

NHA/WASHINGTON

update*

The FDA's New Weapon

Legislative loopholes empower the agency to recall supplements in 2014.

Happy New Year! This year marks the 20th anniversary of the Dietary Supplement Health and Education Act (DSHEA), which protects your right to take safe, natural nutritional supplements. It has been a stormy 20 years, with DSHEA weathering an endless barrage of attacks from the enemies of health freedom. But DSHEA remains strong, thanks to natural health advocates such as you.

Life after 20 for DSHEA isn't getting any easier, though. In fact, DSHEA might face more brutal attacks than ever in 2014.

Last year concluded with the Food and Drug Administration flexing new authority over the nutritional supplement industry. This power was granted by The Food Safety Modernization Act (FSMA). The FDA even made a point of publicizing its use of this "new enforcement tool." While the FDA's new authority was used in this instance to recall a questionable supplement, the act may open the door for FDA to recall safe, time-tested supplements as well.

It begs the question: Does the FDA's sword-rattling at the end of 2013 foreshadow more use of their newfound authority over supplements in 2014?

FSMA May Spell Doom for DSHEA

FSMA bestowed greater control over nutritional supplements on the FDA. Perhaps most significantly, it gave the agency the power to order a mandatory recall on supplements under certain

circumstances. In terms of a bad batch of supplements, this power of recall may be justifiably wielded. But in the uncertain arena of New Dietary Ingredients (NDI), this power may be abused—empowering FDA to obliterate even safe, effective supplements.



This is just one loophole by which the FDA's NDI guidelines may undermine and ultimately destroy DSHEA—and with it, the public's right to take healthful nutritional supplements.

NDI draft guidance says nutritional supplement ingredients are "new" if they were introduced after DSHEA. If the ingredient has been isolated from a food and used on its own for over 20 years, then it is exempt. But here's the gray area: If the ingredient has been consumed in food for hundreds of years, but has never been supplied as an isolated compound, then it will be considered "new" and subject to NDI. With FSMA giving new powers to the FDA, it means any supplements containing that new ingredient may undergo a mandatory recall if the

ingredient has not passed New Dietary Ingredient Notification procedures.

The popular nutritional supplement krill oil exemplifies how DSHEA might be undermined. Krill supplies the omega-3 fatty acids that have been in use for well over 20 years, so they are exempt ingredients. However, krill also supplies astaxanthin, a powerful antioxidant that, despite being consumed in the "food" krill for decades, has only recently been isolated as a supplement ingredient. Because astaxanthin is therefore a "new dietary ingredient," it appears the FDA, under the FSMA, could recall krill oil products from the market.

Would the FDA make such a dramatic power grab? 2014 may be the year that we find out.

Celebrate and Protect DSHEA

Want to keep the dietary supplements you need on health food store shelves? Then take action throughout 2014 to ensure the FDA doesn't abuse its newfound power.

Call or fax your elected officials. Remind them that Congress approved of DSHEA 20 years ago—and that this landmark legislation has been working perfectly ever since. Encourage your elected officials to remain aware of legislation and bill riders that appear designed to weaken DSHEA. Remind them that any revised NDI Draft Guidance must be in accordance with the rules established under DSHEA.

For the sake of everyone's health freedom, it has never been more important for all of us to celebrate and protect DSHEA. Visit NHA2014.com for more information. ♦

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