Natural Products Association™

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NEWS RELEASE

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FDA Considering Vinpocetine Ineligible as a Dietary Ingredient

Agency just now weighing in on the regulatory status without any mention of a public health concern or the economic impact on those firms lawfully selling the ingredient for almost two decades. The first of five successful NDI submissions for vinpocetine goes back to 1997.

WASHINGTON, D.C. – The Food and Drug Administration (FDA) today released an unprecedented Federal Register (FR) notice (Docket No: FDA-2016-N-2523) with major implications for acknowledged new dietary ingredient notifications. FDA appears to be attempting to shift the burden of demonstrating reasonable expectation of safety for vinpocetine on the industry by using the hook that it can't qualify as a dietary ingredient.

Vinpocetine, has not one, not two, but five (5) acknowledgements from the FDA in their New Dietary Ingredients (NDI) Database. This means that Vinpocetine has already undergone intense scrutiny five times over by the leading authority on food safety in the US. Each time, FDA responded with a letter that they had no concerns over the ingredient or the data provided in their safety dossiers. From the FR notice, FDA does not appear to have any clear safety signal based on SAERs or other means. However, the agency is looking to remove the ingredient via a rendering that they have been silent on for approximately 20-years regarding the ingredient's status.

This notice comes on the heels of the recently released redrafted NDI guidance earlier last month, which NPA was the first trade association in the industry to hold an educational session on. Additionally, on October 6, 2015, Senator Claire McCaskill (D-MO), the ranking member of the US Senate Special Committee on Aging, called for the FDA to suspend sales of supplements containing vinpocetine, pending an investigation. In a somewhat unprecedented move for a legislator, Senator McCaskill sent letters to 10 retailers to ask them to voluntarily remove it from their shelves, despite no rendering from the FDA that it was NOT a legitimate dietary ingredient.

"This is a form of double jeopardy. To go through the regulatory gate a 2nd time is akin to finishing a round of golf and winning but then having to play a 2nd round while someone charges at you while you hit each golf shot. This sets a very bad precedent and is no environment to conduct business in." said Dr. Daniel Fabricant, CEO and Executive Director of NPA.

"The FR notice was also absent any economic impact analysis. There is an economic impact here as firms have been lawfully marketing this ingredient since it was successfully notified in the 90's.

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Consistent with the statute, is the agency planning to conduct an economic impact analysis? The original economic impact analysis on 21 CFR 190.6 never presented a situation where a properly notified ingredient, considered lawful for a period of time, could be removed instantaneously approximately 20-years ex post facto," said Dr. Fabricant. It would appear that removal of this ingredient would bear little incremental public health effect (per the notice) but a significant incremental cost associated with the change in regulatory status, which is, by law, generally considered in such actions and how to provide more or other cost-effective alternatives or enforcement discretion. No discussion on enforcement discretion is present either. Why? Is this what responsible industry can expect in the future with other new dietary ingredients?"

NPA will be submitting comments and will release those when available.

FDA will be accepting comments from the public until November 7th, 2016. The pre-publication notice can be viewed here. In addition to engaging government on the matter, NPA will be reviewing the FDA's publication, reaching out to our members to assess its impact on the dietary supplement industry.

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The **Natural Products Association (NPA)** is *the* trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA represents over 1,400 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids. Visit www.NPAinfo.org.
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