Council for Responsible Nutrition
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April 9, 2025

The Honorable James Comer
2410 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Chairman Comer,

Thank you for allowing the Council for Responsible Nutrition (CRN) to submit comments for the record as they pertain to the House Committee on Oversight and Government Reform's hearing: *Restoring Trust in FDA: Rooting Out Illicit Products*. CRN is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. The dietary supplement industry is critical to the American economy, accounting for over $158 billion in total economic impact, over 266,000 direct jobs, and $20.1 billion in tax revenue.[1] Additionally, safe and regulated dietary supplement products are used by millions of Americans to help maintain a healthy lifestyle.

CRN shares the Committee's concerns about the entrance of illicit products in U.S. markets, particularly given that the dietary supplement industry has been adversely impacted by lack of federal enforcement. Specifically, we have long been concerned about products that are illegally marketed as dietary supplements but contain undisclosed ingredients that may pose a health risk to consumers. In some cases, these illegal products contain the same active ingredients found in prescription drugs, anabolic steroids or analogues of these chemicals. To be clear, these products are not legal dietary supplements and have no place in the market.

To highlight a recent example, CRN has worked to educate retailers about tianeptine, a dangerous, illegal ingredient that has been found in products labeled as dietary supplements. While tianeptine is not a legitimate dietary supplement, we recognize that it has been inappropriately labeled as one and, have been working to urge the Food and Drug Administration (FDA), and other federal and state agencies to use their regulatory authority to remove this product from the market.

Also, in 2018, CRN publicly sounded alarms over "phenibut," a central nervous system depressant that had been illegally marketed in products fraudulently labeled as dietary supplements. Phenibut is not an approved drug, nor did it meet any regulatory requirements whatsoever to be sold as a supplement. At the time, the industry notified FDA and supported the agency's legal authority to immediately remove these dangerous products from the market,

[1] Economic impact study of the dietary supplement industry. Economic Impact Study of the Dietary Supplement Industry Council for Responsible Nutrition. (2024, January 23). https://www.crnusa.org/resources/economic-impact-study-dietary-supplement-industry

while also working with online retailers urging them to remove these items from their digital shelves. FDA responded several months later in April 2019 by issuing warning letters to several manufacturers.

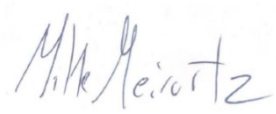
CRN also worked to expose Selective Androgen Receptor Modulators (SARMs) as unapproved drugs that in some cases "masquerade" as dietary supplement products. SARMs have similar properties to anabolic steroids and are prohibited by many athletic bodies for use in sport. In addition to supporting legislation that would expand regulatory authority to protect consumers (the Selective Androgen Receptor Modulators Control Act of 2019), CRN has launched an education initiative, #SARMsCanHarm. This online toolkit serves as a resource for consumers and raises awareness about the danger of SARMs. Unfortunately, despite these efforts, these illicit products can still be found online and elsewhere. More needs to be done at the federal level to remove these items from the market immediately.

CRN prioritizes consumer safety and has consistently acted to assist with the removal of harmful products from commerce. As a requisite for membership, CRN requires companies to comply with all federal and state regulations and agree to adhere to CRN's Code of Ethics. Additionally, to ensure transparency and safety, CRN created and maintains a public dietary supplement database and requires our member companies to list their products and labels. This database, known as the Supplement Online Wellness Library (or Supplement OWL), is an industry-wide, self-regulatory initiative that serves as a resource for these audiences to identify products, their ingredients and the companies who market them, and permit registry users to examine and evaluate labels and other product information. The OWL also includes manufacturing and packaging facility contact information, accessible only to FDA users. This allows regulators to readily identify and contact manufacturers and/or packagers if there is a safety concern identified with a particular ingredient.

CRN continues to work with FDA on ways in which the Agency can do more to protect American consumers. Further, we support broader revisions to the Dietary Supplement Health & Education Act (DSHEA) that will provide FDA with additional enforcement tools and strengthen its inspection authority.

More than 200 million Americans use dietary supplements every year, and it is important that consumers know the products they depend on are safe. As such, CRN will pledge to work with the Committee on policy that punishes bad actors and keeps illicit products off the shelves.

Sincerely,



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