NATURAL PRODUCTS ASSOCIATION

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The Honorable Dick Durbin
United States Senate
711 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Braun
United States Senate
404 Russell Senate Office Building
Washington, DC 20510

April 28, 2022

Dear Senators Durbin and Braun,

Founded in 1936, NPA is the nation's oldest and largest nonprofit organization dedicated to the natural products industry representing over 700 diverse member organizations united in providing consumers with access to safe products that will maintain and improve their health. NPA has taken a leadership role in promoting quality standards and has developed proactive certification programs. For example, NPA was the first organization to offer a third-party good manufacturing practices (GMP) certification program to manufacture dietary supplements and ingredients. NPA's GMP standards include all of the FDA's GMP requirements of 21 C.F.R. Part 111 and specific requirements that exceed Part 111 or reflect best industry practices.

In addition, NPA's "TruLabel" program is a dietary supplement label registration and random-testing program adopted by NPA in 1990 and subsequently made a requirement for supplier membership in 1995. This internal oversight program has created a high level of confidence among retailers and consumers that products sold in the marketplace under NPA's TruLabel program are accurately labeled; established an ongoing self-regulatory process within the industry; demonstrates industry maturity, and provides a comprehensive industry product database. Under TruLabel, products are periodically selected for laboratory analysis to confirm the label. At the same time, we appreciate the efforts made by the Council for Responsible Nutrition. We are supportive of voluntary programs such as the OWL, which has only 12,000 labels compared to the 130,000 plus labels housed within the NIH Dietary Supplement Label Database, for which NPA was a contractor on the feasibility study. It's clear the OWL is not the most appropriate reference point.

As the former Director of the Division of Dietary Supplement Programs and now an industry executive, I write to you with grave concerns regarding the Dietary Supplement Listing Act of 2022, the FDA's Office of Dietary Supplements Programs practices, and the budget request for FY2023. I can tell you during my time as the chief regulator for dietary supplements when we had some of the most impactful enforcement actions in the program's history, we had more than adequate tools to find a specific problem with a product or ingredient. To reiterate, we had no problem "seeing" into the industry and addressing issues when they arose. We have made this point with your staff's who seem to have a different perspective without dietary supplement experience or pointing to a specific dataset to suggest otherwise. As we layout below, the industry already provides plenty of information to the FDA with regard to the market of dietary supplements and ingredients. Unfortunately, FDA fails to use this information currently. Are there any plans to understand the transparency behind this?

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Tianeptine, an ingredient that is not a dietary supplement and is already illegal, was oddly used as an example in the floor speech to introduce this legislation. As CSPI and Consumer Reports[1] reported, FDA knew of the ingredient, and the sellers of the ingredient yet did not take enforcement action for nine months. This legislation would not address that issue or the failures of the FDA. Furthermore, the sellers of tianeptine are criminal drug traffickers. Criminals do not report their illegal activity to the government. Finally, the makers and sellers of tianeptine will not add their products to a mandatory product listing so the FDA can "see" where they are and what they're up to. Even if they sent their labels to FDA, the FDA would still be required to take enforcement action. However, recently, there has been a historical pattern of inactivity and misaligned priorities by the FDA.

This is consistent with the recent *POLITICO* Article, which highlighted the FDA's Center for Food Safety and Applied Nutrition (CFSAN) significant deficiencies that need to be addressed through robust oversight. While the dietary supplement industry's experiences were not expressly included in the *POLITICO* article, our problems with the FDA's lack of action against non-compliant firms are glaring. This is why we were surprised to see experienced legislators introduce legislation that would reduce government accountability when it is clear accountability is needed most. As Chair Murray recently pointed out in a letter sent to Commissioner Califf on April 11, 2022, why would providing the Agency with new authorities when it is clear they are incapable of their current authorities be advantageous to consumers and the public?

The Dietary Supplement Listing Act reduces government accountability to consumers and industry in several different ways, including but not limited to:

- The creation of a tool to administratively remove anything it deems isn't a dietary ingredient from the marketplace, even in instances where they have applied the law inappropriately or incorrectly. This would include but isn't limited to NAC, several probiotics, and CBD/other cannabinoids. The FDA's mismanagement of the CBD/cannabinoid issue has been and will continue to be crippling hemp farmers.

- Increase prices and allow the FDA to abuse its authority by not focusing on priorities. As a result, priorities such as inspections remain at all-time lows, and no plan has been put into place to restore pre-COVID levels.

- Delay new and safe products being made available to seniors, children, women who are pregnant or could become pregnant, those with vitamin deficiencies, and a host of other Americans who rely on supplements to meet their daily nutritional needs.

- Impose a hefty new tax on all existing dietary supplements as retailers, manufacturers, distributors, small business owners, and others would be saddled with a new and unnecessary regulatory burden. This would pour gas on the inflationary fire for products that Americans use every day, especially hitting low-income consumers and those on fixed incomes the hardest.

- Harm consumer safety by leading to fewer FDA inspections and enforcement actions.

