NATURAL PRODUCTS ASSOCIATION

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March 26, 2024

Senator Richard J. Durbin
711 Hart Senate Building
Washington, D.C. 20510

Dear Senator-

As the industry's oldest and largest dietary supplement trade association, the Natural Products Association (NPA) appreciates the opportunity to share our perspective on your planned re-introduction of the Dietary Supplement Listing Act.

NPA opposed this bill when you introduced it in 2022, as did the House and Senate committees of jurisdiction when they rejected it during consideration of the FDA user fee reauthorization bills.

NPA would be happy to discuss amendments to the Bioterrorism Act that would give FDA greater visibility into what and where dietary supplements are manufactured, as long as such information is protected from public disclosure consistent with the Bioterrorism Act, no new prohibited acts are included that would give FDA administrative pre-market approval, and provided that conflicting state laws in this space are pre-empted. Without these considerations, reintroducing the previous legislation would continue to meet with opposition from our membership.

The narrative that the industry isn't adequately regulated is false and should no longer be advanced as the basis for adding unnecessary regulations. As the former FDA director of supplement programs under the Obama administration, I can tell you first-hand the agency has more than adequate authority to address any and all challenges it may face in regulating the dietary supplement marketplace.

I am more than happy to walk through these numerous aspects of the law with your office, as our organization did with the Senate HELP Committee and the House Energy and Commerce Committee. I can also explain to you and your staff how tools like mandatory recall or administrative detention, which Congress put into place through the Food Safety Modernization Act (FSMA), have never been used by FDA to police misbranded drug products masquerading as dietary supplements.

During my time at the agency, I was the first to issue a mandatory recall notice on a supplement that led to cases of non-hepatitis liver injury — so clearly, the laws can work if the will to enforce them is present.[1] And to be clear, FDA is not the only federal agency that seems to lack willpower in this area. Senators Hatch and Heinrich pressed the Department of Justice (DOJ) in

[1] https://www.foodsafetynews.com/2013/11/oxyelite-pro-recalled-as-more-hepatitis-cases-surface/

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2015 to get involved in ridding the marketplace of these misbranded drug products. While DOJ leaders told the Senators that they shared their concern, nothing of consequence followed.[2]

The matter is not and has never been a resources issue for the FDA. The agency's failures stem from a lack of willpower and a misplacing of priorities. Since when is it the agency's job to decide which laws to enforce or not, based on their preferences? The agency charged with policing the food, drug, and dietary supplement industry should be willing to do the police work and effort to uphold the mission of the agency.

As for tianeptine, it has never been a dietary supplement, still, the supposition that the FDA can't find it is not based in fact. While not a dietary supplement, in referencing an existing dietary supplement label database (DSLD) created and maintained by NIH (with over 183,000 labels), there are four (4) references to products containing tianeptine (attached). NIH and FDA are both part of HHS. Is FDA somehow restricted from using a tool created by another branch of its department?

More concerning is that when searching said product names on web search engines, three (3) of those still appear available for sale in addition to others.[3] Does the FDA not have access to search engines?

I'm sure the FDA has discussed or briefed this matter with you or your staff. One would hope that the agency would spend a few dollars conducting such a routine or cursory check of the marketplace and taking action on what it found before asking Congress for tens of millions of new funds and a new legislative mandate to create yet another database that the misbranded drug producers will be sure to ignore.

We will provide more information regarding your questions as to how the industry is self-regulating if there is a clear indication from your office that you are willing to engage in dialogue on a system that wasn't public facing, included no new prohibited acts, and would pre-empt states from introducing novel laws and regulations that aren't identical to existing FDCA federal dietary supplement statutes and regulations without a waiver from FDA as authorized by Congress.

Thank you,
Daniel Fabricant, Ph.D.
CEO & President

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[2] https://www.nutraingredients-usa.com/Article/2015/05/20/Prioritize-the-aggressive-pursuit-those-who-sell-drug-products-masquerading-as-supplements-Sens-Hatch-and-Heinrich-tell-US-AG-Lynch#; https://www.nutraingredients-usa.com/Article/2015/09/17/DOJ-We-have-put-fighting-illegal-activity-in-the-dietary-supplement-industry-high-on-the-priority-list

[3] https://www.earthgrownwellness.com/product/tianna-capsules-kratom-replacement-nootropic-blend/ ; https://rcd.bio/product-category/tianeptine/capsules-tianeptine/