Keep a Watchful Eye on NDI

Be wary of revised New Dietary Ingredient Draft Guidance scheduled for 2013.

Like a bear crawling into its den for wintertime, the FDA's New Dietary Ingredient (NDI) draft guidance appears to have gone into hibernation . . . for now.

Thanks to a tremendous public outcry that generated more than 150,000 written protests against the FDA's draft guidance, as well as complaints from 14 members of Congress led by Senators Tom Harkin (D-IA) and Orrin Hatch (R-UT), the FDA announced that it would withdraw its proposed FDA draft guidance on NDIs.

However, we're not out of the woods just yet: A revision of NDI guidelines is now underway, and should be revealed at some point in 2013. Reports have suggested that the FDA is willing to cooperate with the natural products industry as it defines NDI guidelines in the forthcoming revision. We'll believe that when we see it.

The NDI draft guidelines issue remains potentially catastrophic to the nutritional supplement industry and the health freedom of consumers everywhere. Anyone who wishes to continue taking nutritional supplements should closely monitor any NDI developments this year.

A Failure from the Start

The FDA's first proposed NDI guidelines failed for several reasons. They were needlessly redundant, directing that supplement manufacturers submit NDI paperwork not just for the "new" ingredient, but for every supplement that contained that ingredient. They also proposed that newer dietary supplement ingredients—such as certain probiotic strains; dynamic newcomers like ubiquinol, astaxanthin and zeaxanthin; and any other nutrient discovered or developed since 1994—be recalled from the market until NDI notifications were submitted and

processed. Further, the FDA directed that any product that was improved with breakthrough ingredients, cutting-edge quality control processes or new testing methods would also require NDI notifications.

In a nutshell, the NDI as proposed would have decimated the natural products industry by draining its resources with unreasonable NDI demands while punishing innovation with even more time-consuming paperwork. Had the FDA's plans been realized, the Dietary Supplement Health and Education Act (DSHEA) that protects our health freedom would have been compromised—which might have been the beginning of the end for affordable and abundant nutritional supplements.

Where We Stand

History has taught us to be wary of the FDA and its efforts to come up with NDI draft guidelines. When we do see the new NDI draft guidelines at some point this year, we should keep several important questions in mind. Is this new NDI guidelines revision in accordance with DSHEA? Does this revision encourage innovation within the nutritional supplements industry? Will this revision lay the groundwork for an efficient NDI system in terms of new ingredient notifications? Is this revision going to pull health-enhancing nutritional supplements from store shelves?

We must be prepared to take swift action should the FDA's revised NDI guidelines prove to be as devastating as the deeply flawed first set of guidelines. We do not have to compromise our health freedom. As we have shown, by making our voices heard we can sway the FDA—and secure access to nutritional supplements for generations to come.

Throughout the upcoming year, contact your local elected officials to maintain pressure on the FDA as the agency works through the NDI revisions process. A great starting point would be to send a fax of thanks and encouragement to Senators Tom Harkin (202-224-9369) and Orrin Hatch (202-224-6331). Hatch and Harkin were instrumental in fighting off the FDA's first NDI draft guidelines. For the latest updates on the NDI revision, visit the Nutritional Health Alliance at www.nha2013.com. And for the sake of health freedom, join the NHA today! ❖

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