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Comments from the Council for Responsible Nutrition (CRN)

Re: Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients
Docket Number: 250414-0065
XRIN: 0694-XC120
Submitted via www.regulations.gov

Dear Deputy Secretary Longnecker,

The Council for Responsible Nutrition (CRN)[1] appreciates the opportunity to submit these comments in response to the Department of Commerce's request regarding the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Federal Register Notice 2025-06587, April 16, 2025).

CRN is the leading trade association representing dietary supplement and functional food manufacturers, ingredient suppliers, and service providers. Our members produce the majority of dietary supplements consumed in the United States, contributing significantly to domestic employment, manufacturing, public health, and economic resilience. As we understand this Request for Comments, the inquiry is whether the widespread importation of pharmaceuticals and their components poses a risk to U.S. national security. As we will explain, dietary supplements and their ingredients often share similarities with pharmaceuticals, even common Harmonized Tariff Schedule (HTS) codes, but these markets are dramatically different. The importation of ingredients used in dietary supplements is both unavoidable and necessary to maintain the health of Americans, and thus, the differences between these two industries should be recognized in the Department of Commerce's evaluation.

Executive Summary

The dietary supplement industry supports more than 616,762 American jobs and generates nearly $158 billion in total economic output annually[2]. The industry generates $6.76 billion annually in state and local taxes—money that helps build and supply schools, police and fire departments, roadways, and other projects—and $10.7 billion in federal taxes.

[1] The Council for Responsible Nutrition (CRN), founded in 1973, is the leading trade association representing over 180 dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control, and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics.

[2] Economic Impact Study of the Dietary Supplement Industry.

Most dietary supplement finished products sold in the U.S are manufactured, packaged, and labeled in the United States. This is true not only for dietary supplements intended for the domestic U.S. market, but also for a large portion of dietary supplements that are manufactured in the United States for export.

Dietary supplements are different from pharmaceuticals — they are sold directly to consumers through a wide range of market channels (e.g., through pharmacies, grocery stores, vitamin retailers, multi-level marketers, direct-to-consumer, online retail platforms, etc.), and are price sensitive to consumer needs.

However, many dietary supplement ingredients, including vitamins[3] and minerals,[4] are classified under HTSUS Chapters 29 (Organic Chemicals) and 30 (Pharmaceutical Products)—the same headings used for pharmaceuticals and for pharmaceutical ingredients.

CRN recommends the Department recognize the differences between pharmaceuticals and dietary supplements and expressly exclude dietary supplements and their ingredients from this Section 232 investigation. CRN encourages the Department to take into account the robustness of domestic production for certain ingredients, while acknowledging that the majority of dietary supplement ingredients for which U.S. production is not viable or scalable in the near term.

1. Distinguishing Dietary Supplements from Pharmaceuticals

Dietary supplements are not pharmaceuticals, but their components often utilize the same Harmonized Tariff Schedule (HTS) codes as pharmaceuticals or their inputs. Not surprisingly, many of the ingredients used in dietary supplements[5] that contribute to better nutrition and preventive healthcare are also found in drugs[6] intended to treat, cure, and mitigate disease—but the two categories are vastly different. Dietary supplements are regulated by the Food and Drug Administration (FDA) separately under the Dietary Supplement Health and Education Act of 1994 (DSHEA) within the Federal Food, Drug, and Cosmetic Act (21 USC Sec 301 et seq.) and are intended to support general health and wellness, not to treat, cure, or prevent disease.

Nevertheless, many dietary supplement ingredients, including vitamins[7] and minerals,[8] are classified under HTSUS Chapters 29 (Organic Chemicals) and 30 (Pharmaceutical Products)—the same headings

[3] See, e.g., HTSUS 2936.29 "Other vitamins and their derivatives."
[4] See, e.g., HTSUS 3004.50.50 "Single or multiple vitamins combined with minerals or other nutrients."
[5] The federal Food Drug & Cosmetic Act defines a "dietary supplement" as a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any ingredient described therein. see 21 USC 321(ff)(1).
[6] The federal Food, Drug & Cosmetic Act defines a "drug" as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, see 21 USC 321(g)(1).
[7] See, e.g., HTSUS 2936.29 "Other vitamins and their derivatives."
[8] See, e.g., HTSUS 3004.50.50 "Single or multiple vitamins combined with minerals or other nutrients."

used for pharmaceuticals and for pharmaceutical ingredients. Historically, certain dietary supplement ingredients such as vitamins and minerals have been captured under these tariff codes, so many dietary supplement ingredients are also included in Annex II[9] of the recent Executive Order on reciprocal tariffs. Attached as Appendix A is an illustrative but not exhaustive list of dietary supplement ingredients set forth on Annex II.

