FDA issues revised draft for new dietary ingredient guidance for supplements

I truly wish that I had been wrong. Four years ago I predicted in writing that the whole-food industry's jubilance over the decision of the U.S. Food and Drug Administration (FDA) to revise the FDA's Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues would be short-lived and lead to nothing more than crumbs for the industry and consumers alike. And, on August 11, 2016, the FDA finally issued its revised New Dietary Ingredient (NDI) draft Guidance,[1] proving me right and throttling any industry glee in its collective throat. Crumbs for all of us, imperiously cast down by a rogue agency that does not listen to Congress or to its supposed, ultimate masters, the U.S. citizenry.

But, then, my prediction was an easy one. We live in a time when all government agencies are rogue and out-of-control, where they defy the wishes of the people and even assault them continually with new taxes disguised as "fines," stultifying rules and regulations, and arbitrary and whimsical dictates. Yes, a five-year-old could have made my prediction; it just took recognizing the nature of the Beast – a nature that will not ever change through our feeble begging.

The NDI Draft Guidance

The FDA's Draft Guidance, as you will recall, requires, among many other things, that all dietary ingredients introduced into the marketplace as of and since October 15, 1994, undergo drug-like safety testing prior to marketing. The tests – which are actually more onerous than those for new drugs – could cost millions of dollars per each new ingredient.[2] And, that

includes each variation on those ingredients too.

These requirements will not make supplements any safer than they are today but they will require supplement makers to lay aside 20 years of profits to conduct the tests. To make matters worse, tens of thousands of workers could lose their jobs as the supplement industry would be forced to remove products from store shelves and smaller supplement companies close their doors.

In addition, the original Draft Guidance stated that a synthetic herb or botanical would not be considered a dietary ingredient; and it called for NDI submissions to the FDA for each new product even if the ingredients in that product had originally been the subject of an earlier NDI notice. These are all onerous, unrealistic and unjustified requirements on any industry.

Unfortunately, in its own haste to seek clarity on new dietary ingredients, the industry itself created this Frankenstein monster of a Guidance when some members lobbied for inclusion in the FDA Food Safety Modernization Act of 2011 (FSMA) of a clause actually directing the FDA to issue a Guidance by July 2011. As is often said, “Be careful of what you ask for. You might just get it.” In this case, we all did, good and hard.

Victory Has 100 Fathers

So, four years ago, when the news started to spread that the FDA might actually back down from its then-published Draft Guidance, the industry and consumers were, of course, jubilant. A breakthrough in the Industry–FDA fight over this Guidance, it appeared, had at long last emerged. One can especially imagine that the morons responsible for the inclusion of the FSMA clause were especially jubilant, and relieved.

“There’s an old saying that victory has 100 fathers and defeat is an orphan.” These words spoken by John F. Kennedy, and

others before him, resonate in this situation. Some trade organizations and two health-freedom organizations immediately sent out news releases jubilantly trumpeting “their” victory, while also effusively applauding the FDA for its willingness to revise the Guidance document. So many claimed the credit, in fact, it was hard for me to tell who was truly responsible for this “victory.”

Unfortunately, there was no victory. All we ever had were words from the FDA, hardly the most trustworthy of agencies. After all, wasn’t the FDA the same agency that had originally promised it would not enforce the Draft Guidance until it became final only to see it then immediately send out 10 enforcement letters complaining about purported new dietary ingredients? Rather, we have an orphan, so where now are all of its fathers? Busy wiping the egg off their collective faces we can assume.

The Applause Was Premature

Now that the FDA has issued its revised Draft Guidance, five years later, what has the Industry achieved? Frankly, after five years of “consultations” between Industry and the FDA, there are few changes in the Draft Guidance. Yes, the new Draft Guidance says that a synthetic copy of an herb or botanical ingredient may qualify as a dietary ingredient under Section 201(ff)(1)(E) of the Federal Food, Drug, and Cosmetic Act, as amended, if the synthetic ingredient has been lawfully used as an ingredient in the conventional food supply. And, yes, the revised Draft Guidance does now allow a manufacturer or distributor to submit only one NDI notification to the FDA in place of the multiple notifications (with costly support) and when the conditions of use for any new dietary supplement are still within the conditions of use stated in the original NDI notification. And, yes again, the FDA has conceded that a list of grandfathered-in supplement ingredients could be developed in the future. However, after five years, that is really all that has been gained.

