Enough is Enough

Two years on, the FDA's NDI concept is as ill-conceived and flawed as ever.

Next month marks two years since the Food and Drug Administration (FDA) introduced its New Dietary Ingredient (NDI) notification draft guidance for nutritional supplements. As we approach this anniversary, the potential legislation remains in a holding pattern, clouded by confusion. Many people are still unclear about which ingredients will be considered "new." What's more, supplement industry groups recently contacted the FDA requesting clarification on what type of information must be supplied in new dietary ingredient notifications.

Perhaps if more thought had been put into the NDI process in the first place, there wouldn't be so many questions remaining after two years. Let's investigate the questions behind the confusion.

Hardly Crystal Clear

NDI draft guidance asserts ingredients are "new" if they were introduced after the Dietary Supplement Health and Education Act (DSHEA) was passed in 1994. Supplements that were in place before 1994 are "grandfathered" in place and not subject to the NDI process. The FDA has proposed these guidelines with the intent of establishing that ingredients are safe for public consumption.

But NDI is still confusing: Nutrients that are isolated for supplements often exist in our food. The antioxidant astaxanthin, for example, is present in fish and shellfish that have been part of our diet since the dawn of time. In fact, a four-ounce serving of wild sockeye salmon supplies about 4 milligrams of astaxanthin, more than some supplements supply.

Astaxanthin, therefore, is part of our food, as safe and natural as peas or carrots. However, since the availability of

supplemental astaxanthin is relatively recent, under the FDA's guidelines it is considered a "new" dietary ingredient—even though it has been consumed safely for eons.

It would seem that astaxanthin NDI notifications would need to supply little, if any, information. But according to recent requests from industry groups, even this aspect of NDI is unclear. The FDA has since been asked to clarify exactly what kind of information is needed to adequately identify and document a new dietary ingredient. Without those parameters in place, the risk will remain that supplement manufacturers must provide reams of irrelevant and redundant information for each ingredient.

The open-ended language of NDI looks like it may be a Trojan horse designed to bring "death by paperwork" to the supplement industry.

Still Hanging On

While it's distressing that NDI confusion remains, it is far more disturbing that the NDI draft guidance is still kicking around. Over the past two years, 150,000-plus consumers have voiced their feelings on the draft guidance. Fourteen members of Congress took a stand against NDI. The FDA advocated NDI, backed off, then pushed for it again.

With public resistance, industry outcry and an apparent complete inability of the FDA to finalize and implement a clear and cohesive NDI, doesn't it make much more sense to simply throw this deeply flawed draft guidance into the garbage?

The staying power of NDI against all odds suggests that certain forces desperately want it to be implemented. Despite the repeated failure of NDI to stick, these forces are not letting go and not giving up. That means we can't give up, either.

Please contact your elected officials and let them know that it's time to put the FDA's failed NDI draft guidance to bed—once and for all. Please keep supporting those valued officials who have been defending your health freedom against the FDA. The supplement industry is fed up too, and will soon join forces to end NDI permanently. Stay tuned for ongoing updates on the NDI situation by visiting www.NHA2013.com for more information. ❖

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