But dietary supplements are vastly different from pharmaceuticals in many respects, and do not typically pose the type of national security threat that the administration seeks to assess in this investigation. Dietary supplements support general health and wellness and provide preventive health benefits, but their availability does not represent the same level of immediate or strategic national vulnerability as other products might.

It is critical that, if the Department pursues sector-specific tariffs on pharmaceuticals under Section 232, those ingredients intended for use in dietary supplements be removed from actions intended to target the prescription drug market. For those dietary ingredients that are overwhelmingly sourced outside of the United States, their inclusion in trade actions intended to target pharmaceuticals could be devastating.

2. Economic Impact of the U.S. Dietary Supplement Industry

One of the unique aspects of dietary supplements is that, although the majority of their ingredient inputs are sourced globally, most dietary supplement finished products sold in the U.S are manufactured, packaged, and labeled in the United States. This is true not only for dietary supplements intended for the domestic U.S. market, but also for a large portion of dietary supplements that are manufactured in the United States for export. The majority of finished product dietary supplement manufacturing occurs in the US because the US is the largest supplement market in the world, accounting for 34% of the global market.[10] The North American market is twice as large as the next region[11] and this in turn is due to the early development of the dietary supplement industry in the United States and the favorable manufacturing requirements imposed by the Dietary Supplement Health & Education Act of 1994 ("DSHEA"),[12] as well as consumer sentiment that drives demand for U.S.-made products.[13] However, finished product manufacturing could move offshore depending on the impact of tariffs.

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[9] Annex II, https://www.whitehouse.gov/wp-content/uploads/2025/04/Annex-II.pdf.

[10] Nutrition Business Journal. Rep. Global Supplement Business Report 2024. Informa. https://store.newhope.com/products/global-supplement-business-report-2024.

[11] Global Supplement Business Report 2024.

[12] S.784 - 103rd Congress (1993-1994): Dietary Supplement Health and Education Act of 1994. (1994, October 25). https://www.congress.gov/bill/103rd-congress/senate-bill/784.

[13] Economic Impact Study of the Dietary Supplement Industry | Council for Responsible Nutrition. https://crnusa.org/resources/economic-impact-study-dietary-supplement-industry.

As a result, the U.S. dietary supplement industry is a major driver of American jobs, economic growth, and public health. A 2023 economic impact study revealed that the dietary supplement industry supports more than 616,762 American jobs and generates nearly $158 billion in total economic output annually[14]. The industry generates $6.76 billion annually in state and local taxes—money that helps build and supply schools, police and fire departments, roadways, and other projects—and $10.7 billion in federal taxes.[15] These contributions to American jobs, growth, and wealth have resulted from the existing balance of imported ingredients and finished product manufacturing, packaging, and labeling that occurs here is the U.S.

Today, dietary supplement usage has become nearly ubiquitous and indispensable to Americans. The U.S. dietary supplement market reached $69.3 billion in 2024, according to Nutrition Business Journal.[16] CRN's annual consumer survey revealed in 2024 that approximately 75% of American adults use dietary supplements.[17] Among those supplement users, 91% of them affirm that supplements are essential to maintaining their health, and nearly eight in ten supplement users report that they prefer using supplements to over-the-counter or prescription medications whenever appropriate.[18] Popular dietary supplements include such diverse products as multivitamins, prenatal vitamins, omega-3 fatty acids, probiotics, fiber, protein, collagen, enzymes, electrolytes, minerals like iron and magnesium, herbal and botanicals like turmeric, saw palmetto, and ashwagandha, to name just a few. Undeniably, American consumers rely on dietary supplements to support their health.

Dietary supplement use by Americans can also help lower overall healthcare spending. In 2023, CRN commissioned an independent economic analysis of healthcare savings achieved from dietary supplement use. ***Supplements to Savings***[19] data demonstrate how specific dietary supplement regimens dramatically lower healthcare costs through disease prevention. For example, regular supplementation with calcium and vitamin D to reduce the risk of osteoporosis already generates over $179 billion in savings through lower incidences of falls and fractures from the disease and has the potential to nearly double that savings with more adherence to this supplement regimen. Use of dietary supplement probiotics to reduce Irritable Bowel Syndrome (IBS) saves the healthcare system over $110 billion and could save another $94 billion with greater usage by affected populations. While these savings are not limited to the U.S. government's spending on healthcare, the large direct federal expenditures on