Except for one thing. Those five years of delay have given the FDA time to place and gradually tighten the yoke of wrongful NDI notifications upon an increasingly compliant industry. As one commentator wrote, “the howls of outrage heard in 2011 are silent.”[3] Yet this same commentator essentially tells us “to get used to it.” We are asked to accept what has been a wrongful usurpation of authority in the first place, not authorized to this extent by the Dietary Supplement Health and Education Act of 1994 (“DSHEA”), by a rogue agency that is allowed to continue to destroy an industry that provides health and jobs to millions. Again, where is the outrage?

This is No Time to Beg for Crumbs

This latest development sets the stage for the continuation of regulatory misinterpretation, confusion, and misguided enforcement by the FDA on the subject of new dietary ingredients. Nowhere in DSHEA is the FDA authorized to impose this kind of burden upon dietary ingredients, old or new. It simply usurped to itself the authority to override the intent of Congress when Congress passed DSHEA, deliberately imposing costly and burdensome regulations upon “new” dietary ingredients.[4]

The FDA has yet to be either humbled by the judiciary or sent a clear directive by Congress. There is nothing in the last 22 years of FDA conduct or in the FDA’s recent regulatory actions that provides us with even the least hint that it will act in good faith.

Yet, the regal FDA has thrown us a crumb and industry yawns. This bodes poorly for our future bargaining positions with the FDA. Look at it through the eyes of the FDA: It ignores our views for 17 years, and then really another five, and then when it changes a few, measly “dots and dashes” in an abominable guidance document that it never, ever should have created and that is wildly off the mark and exceeds FDA authority, the industry yawns and simply settles into its yoke

with a slave's willingness to shoulder an undeserved burden. Who could blame the FDA for thinking we are easy marks?

Keep the Pressure On

All of this explains why the National Health Federation ("NHF") came out with legislation in the Fall of 2011, so that consumers and industry would not have to supplicate the FDA for mercy. H.R.3380, the Dietary Supplement Protection Act (DSPA) was introduced by then-Rep. Dan Burton (R-IN) and intended to thwart for the time being the FDA's attack on new dietary ingredients. It was to do this by moving the defining date of October 15, 1994 (separating "old" supplements from "new" ones), to a more realistic and then-recent date of January 1, 2007.

By this one simple act, the Bill expanded the protection of the grandfathering clause to include all of the "new" dietary-supplement ingredients that had appeared in that almost 13-year interval (1994-2006) and that would otherwise be subject to the onerous requirements of the Guidance. The bill would have drastically narrowed the arbitrary power the FDA wants to exercise over new supplements and thereby protected thousands of supplements that have been safely consumed from being removed from the marketplace. It also would have set a precedent for altering the date in the future as well.

Unfortunately, only a few health-freedom groups supported NHF's legislative action, while one (which ironically now calls upon its members for congressional action) actually opposed our legislative efforts! Some in the industry were aghast and worried that Pandora's Box (i.e., DSHEA) might be opened. So, after much effort on NHF's part, the bill died in committee and Rep. Dan Burton retired from Congress.

H.R.3380 may have failed, but we must still maintain pressure on the FDA through action both in Congress and in the courts. Just hoping that talks with the FDA will produce tangible

results is foolish. Even attorney Jonathan Emord has acknowledged that “substantial changes are rare” on the part of the FDA. Pressure must be kept on the FDA. And most likely, that will have to be through litigation. After all, how many times did Durk Pearson and Sandy Shaw have to sue the FDA over health claims for supplements just to force the FDA to follow the law enacted by Congress? The FDA gives an upright middle digit to Congress just as often as it does to us.

