent hiring of Johnson & Johnson's executive Spielberg who was tapped by FDA Commissioner Margaret Hamburg, as the latest deputy commissioner within the Office of the Commissioner to oversee the Agency's drug and device centers. This is not an exception, this is the rule.

The Compromise

Unfortunately, when DSHEA was passed, a compromise was reached in order to get unanimous passage. The parties agreed that all dietary supplements not marketed as of the date of DSHEA's passage (October 15, 1994) would be "new dietary ingredients" (NDIs) for which notification would be sent to the FDA. At the time, some did not think much was wrong with this compromise. After all, most supplements had already been discovered. But, now, almost 17 years later, the health-food market is awash with these new dietary ingredients, such as resveratrol, ubiquinol, GABA, curcumin, and bioperine. Notifications to the FDA have been made for many, but what is to happen to them now, with the FDA changing the law, all on its own?

Fantasy Land

This draft Guidance is a step into fantasy land. One night the FDA went to sleep and had a wonderful dream, a dream about a land where bureaucrats reigned supreme and the common citizen answered to every edict that flowed from the lovely bureaucrats' mouths. If the bureaucrat said jump, then the citizen would jump; if the bureaucrat said roll over, then the citizen would roll over. It was a wonderful place, this bureau-paradise. But then the FDA woke up, and the non-dream reality was not nearly that perfect, yet the urge to make it bureau-perfect remained. Hence, these constant bureaucratic attempts to whittle down our freedoms until we can only jump to the tune of some unknown functionary sitting in some unknown office thinking that he or she knows better for us than we do.

This draft Guidance is just such an attempt. It turns the law on its head by changing a very basic *notification* system into an *approval* system subject to the arbitrary whims of the FDA. It requires *very safe* NDIs to go through unnecessary, expensive tests so that they can meet drug-like safety requirements. In essence, this Guidance ignores the incredible, *proven* safety record of supplements, both new and old. The FDA can produce no dead bodies whatsoever coming from the use of these new dietary ingredients.

Yet the FDA, ignoring the many tens of thousands of actual dead bodies coming from its expensive drug-approval regulatory regime, wants to imprint that badly flawed drug-approval regime upon the dietary-supplement market. In doing so, it ignores the clear intent of Congress when passing DSHEA that "the Federal Government should not

take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers” and that “the right of access of consumers to safe dietary supplements is necessary in order to promote wellness.”

Flood Them with Letters

The Guidance document is not law, but it is a clear expression of how the FDA intends to enforce *its* interpretation of the law. This interpretation is badly flawed. And its implementation will result in unnecessary high costs, arbitrary discrimination against small- and medium-sized businesses that will put thousands of people out of work by destroying jobs in a time of economic decline, and the loss of many useful and healthful supplements.

The FDA must withdraw this Guidance document at once, consult with industry and consumers on a longer-term basis than this miserly 90-day period, and come out with a new Guidance that better reflects the realities of the marketplace and the safe track record of supplements, including those with NDIs. The FDA’s proposed document is unauthorized under Law and will guarantee a backlash of legislative action the likes of which have not been seen in this legislative arena since the passage of DSHEA in 1994. The NHF suggests that the cut-off date for NDIs either be eliminated entirely or else pushed forward to a date 15 years after 1994.

Please mail, fax, or e-mail your protest letter to the FDA as soon as possible, but in no event later than December 2nd, 2011. They need to be awakened from dreamland.

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