[14] Economic Impact Study of the Dietary Supplement Industry.
[15] Economic Impact Study of the Dietary Supplement Industry.
[16] "The State of Supplements: U.S. Market Approaches $70 Billion." Nutraceuticals World, April 2, 2025. https://www.nutraceuticalsworld.com/exclusives/the-state-of-supplements-u-s-market-approaches-70-billion/.
[17] CRN Survey Shows Consistent Supplement Usage with Increase of Specialty Product Use Over Time | Council for Responsible Nutrition. https://crnusa.org/newsroom/crn-survey-shows-consistent-supplement-usage-increase-specialty-product-use-over-time.
[18] CRN Survey Shows Consistent Supplement Usage with Increase of Specialty Product Use Over Time.
[19] Supplements to Savings | Council for Responsible Nutrition. https://www.crnusa.org/resources/supplements-savings.

healthcare through programs like Medicare, Medicaid, and VA benefits mean that the government stands to reap significant savings from more, not less, supplement usage.

3. Global Supply Chains and Practical Realities

Many dietary supplement ingredients are sourced internationally. This global sourcing is necessary because:

- Certain botanicals cannot easily be cultivated domestically due to various reasons, including climate conditions;
- Fish-derived omega-3 fatty acids are largely sourced from fishing fleets off the coast of South America where these species exist and can be sustainably harvested;
- Vitamin synthesis often requires highly specialized facilities at scale with substantial capital outlays and waste management limitations that depend on government investment, which to date are largely located outside of the U.S.;
- Processing, extraction, and synthesis of some dietary ingredients is not only capital-intensive, but also produces byproducts (solvents, extracted contaminants) and large quantities of wastewater that other countries have developed systems for disposing. Onshoring their production in the U.S. would require developing similar systems here that do not currently exist.

Relocating the production of these ingredients to the United States would be prohibitively expensive, impractical, and in many cases, impossible in the near term to meet production needs. While the manufacturing of finished dietary supplement products largely occurs in the United States (as discussed above), these obstacles significantly hinder the relocation of dietary supplement ingredient supply chains. At the same time, some dietary ingredients are available domestically and are sourced in the U.S., providing finished supplement manufacturers with reliable, high-quality supplies of these ingredients. Thus, the current thriving dietary supplement marketplace in the U.S. results from a combination of global ingredient supply chains and domestic product manufacturing.

4. Risks of Imposing Section 232 Tariffs on Dietary Ingredients

The supplement industry is concerned that, because of the overlap of HTS codes of dietary ingredients with pharmaceutical inputs,[20] these ingredients could inadvertently get wrapped into this Section 232 investigation of prescription drugs and become subject to sector-specific tariffs targeting prescription drug production. As discussed earlier, dietary supplements are vastly different from pharmaceuticals, are sold directly to consumers through a wide range of market channels (e.g., through pharmacies, grocery stores, vitamin retailers, multi-level marketers, direct-to-consumer, online retail platforms, etc.), and are often far more economical as well as price sensitive than prescription drugs.

[20] As discussed earlier, many dietary supplement ingredients are classified under HTSUS Chapters 29 (Organic Chemicals) and 30 (Pharmaceutical Products)—the same headings used for pharmaceuticals and for pharmaceutical ingredients.

If dietary supplement ingredients are subjected to pharmaceutical sector tariffs, the consequences could include:

- *Product Shortages:* Imposing pharmaceutical-specific tariffs on dietary supplements and their ingredients would likely create disruptions in supply chains of ingredients creating shortages of finished products for U.S. consumers and "out of stocks" on the shelf.
- *Price Increases*: Imposing pharmaceutical-specific tariffs on dietary supplements and their ingredients would also likely raise costs for dietary supplements, including supplements that are critical for public health, such as prenatal multivitamins. Dietary supplement sales are more price sensitive than pharmaceuticals, and demand is more elastic. Additional costs for dietary supplements would likely be passed on to consumers as higher prices, ultimately leading to reduced access. At a time when there is renewed attention to making America healthy and promoting more proactive behaviors directed toward nutrition and preventive health measures, reducing the accessibility and affordability of dietary supplements seems counterproductive.
- *Increased Risk of Adulteration*: Higher tariff rates that would result from including supplement ingredients in pharmaceutical-specific tariffs could disrupt established supply chains for the dietary supplement industry and open opportunities for disreputable ones. This industry already regularly battles against less reputable market entrants who are willing to offer lower quality, adulterated or contaminated ingredients that harm public health and market integrity. The further stress on pricing from additional tariffs would likely exacerbate those pressures and create temptations to "cut corners" on quality and engage in economic adulteration to maintain lower costs.
- *Offshoring of U.S. Finished Product Manufacturing to the Country of Origin of the Ingredients:* The imposition of pharmaceutical-specific tariffs on supplement ingredients intended to bring ingredient jobs to the U.S., could instead provoke companies to relocate finished product manufacturing (now largely in the U.S.) to countries where ingredients are sourced due to lower overall costs (even with increased tariffs), reducing U.S. jobs and driving manufacturing offshore.
- *Offshoring of U.S. Finished Product Manufacturing to Other Countries with Low Tariff Rates or Lower Labor Costs*: Similarly, the imposition of pharmaceutical-specific tariffs on supplement ingredients could lead companies to relocate finished product manufacturing to countries with lower tariff rates or ones with significantly lower labor costs. Supplement companies could find it is less expensive to substantially transform the ingredients into finished products in these third countries and then import the finished products at the combined tariff rate than to pay the pharmaceutical rate on the raw materials and incur the expense of the U.S. labor market. This eventuality would also reduce U.S jobs in the sector and drive manufacturing offshore.