But, still, keep the pressure on FDA. Write your congressional representatives at act.thenhf.com. Also, contact NHF at contact-us@thenhf.com if you wish to join us in a lawsuit against the FDA[5]. Donations toward the lawsuit can be made here. And finally, you may still make known and publish your thoughts to the FDA by submitting your comments directly to the FDA. You have sixty days from the date of the Draft Guidance’s issuance on August 11th to submit your comments to the FDA.

The Ultimate Questions to Be Asked Here

As health researcher and writer Bill Sardi has repeatedly asked of these FDA actions, ‘What are we trying to fix? What is actually broken?” There is nothing that needs fixing. Are we really improving the safety of supplements through complex and costly regulatory guidance? Supplements are already safer than water and aspirin, not even to mention heavily regulated drugs! More paperwork and more money spent will not make our supplements any safer than they already are.

Let’s be honest with ourselves and others. The real reason for FDA’s Draft Guidance has nothing to do with safety; it is intended to drive more supplements off the shelves, raise their prices beyond the reach of everyday Americans, and to bankrupt or drive out of business the smaller dietary-supplement companies, thus paving the way for the large pharmaceutical industry’s use of many of the very same ingredients, with now-skewed molecular structures, to sell

them as drugs at a premium.

Safety has never been a real concern for the FDA when it comes to supplements; safety is simply its tool to use to force the public to accept a drug-happy world of medicine. If the FDA were truly concerned about safety, then it would turn away from enforcement actions on the dietary-supplement industry and focus its efforts upon the industry where the real deaths occur: the pharmaceutical industry.

Make no mistake, the revised Draft Guidance will drive up dietary-supplement costs, destroy jobs and companies, stifle innovation in the supplement industry, seriously harm the health of Americans, and move consumers yet further towards dangerous drugs and vaccines and away from safe supplements. But our paperwork will be in order! This nonsense must be opposed and stopped.

We must remember Felix Frankfurter's advice. Written some 70 years ago while a Justice of the U.S. Supreme Court, he noted, "the history of liberty has largely been the history of observance of procedural safeguards." The FDA has shown itself all too often to be a rogue agency that refuses to adhere to procedural safeguards. It must be reined in, through clear laws binding it down. Write your congressional representative now and help fund a lawsuit to halt the FDA's destructive rampage. This is no time for half-hearted measures. The yoke that will break the back of the supplement industry while it breaks your health is being locked in place.

Footnotes:

1. This Guidance can be found here.
2. Keep in mind, that in a compromise agreement under the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), "new dietary ingredients" were arbitrarily defined as those ingredients introduced into the marketplace from the date of

enactment of DSHEA, October 15, 1994, onwards. It is an entirely artificial date that has no correlation with the safety of any dietary-supplement ingredient. Indeed, "new" dietary ingredients have been proven historically to be as safe as "old" ones.

3. Stephen Daniells, "NDIs: The biggest changes may be on the industry side," NutraIngredients-USA.com, August 16, 2016.

4. In a well-written article entitled, "Does the NDI Draft Guidance Significantly Impact the Safety of Supplements?" (www.fdli.org), Cara Welch, Ph.D., and Liz Hurst of the NPA quite correctly pinpoint the many ways in which the FDA's Guidance has strayed from the intent of DSHEA. Unfortunately, though, one solution suggested by the authors is to increase funding for the FDA. With a budget pegged at $2.5 billion ($4.5 billion if user fees are included), the FDA is a badly bloated agency that does not need even another dime when it cannot properly allocate and use those resources it has already been given. No, the FDA needs less funding, not more. With its major fat trimmed, coupled with wiser and more-core-mission-focused leadership, the Agency might just rediscover its pro-consumer roots.

5. Comments may be submitted electronically here. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Maryland 20852. All comments should be identified with the docket number FDA-2011-D-0376.

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