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NPAinfo.org

NEWS RELEASE

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NPA Developing Massive Safe Harbor Dietary Ingredient Database for Industry Members in Response to NDI Draft Guidance

Will Work with FDA to Finalize in Near Future

WASHINGTON, D.C. – The Natural Products Association (NPA), the oldest and largest trade association representing the dietary supplement industry, announced today it is in the later stages of developing a comprehensive safe harbor list of pre-DSHEA dietary ingredients for the industry based largely on evidence from past media reports, advertising, and other public sources.

“NPA has a treasure trove of useful labels and label information dating back to the 1940s from our retailing magazines, which will be used as evidence of dietary ingredients sold in interstate commerce before October 15, 1994,” said NPA CEO Dr. Daniel Fabricant. “There are industry lists from the late 1990s and NPA’s own list from 1996. In short, we have the evidence FDA is seeking to make these determinations, and we look forward to engaging FDA on developing a safe harbor list. We cannot afford to sit on our hands any longer,” added Dr. Fabricant.

“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. While future dietary ingredients may be appropriately subjected to that process, we are developing a safe harbor list now for greater clarity as to exactly what ingredients fall safely into the approved category and can be used in products today.”

Likewise, FDA’s recent NDI guidance stated it was “unlikely to regard a listing in Herbs of Commerce [1992 edition] as being solely determinative of whether a dietary ingredient was marketed as such before October 15, 1994.” “The 1992 Herbs of Commerce book includes house plants and herbs not intended for human consumption, so it was not recognized by FDA as an authoritative list of pre-DSHEA dietary ingredients. It also focuses on herbs and does not include the myriad of other dietary ingredients falling within the statutory boundaries of a dietary ingredient created by DSHEA,” added Dr. Fabricant.

NPA hopes to complete the Safe Harbor database of dietary ingredients in the near future, and will engage FDA in the coming months on its methodology and evidence.

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



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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:

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