Warning Shot on Supplements

The Food and Drug Administration throws down the gauntlet on NDI.

In last month's Washington Update, we reported on the Food and Drug Administration's announcement that it will finalize its New Dietary Ingredient (NDI) guidelines for supplements sometime this year. The manner in which this finalization takes shape may define public access to nutritional supplements for generations to come.

Now, a new report suggests that the FDA might be moving to finalize its NDI guidelines even faster than we anticipated.

In a story first published by the supplement trade magazine *Nutra-Ingredients-USA*, a recent FDA inspection of a supplement manufacturer's facilities resulted in violations that triggered a warning letter. While this is not unusual in and of itself, the letter also included an NDI warning on an ingredient in one of the company's supplements—resulting from that company's failure to file a new dietary ingredient notification with the FDA.

This apparent practice of parlaying a standard-issue facility violation into a formulation investigation has not been seen before, and has been suggested by some to be a "warning shot" from the FDA. After years of the agency's waffling, uncertainty and heading back to the drawing board, the recent warning letter might just signal the beginning of the NDI era. And as the FDA moves to finalize NDI in 2014, its warning shot suggests the agency means business: The ultimate NDI guidelines may be among the harshest yet.

Piggybacking on Inspections

Random FDA inspections of manufacturing facilities are routine, and a warranted, accepted practice. These inspections help to ensure product quality, safety and purity. The best supplement manufacturers are always

prepared for the FDA to show up and inspect their facilities. Therefore, there is no controversy or complaint—facility inspections are clear-cut and well-understood.

NDI guidelines, are a completely different story, however. This controversial topic has been in a state of flux for years now and NDI benefits to the consumer are elusive, at best. In fact, many have argued that NDI will curtail nutritional supplement innovation and revoke consumers' access to some of today's most popular health-enhancing supplements. NDIs are not clear-cut or well-understood; they are rife with questions and complications.

When the FDA leverages a facility inspection into an NDI warning, it appears to be placing two entirely separate practices under the same umbrella. By piggybacking NDI onto the well-established practice of facility inspections, the FDA may be trying to create artificial NDI credibility—when in fact, NDI guidelines have been on shaky ground from day one.

It is possible that by weaving NDI-targeted formulation investigations into existing facility inspections, the FDA may be making NDI guidelines more powerful—and more destructive to health freedom—than anyone could have ever imagined.

Take a Stand in 2014

The FDA appears to have thrown a gauntlet to the ground, putting many supplement manufacturers on alert. If manufacturers' facilities are being inspected it might very well mean their product formulations will now be audited, too. And if any of those formulations supply an ingredient not in use prior to 1994, then all of those products might be destined for a dumpster—even if health-conscious consumers swear by them.

We may still have time to fight these recent NDI developments. If you wish to create a future in which nutritional supplement innovation—using breakthrough new ingredients—is encouraged rather than quashed, then make your voice heard. Contact your local elected officials! Visit NHA2014.com to stay updated on the latest NDI developments, along with information on how you can keep safe, natural nutritional supplements in your life. For the sake of health freedom, join the NHA today! ❖

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