NATURAL PRODUCTS ASSOCIATION

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NEWS RELEASE

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Petitioning the Agency with Skip Lot Testing for Nutritional Supplements Requires 200 Hours to Complete, Not 8 as Claimed by FDA

NPA Points Out Error in Omitting Bergstrom's Citizen Petition

WASHINGTON, D.C.– In comments to the Food and Drug Administration (FDA) the Natural Products Association (NPA) said the government's estimate for the amount of time required to submit a Citizen Petition for proposing skip lot testing is approximately 200 burden hours, not eight, as the FDA recently stated. NPA also drew attention to the FDA's omission of Bergstrom's Citizen Petition, filed in December of 2017.

"We support FDA's efforts to streamline their approval process for products with strong science and statistical evidence," said Daniel Fabricant, Ph.D., President and CEO of NPA. "We look forward to working with the FDA to identify ways to save the government and consumers money and increase the quality of nutritional supplements. Bergstrom was the first firm to file this type of request, and we expect this could have big implications across the industry once approved. We look forward to working with the agency to highlight member firms with excellent track records."

NPA said that it "supports the Agency's petition process and request that it keep the ability for firms to file an exemption from one hundred percent identity testing of identity ingredients open." NPA stated "there might be some cases where one hundred percent identity testing may not be required because identity testing was performed at the end or implementation of a statistically sound sampling plan may obviate the need for less than one hundred percent identity testing."

"This exemption by the Agency to offer skip lot testing is also not a one-size-fits-all for everyone," noted Dr. Fabricant. "It will probably only be successfully applied in only a few instances where a company demonstrates very low error rates in their history," he added.

NPA pointed out incorrect information in the Federal Register notice, stating: "Bergstrom, one of our members, submitted a Citizen Petition with the aim of achieving an exemption from one hundred percent identity testing by offering a statistically-sound plan for skip lot testing, akin to the pharmaceutical industry, without any material diminution of assurance compared to the assurance provided by one hundred percent identity testing."

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"NPA estimates, based upon practical experience in helping to complete this Citizen Petition to address the Agency's concerns, approximately 200 burden hours to obtain and prepare the references, science, statistical modeling, writing, and legal information necessary to support this petition filing, pursuant to an exemption from one hundred percent identity testing."

Finally, NPA highlighted its support for the development of GMPs for dietary supplement manufacturing, holding and distributing operations, emphasizing that "each manufacturer SHALL have in place procedures to verify the identity of each lot of raw material."

View NPA's comments 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 approximately 1,000 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.npanational.org.

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