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By Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Public Meeting: Modernizing Recalls of FDA-Regulated Commodities. Docket No. FDA-2023-N-2393.

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to provide comments to the Food and Drug Administration (FDA) related to its public meeting titled, "Modernizing Food and Drug Administration Recalls Listening Session."[2] We support FDA's efforts to modernize and improve recall processes to better protect public health.

CRN's members prioritize the safety of consumers and implement quality and safety controls in accordance with current good manufacturing practices (cGMP) to ensure safe and properly labeled products. As needed, firms act quickly to voluntarily initiate product recalls when there is a potential safety issue, including cGMP deviation, undeclared allergens, and nonconformance with specifications. We encourage and support responsible practices and FDA enforcement to promote regulatory compliance and consumer access to safe products.

There are, however, products sold to consumers that are marketed as dietary supplements (by using the term "Dietary Supplement" in their statement of identity and a Supplement Facts panel on their labels) but are in fact illegal products because they contain illicit substances, unapproved drugs, or undeclared

[1] The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 200 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

[2] FDA. Public Meeting: Modernizing Recalls of FDA-Regulated Commodities. September 29, 2023. https://www.fda.gov/about-fda/regulatory-news-stories-and-features/public-meeting-modernizing-recalls-fda-regulated-commodities-09292023.

active pharmaceutical ingredients, including tadalafil, sildenafil, and sibutramine. Products containing such substances are not legitimate dietary supplements and have no place in the market. Enforcement action initiated by FDA to remove these illegal products is essential to protect public health.

FDA's enforcement activities against health fraud products, including products marketed as dietary supplements with undeclared drug ingredients and chemicals, have included issuing warning letters, online advisory letters, recalls, public notifications, and press announcements.[3] On several occasions in the past year, FDA has announced public notifications that identify the presence of hidden drug ingredients in products marketed as dietary supplements and listed these products in its Health Fraud Product Database.[4] However, additional outcomes, such as a recall, either voluntary or mandatory, and/or a warning letter were not listed for many of these products. FDA's public identification of these products in the market without timely efforts to remove them presents both a risk to public health and undermines consumer confidence in the dietary supplement industry generally. CRN recommends that FDA utilize all the available tools, including the recall process, to prioritize enforcement against firms and individuals marketing illegal products as dietary supplements.

However, CRN is pleased to see examples of follow through on the agency's part to alert consumers to the dangers of tainted products and to remove them from the market by engaging firms in voluntary recalls and issuing warning letters. On February 7, 2023, FDA issued a public notification warning consumers about a product called "PrimeZen Black 6000" that was confirmed by FDA laboratory analyses to contain hidden drug ingredients.[5] It appears FDA engaged with the product marketer, which initiated a voluntary recall of one lot of the product on February 13, 2023.[6] The agency subsequently issued a warning letter to the marketer identifying the Federal Food, Drug, and Cosmetic Act (FDCA) violations, including assertions that the undeclared active pharmaceutical ingredients in the product cause the product to be misbranded and that the label and labeling contain claims that make the product an unapproved new drug.[7] We note that the voluntary recall was initiated shortly after the public notification, both helping to prevent, in a timely manner, the violative products from reaching consumers. The activities occurred within a span of less than three months, and FDA initiated laboratory tests prior to issuing the public notification.

In another case, FDA issued a warning letter to the marketer of a product confirmed to contain hidden

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[3] FDA. Health Fraud Product Database. Updated October 2, 2023. Accessed October 18, 2023. https://www.fda.gov/consumers/health-fraud-scams/health-fraud-product-database.
[4] *Id.*
[5] FDA. Public Notification: PrimeZen Black 6000 contains hidden drug ingredients. February 7, 2023. Accessed October 18, 2023. https://www.fda.gov/drugs/medication-health-fraud/public-notification-primezen-black-6000-contains-hidden-drug-ingredients.
[6] FDA. Company Announcement: Volt Candy Issues Voluntary Nationwide Recall of PrimeZen Black 6000 Capsules Due to Presence of Sildenafil and Tadalafil. February 13, 2023. Accessed October 18, 2023. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/volt-candy-issues-voluntary-nationwide-recall-primezen-black-6000-capsules-due-presence-sildenafil.
[7] FDA. Warning Letter: Tager Online, Inc. DBA Volt Candy; Volt Candy Wholesale Club. April 27, 2023. Accessed October 18, 2023. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tager-online-inc-dba-volt-candy-volt-candy-wholesale-club-652780-04272023.