- Overburdened the FDA with a brand new and unnecessary requirement. The Agency has clearly demonstrated that it is unable or unwilling to do the vital work that Congress has already authorized it to carry out.

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[1] https://www.consumerreports.org/dietary-supplements/fda-waited-9-months-to-warn-public-on-tianeptine-supplement-worse-than-heroin-a1151438241/

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- Reward criminals and penalize law-abiding companies as the bad actors would ignore this requirement and give them a significant market edge. They could create cheap imitations of products with illegal substances. At the same time, a legitimate company awaited FDA action on being added to the approved list of labels.

- Impose an unfair burden on dietary supplements by making products like daily multivitamins, fish oil, Vitamin D, B, and other building blocks of good health be subjected to a label submission as vitamin-fortified orange juice, milk, and every other food that the FDA regulates would not.

- Prior legislation dealing with FDA authority on supplements and other related industries has always provided for pre-emption of the states. This bill with a proposed public-facing list will be used most frequently by plaintiff's attorneys looking to bring meaningless nuisance lawsuits against the industry. The industry needs one regulator, not fifty-one.

The Food Safety Modernization Act (FSMA) was enacted to strengthen the food safety system and protect public health. FSMA effectively amended the Food, Drug, and Cosmetic Act (FD&C Act) to make the Agency more proactive than reactive to food safety problems. FSMA also provided the FDA "with new enforcement authorities designed to achieve higher compliance rates and better respond to problems when they occur." The additional authorities to ensure compliance included the power to suspend a food facility's registration, issue a mandatory recall order, and administratively detain certain foods.

Another mandate from FSMA was that FDA increases the frequency of its inspections of domestic food facilities based on risk. All facilities that manufacture, process, pack, and store food must register their facility with the FDA. This registration will allow the Agency to know where [firms] are located and allow for regular inspections.[2]

However, in 2017, the Office of the Inspector General published a report about the Agency's progress toward food facility inspection goals[3]. The annual number of food facilities inspected dropped from 29% in 2004 to 19% in 2015. The report highlighted that despite increasing spending for domestic food facility inspections, the number of reviews proportionately decreased. This was five years before the global pandemic, but inspections continue to drop further.

The same Office of Inspector General report also analyzed FDA's follow-up inspectional findings. The report highlighted that the Agency "often took no action in response to significant inspection violations.[2]" Furthermore, when the Agency was decisive and proceeded, the actions did not effectively address the violations. When the Agency required follow-up after violations were identified, they relied upon voluntary compliance from facilities. Furthermore, the Agency did not provide deadlines for "voluntary compliance," so firms with significant violations were allowed to address them when they chose to do so, without a sense of urgency. And finally, the Agency did not proactively follow up with firms identified as having significant violations to ensure that all of the violations were corrected. The report stated very clearly, "FDA rarely took advantage of the new authorities provided by FSMA" over the four years after FSMA was enacted. In response to significant violations, the Agency initiated judicial actions (i.e., seizures or injunctions) in just 4% of cases and only initiated administrative activities (i.e., detention of food products or suspension of facility registration) in just 1% of cases. The Agency suggested a four-month deadline to issue warning letters following inspections but frequently missed its deadline. FDA issued 20% of warning letters over six months after the review was completed, and 2% were issued more

[2] FSMA mandated that FDA inspect high-risk facilities at least once during the initial 5-year inspection cycle and then at least once very 3 years for subsequent cycles. FSMA requires that FDA also inspect non-high-risk facilities at least once during the 7-year initial inspection cycle and then at least once every 5 years for subsequent cycles.
[3] https://oig.hhs.gov/oei/reports/oei-02-14-00420.pdf

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than a year later. The FDA's inaction allowed firms identified as having violations to continue operating. In cases where follow-up action was mandated, the Agency failed to conduct inspections within one year in almost half of cases with significant inspection violations. For 17% of significant violations, the Agency did not reinspect facilities.

As noted in the 2017 OIG report, the FDA was unable to effectively utilize an increase in both resources and authorities in a manner that was directly applicable to enhanced enforcement of their regulatory powers. Despite these regulatory deficiencies, the FDA is now advocating for new authority, such as mandatory product listing for dietary supplements,

NPA has significant concerns with the Dietary Supplement Listing Act of 2022. Responsible natural product retailers and manufacturers go to great lengths to ensure consumers access safe products. FDA has a robust regulatory framework to understand what dietary supplements are being sold and who is selling them. The FDA has several tools with associated penalties for failure to comply. Retailers and manufacturers also have strong market incentives to make safe products. We have built a strong reputation and brand loyalty with the millions of American consumers who use these products every day.

By law, the dietary supplement industry must register all facilities that manufacture, process, package or hold dietary supplements for consumption in the United States. The FDA has the power to inspect these facilities to gather critical information related to products that come from those facilities. As part of this evaluation, labeling review is a required element, and labels lacking necessary information are described as misbranded and thus not compliant with the law. In addition, compliance and surveillance samples may be collected during inspections. Samples will generally consist of the label and any labeling available with the product at the time of purchase; this may include labeling and marketing information available on the product page for the website where the product is sold.

