Paper Avalanche

The FDA wants to bury your health freedom in a pile of paperwork.

At the time this column was written, the "Comment Period"—in which nutritional supplement industry leaders get to voice their feelings about the FDA's recently proposed New Dietary Ingredient (NDI) guidelines—was approaching deadline. Multiple industry experts have pointed out incongruities in the proposed new guidelines, and have requested that an extension of the Comment Period be granted.

By the time you read this, the NDI guidelines may have been approved or postponed. If the latter is true, then take this time as an opportunity to contact your local elected officials and ask them to put an end to the FDA's latest attack on our health freedom.

NDI guidelines are nothing more than FDA's weapon-du-jour. Recall that a New Dietary Ingredient (NDI) is a supplement ingredient that came onto the market after the Dietary Supplement Health and Education Act of 1994 (DSHEA). The rules were established: Ingredients on the market before DSHEA were "grandfathered" into place, and made exempt from regulation. But with the proposed NDI guidelines, the FDA is trying to rewrite these nutritional ingredients' proven history of safety.

Changing the Rules

NDI notifications are the ultimate bureaucratic busy work—a total waste of time. How can this be harmful? Consider: A new nutritional ingredient will now need an NDI notification from each company that uses the ingredient in a dietary supplement. Previously, only one notification was required for that ingredient to enter the market. Smoothly running companies will suddenly be grappling with mountains of paperwork.

Even the so-called "grandfathered" ingredients are at risk for needless paperwork. The FDA's proposed new NDI guidelines say if a supplement manufacturer used an ingredient before DSHEA, they must prove it with documentation. If they cannot find documentation, they must file an NDI notification as if the ingredient were new—even if it had been safely in use for decades.

Add to all of this Senator Dick Durbin's bill: S. 1310, the Dietary Supplement Labeling Act of 2011. S. 1310 would pile on even more needless paperwork, demanding time-intensive filings for even the simplest nutritional supplement label.

It's a multi-pronged snafu as FDA places the entire burden of proof on one industry —even if that industry has a legacy of overwhelming safety.

Paper, Paper Everywhere

The FDA's proposed guidelines will hit like an avalanche, burying nutritional supplement companies in bureaucratic paperwork. The economic impact on the industry will be staggering. Plus, by not allowing electronic filing of NDIs, the FDA makes the new guidelines even more burdensome.

Resources usually dedicated to the development of cutting-edge supplements could instead be devoted to "busy work." New product launches could slow to a crawl. Health food stores' shelves would be stripped bare, as "grandfathered" supplements without pre-1994 documentation would be recalled. Drained of money, time and resources, the nutritional supplement industry could screech to a halt.

What may be most disturbing about this scenario is its timing. The supplement industry is on the cusp of an exciting tipping point. Over 183 million Americans take supplements. Interest in nutritional well-being is rising every day. Product advancements are making supplements more dynamically effective than ever.

At precisely this moment, the FDA tries to change the rules and rewrite DSHEA. If you believe in health freedom, you cannot let this happen. Unless we stop NDI, the FDA may take away your right to take supplements forever. Visit www.nha2011.com for more information on how to persuade your local representatives to put an end to the proposed NDI guidelines and S. 1310! For the sake of health freedom, join the NHA today! ❖

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