drug ingredients over a year after the agency issued a public notification warning consumers of the potentially dangerous product.[8,9] Although the marketer initiated a voluntary recall following FDA's public notification,[10] it is unclear why the warning letter was not issued sooner. In another example, FDA issued a public notification on February 2, 2023, warning consumers about a product called "MANNERS Energy Boost" found to contain a hidden drug ingredient.[11] However, we were unable to identify a recall or warning letter related to this product. We appreciate the extensive analyses required to support enforcement activities and encourage FDA to consistently use available tools and to enhance removal of violative products, particularly illegitimate products marketed as dietary supplements, from the marketplace as swiftly as possible to protect consumers. However, FDA's enforcement processes against these products have been slow at times and lacked consistency, which potentially leaves consumers at risk.

CRN has consistently advocated for additional funding of the Office of Dietary Supplement Programs (ODSP) and urges the agency to use those funds to support inspections and enforcement. Recently, in response to FDA's proposed reorganization of the Human Foods Program, CRN voiced[12] grave concerns that eliminating ODSP and co-locating dietary supplement oversight under a new Office of Food Chemical Safety, Dietary Supplements and Innovation would effectively diminish attention and resources towards dietary supplement priorities, including enforcement. We recognize that coordination between ODSP and other FDA Offices and Centers is needed to take action against unlawful products. CRN continues to seek assurances that under this proposed reorganization, there would be no diminution in attention, funding, and staffing given to critical enforcement for dietary supplements, including use of mandatory recalls by FDA when warranted.

Dietary supplements are used by three out of four Americans and most users express confidence in the safety and quality of these products.[13] However, the perception of FDA enforcement of the FDCA, as

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[8] FDA. Public Notification: The Silver Bullet contains hidden drug ingredients. January 10, 2019. Accessed October 18, 2023. https://www.fda.gov/drugs/medication-health-fraud/public-notification-silver-bullet-contains-hidden-drug-ingredients.

[9] FDA. Warning Letter: Natures Rx, LLC. February 21, 2020. Accessed October 18, 2023. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/natures-rx-llc-596516-02212020.

[10] FDA. Company Announcement: Nature's Rx Issues Voluntary Nationwide Recall of Silver Bullet 10x to Undeclared PDE-5 Inhibitors in the Product. January 29, 2019. FDA Publish Date: May 9, 2019. Accessed October 18, 2023. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/natures-rx-issues-voluntary-nationwide-recall-silver-bullet-10x-undeclared-pde-5-inhibitors-product.

[11] FDA. Public Notification: MANNERS Energy Boost contains hidden drug ingredient. February 2, 2023. Accessed October 25, 2023. https://www.fda.gov/drugs/medication-health-fraud/public-notification-manners-energy-boost-contains-hidden-drug-ingredient.

[12] CRN letter to Dr. Robert Califf re: FDA Reorganization of the Human Foods Program - Office of Dietary Supplement Programs. July 10, 2023. Accessed October 18, 2023. https://www.crnusa.org/sites/default/files/pdfs/comments-pdfs/CRN-Letter-FDA-ODSPReorg7-10-23.pdf.

[13] Three-quarters of Americans Take Dietary Supplements; Most Users Agree They are Essential to Maintaining Health, CRN Consumer Survey Finds. Press Release. Council for Responsible Nutrition. October 5, 2023. Accessed October 25, 2023. https://www.crnusa.org/newsroom/three-quarters-americans-take-dietary-supplements-most-users-agree-they-are-essential.

well as the actual enforcement activities of the agency, are important to maintain consumer trust in this industry. Consumers need to know that when a risk to public safety arises that FDA uses the tools at its disposal to address the issue. Clear communication to consumers of those efforts, including the use of recalls to remove products that have been identified as unsafe, is critical to demonstrate robust and timely enforcement and to maintain consumer confidence in both FDA and dietary supplements.

As FDA modernizes recall processes, we recommend that the agency conduct an analysis of the effectiveness of its communication strategies related to product safety and consider currently available tools and technologies to enhance dissemination of recall information, public notifications, and other relevant communications to reach as many consumers as possible to alert them to possible safety risks related to products on the market.

We look forward to FDA's next steps towards modernizing recalls. Thank you for considering our comments.

Sincerely,

Haiuyen Nguyen

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