



440 1st St. NW, Ste. 520, Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250
NPAinfo.org

NEWS RELEASE

For Immediate Release
December 13, 2016

Contact: Justin Bartolomeo
(202) 789-4365

jbartolomeo@hdmk.org

New FDA Guidance for New Dietary Ingredients Might Encourage More Skirting of Regulations Altogether, says NPA *Could Harm Small Businesses and Create a Chilling Effect on Innovation*

WASHINGTON, D.C. – The Natural Products Association (NPA) today submitted comments to the Food and Drug Administration (FDA) regarding its draft guidance for New Dietary Ingredients (NDI). NPA expressed concerns the guidance could lead to unintended consequences and undermine the FDA’s ability to promote public health.

“The way it stands now, the guidance could actually result in more bad actors skirting the law entirely, which is the opposite of what a sensible regulatory regime should be,” said Dan Fabricant, Ph.D., CEO and Executive Director of NPA. “This economic burden to industry in following the food additive-level toxicology tests proposed in this draft guidance could harm small businesses and create a chilling effect on innovation, and lead to fewer submissions from legitimate firms, while encouraging fly-by-night companies to operate through NDI “piggybacking” until they are caught. It becomes FDA whack-a-mole all over again. NPA’s 98-page comment brief underscores the need for significant changes to the current guidance in the best interest of public health.”

In the Executive Summary, NPA highlighted that the FDA:

- continues to blur the distinction between dietary supplements and conventional food ingredients in their testing recommendations;
- should rewrite the toxicology sections in the revised guidance and not link NDI safety to a food additive-level of testing protocols and study designs;
- should avoid referencing testing protocols and study designs created for food and color additives in NDI draft guidance;
- should clarify the status of live microbial ingredients as dietary ingredients;
- should not treat synthetic copies of botanical constituents differently from other ingredients when there is no public safety issue; and
- should officially recognize NPA’s newly developed safe harbor database of pre-DSHEA dietary ingredients based upon evidence collected from past media reports, advertising, and other public sources.



440 1st St. NW, Ste. 520, Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250
NPAinfo.org

NPA earlier this year developed a comprehensive safe harbor list of pre-DSHEA dietary ingredients, which it asked the FDA to accept for use in NDI applications. NPA requested a meeting with FDA to discuss its safe harbor database and evidence to help the industry.

“The most common question we get from our members is whether something is an old ingredient and therefore off-limits to FDA or a new dietary ingredient, which triggers the NDI notification process.” added Dr. Fabricant. “We are developing a safe harbor list now for greater clarity as to exactly what ingredients fall safely into the already-approved category and can be used in products today.”

NPA also asked the FDA if it is planning on meeting with representatives from the industry as well as a timeline for finalizing the guidance.

NPA’s comments can be viewed [here](#).

Natural Products Association

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. Follow NPA on social media:

- Facebook: [Natural Products Association](#) and [The Natural Seal](#)
- Twitter: [NPA National](#) and [NPA Natural Seal](#)
- LinkedIn: [Natural Products Association](#), [Natural Products Group](#) and [Grassroots Action Network](#)

Natural Products Association: 440 1st Street, NW, Ste. 520, Washington, DC, 20001

###