The Food, Drug, and Cosmetic Act also requires manufacturers and distributors who wish to market dietary supplements that contain a new dietary ingredient to notify the FDA about these ingredients before interstate commerce. The notification must include information that is the basis on which the manufacturer or distributor has concluded the dietary supplement containing a new dietary ingredient is expected to be safe under the conditions of use. The NDI provision is a 75-day pre-market notification system dealing with safety. What is proposed in this legislation would require companies marketing products with "old dietary ingredients" such as vitamins and minerals but with a new flavor to get FDA approval via a listing before entering the market. This is an excessive administrative burden that exceeds the current safety scientific safety evaluation for FDA if you want to introduce a new dietary supplement into the market. Giving the FDA the authority to decide administratively what is listed will only be abused. This will cause significant economic harm to anything not listed, as retailers and e-retailers will use such a listing to decide how to stock their shelves. So if there is any disagreement between the industry and the FDA on an ingredient's status rather than a scientific rendering FDA is allowed to eliminate that product from a listing and effectively the marketplace. This is not for an unsafe product or a product making illegal claims. This is for anything that FDA's opinion is different from the industry's on a technicality. There is nothing is this legislation that provides any protection for misuse or disagreement on technical status of ingredients. We have experienced this with NAC, an amino acid, CBD, probiotics, vinpocetine, and likely other ingredients in the future. If the Agency truly wants labels, it would seem more appropriate to add a simple rulemaking through existing authorities like facility registration post-market.

Additionally, much of the current legislative text is redundant. For instance, Section 403(r)(6)(C) of the Food Drug and Cosmetic Act addresses the requirements for dietary supplements to make what are called structure/function claims. It requires dietary supplements that carry a structure/function claim have to submit to the Agency no later than 30 days after the marketing of the dietary supplement the following:

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1. The name and address of the manufacturer, packer, or distributor of the dietary supplement product;
2. The text of the statement that is being made;
3. The name of the dietary ingredient or supplement that is the subject of the statement;
4. The name of the dietary supplement (including the brand name); and
5. The signature of a responsible individual or the person who can certify the accuracy of the information presented must certify that the information contained in the notice is complete and accurate and that the notifying firm has substantiation that the statement is truthful and not misleading.

Since the industry widely uses structure/function claims, the FDA already maintains a massive database of information concerning ingredients, products, claims, and companies. However, since 2013, the FDA has allowed for electronic submissions. The FDA has never stated why these submissions cannot be used as an enforcement tool. Frequently, labels are submitted through an existing electronic portal and cataloged in a database with this requirement. However, they have never reported on what they do with this current cache of labels. As recently as the week of the 20th, the Agency, when asked for the number of submissions they received annually, was unable to provide an answer.

The Agency also has access to adverse event reports for dietary supplements. Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act, a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States must submit to the FDA all serious adverse event reports associated with the use of the dietary supplement. The reporting includes five data elements: the patient's initial reporter, contact information for the responsible person, the dietary supplement, and a problem summary. Serious adverse event reports received through the address or phone number on the label of a dietary supplement and all follow-up reports of new medical information received within one year after the initial report must be submitted to the FDA no later than 15 days after the report is received. These reports for dietary supplements are submitted to the FDA on either the paper or electronic version of the MedWatch form. The dietary supplement industry must use a MedWatch form when submitting a serious adverse event report to the FDA. These are also available to the public, the healthcare community, researchers, experts, and the media.

The FDA already has access to information regarding who is making dietary supplements, where they are making them, what products are made at which facilities, when new ingredients are introduced into commerce, and whether any products are associated with serious adverse events. Additionally, the FDA and consumers have access to the National Institute of Health's Dietary Supplement Label Database, which already competes with information publicly accessible through FDA's MedWatch and other government sources maintained by the Federal Trade Commission, United States Department of Agriculture, and the National Academies. Therefore, instead of providing funding for mandatory product listing, we urge you to support increased oversight of FDA's Office of Dietary Supplement Programs and support a budget that increases enforcement actions spelled out through DSHEA.

As proposed, there are only two primary winners/benefactors of the so-called transparency of mandatory product listing. First, are disreputable individuals looking to create counterfeit products based on the ingredients and formulations in the database submitted by legitimate companies, hoping they can turn a quick profit with imitation products likely comprised of illicit ingredients. The second is the plaintiff bar, which would eagerly pull in as many companies as possible into class-action lawsuits based on alleged injuries caused by foods or supplements.

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We would welcome the opportunity to meet with you regarding our opposition to this legislation and discuss these matters further. NPA wants to ensure millions of Americans who use their supplements safely every day don't have their access taken away and choices restricted due to inappropriate policy decisions. The current laws are more than adequate to balance consumer access and consumer protection, and those never included pre-market approval for dietary supplements. The existing laws need to be enforced adequately by the FDA.

Thank you,

Daniel Fabricant, Ph.D.
President and CEO

CC:

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