

NEWS RELEASE

FDA Salami-Slice Strategy Continues

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The Food and Drug Administration (FDA) has continued to turn a deaf ear to consumers and their health in pushing forward its agenda to remove thousands of safe supplements from the American marketplace.

The FDA is Deaf and Dumb

Daniel Fabricant, Ph.D., the director of the Division of Dietary Supplement Programs at the FDA, again has stated that the Agency has no intention of withdrawing its proposed Draft Guidance for New Dietary Supplement Ingredients (NDIs) that it published last July. The FDA has not changed its position despite receiving over 7,000 comments on the draft industry guidance, which would subject many thousands of supplements to very expensive, drug-like testing and approval requirements in order to stay on store shelves.

Fabricant says “alternative approaches” by the FDA to satisfy the FDA’s proposed requirements in the NDI Guidance might be reviewed. However there was no clarification on whether the requirements imposing prescription-drug-like clinical testing and scientific testing to gain FDA approval for supplements sold since 1986 and in the future would be subject to amendment, or dropped from the Guidance. He had previously implied that it could take 3-4 years to resolve these issues but now says the timeline “is really up in the air.” Fabricant’s comments can be read at <http://www.nutraingredients-usa.com/Regulation/Fabricant-on-NDI-draft-guidance-Thanks-for-your-146-000-pages-of-comments.-We-ll-get-back-to-you>. Interestingly enough, before joining the FDA in February 2011, Fabricant was a vice president with the Natural Products Association (NPA), which makes it very clear that Fabricant has abandoned his obviously sparse roots along with whatever understanding he ever had of the industry.

The FDA Blames Industry & Punishes the Consumer

More telling about the FDA’s strategy for more heavy-handed regulation is the statement that *“If you look at the numbers of NDI submissions versus the number of supplements introduced to the market since 1994, it would appear there is a significant lag in compliance.”* On its face, the marketplace has changed over the last seventeen years. But who is responsible for this 17-year lag in compliance?

The Dietary Supplement Health and Education Act of 1994 (DSHEA) required manufacturers to submit pre-market notification applications for supplements and new ingredients when there is a history of use or other evidence establishing that an ingredient is safe when used as directed. The FDA has 75 days to accept or reject the application. A non-decision by the FDA means that the Agency accepts the evidence and that the product has complied, is approved, and can be marketed to the consuming public. Alternatively, a formal petition for a review and FDA issuance of an order prescribing the conditions under which a new dietary ingredient can be used and reasonably be expected to be safe, with the FDA having to respond within 180 days,

can be filed. Again, shouldn't a non-decision on a petition be considered as final Agency approval? If the Agency does not issue a decision either way, or if it cannot find a decision that was issued over the previous seventeen years, has it been the industry or the FDA itself who has not been in compliance with DSHEA?

Apparently, the FDA believes that manufacturers and suppliers have not met the FDA's own self-interpreted DSHEA burden of proof standard to show to the FDA that there is reasonable evidence that supplements and new ingredients in supplements are safe. The NHF believes, based upon the DSHEA law language, that this is a total misapplication of the DSHEA burden-of-proof standard. The burden of proof has been, and is on, **the FDA** to prove that supplements, which they have *de facto* approved through the pre-marketing notification process, are unsafe in the post-marketing stage of consumer use.

Since DSHEA, there have been seventeen years of additional historical use-safety experience conducted by many millions of Americans. The FDA is choosing to ignore evidence and is attempting to paint this as non-compliance. In other words, it has not done its job but instead claims that it is not the FDA's fault – instead, supplement consumers and industry should pay the price.

Take Action Now

The NHF has created a solution for all of us to rally behind - the Dietary Supplement Protection Act (DSPA) as H.R.3380. Some timid souls in the industry cower in a corner, saying they are afraid to support this bill because it will "open up DSHEA." In case they had not already realized it, DSHEA gets "opened up" by our anti-health-freedom opponents each and every year with their new legislation! Are we to be nothing but cowards when we have the chance to regain some of our own freedoms? The NHF isn't and knows that we need to be as bold as, even bolder than, our opponents.

Both companies and consumers must support H.R.3380, especially when Congress gets back to work in mid-January 2012. The bill changes a key date in the DSHEA law that will save thousands of our supplements. It does this by acknowledging and using in our favor the new regulatory environment for supplements as well as supplements' incredible safety record. It will put FDA bureaucrat's feet to the fire and an end to their seventeen-year efforts to salami-slice the DSHEA law to fit their own public-policy agenda for dietary supplements.

Contact your member of Congress to sponsor H.R.3380. The NHF needs everyone to contact their representatives and urge them to co-sponsor H.R.3380. We need the same consumer outrage that was seen pre-DSHEA to make this legislation a reality! Be bold and be persistent.

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