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NPAinfo.org

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## **FDA to Hold Meeting on Development of Pre-DSHEA Dietary Ingredients List (CFSAN)**

FDA has announced a public meeting on October 3rd, to discuss Development of a List of Pre-DSHEA Dietary Ingredients. The location is posted below and the notice will be posted [here](#) later in the month. NPA will be in attendance, please don't hesitate to contact us with any thoughts you may have on the matter, so we can best represent the Industry's views at the meeting.

FDA's Center for Food Safety & Applied Nutrition:

Wiley Auditorium

5001 Campus Drive

College Park, MD 20740

With that stated, it is important to note that the NPA has approached the agency about meeting prior, since April of this year on NPA's newly composed pre-DSHEA list, which contains over 2,000 ingredients to date. NPA's newly composed list is based off of the Association's historical copyrighted publications (e.g. health food retailer) which we are confident would meet the FDA standard of "independent and verifiable" as the publications indicate the intended use (for humans) as well as intended form, placing the product clearly in the diet.

Unfortunately, and for no clear reason the agency has delayed us from sharing that information with them and establishing a pre-DSHEA list. While we want a pre-DSHEA list established, it is important to note that the agency does not have clear statutory or regulatory authority to establish such and is therefore establishing such a list on their own discretion, and other processes must be considered in evaluating what meets the independent and verifiable standard. In this instance that discretion has been used to delay us, the NPA, from establishing such a list for the industry for over six (6) months by the time of this proposed meeting.

We don't believe this is an acceptable use of agency discretion and doesn't show an open or flexible approach (as required by the Regulatory Flexibility Act) in considering data for development of a list going forward. To that end we will post a link tomorrow where you can let congress know that, in such a volatile business environment, you don't appreciate FDA using their discretion to slow down development of a pre-DSHEA list, backed by "independent and verifiable" data by six months without a



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clear reason other than to have bigger audience. In the meanwhile, you can also contact Steven Tave [Steven.Tave@fda.hhs.gov](mailto:Steven.Tave@fda.hhs.gov) or Cara Welch [Cara.Welch@fda.hhs.gov](mailto:Cara.Welch@fda.hhs.gov) and let them know that development of a pre-DSHEA list shouldn't wait.

**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](http://www.NPAinfo.org). Follow NPA on social media:

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