5. Policy Recommendations

Accordingly, CRN respectfully urges the Department to protect the U.S. dietary supplement industry's role in supporting the health, jobs, and economy for Americans. CRN recommends the Department recognize the differences between pharmaceuticals and dietary supplements and expressly exclude dietary supplements and their ingredients from this Section 232 investigation. The Department should exclude ingredients found on Annex II that are used in dietary supplements (an illustrative but not exhaustive list found in Appendix A) from any pharmaceutical-specific tariffs imposed for purposes of national security.

CRN recognizes that while most, but not all, dietary supplement ingredients are dependent on international sources, some ingredients are currently available from U.S.-based producers. CRN supports a nuanced approach to trade policies that distinguishes between ingredients with robust domestic manufacturing capacity and those that are not feasible to produce in the United States. Accordingly, CRN encourages the Department to take into account the robustness of domestic production for certain ingredients, while acknowledging the majority of dietary supplement ingredients for which U.S. production is not viable or scalable in the near term.

As an aside, CRN notes that the tariff-free treatment preserved under the U.S.–Mexico–Canada Agreement (USMCA) quietly underpins North American dietary supplement supply chains, keeping cross-border ingredient flows economical and sustaining value-added jobs in the United States. Maintaining this framework helps avoid added costs to the market and supports continued consumer access to affordable, high-quality supplements and their associated public health benefits.

6. Conclusion

CRN appreciates the Department's careful consideration of the unique role of dietary supplements in supporting both public health and the U.S. economy. We stand ready to assist in further discussions to ensure national security goals are achieved without unintended harm to domestic manufacturing, public health, and consumer affordability.

Sincerely,

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Council for Responsible Nutrition

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Appendix A.

HTSUS	Description
25199010	Fused magnesia; dead-burned (sintered) magnesia, whether or not cont. small quant. of other oxides added before sintering
25309080	Other mineral substances, not elsewhere specified or included
28049000	Selenium
28332951	Other sulfates nesoi
29146200	Coenzyme Q10 (ubidecarenone (INN)
29161930	Unsaturated acyclic monocarboxylic acids, nesoi
29181650	Salts and esters of gluconic acid
29181960	Malic acid
29211961	N,N-Dialkyl (methyl, ethyl, N-Propyl or Isopropyl)-2-Chloroethylamines and their protonated salts; Acylcic monoamines and their derivatives, nesoi
29224100	Lysine and its esters and salts thereof
29224250	Glutamic acid and its salts, other than monosodium glutamate
29224910	m-Aminobenzoic acid, technical; and other specified aromatic amino-acids and their esters, except those with more than one oxygen function
29224980	Non-aromatic esters of amino-acids, other than those containing more than one kind of oxygen function; salts thereof
29232020	Lecithins and other phosphoaminolipids, nesoi
29239001	Quaternary ammonium salts and hydroxides, whether or not chemically defined, nesoi
29241911	Acyclic amides (including acyclic carbamates)
29241980	Acyclic amide derivatives; salts thereof; nesoi
29252990	Non-aromatic imines and their derivatives; salts thereof

29309049	Nonaromatic organo-sulfur acids, nesoi
29321951	Nonaromatic compounds containing an unfused furan ring (whether or not hydrogenated) in the ring
29329961	Aromatic heterocyclic compounds with oxygen hetero-atom(s) only described in additional U.S. note 3 to section VI, nesoi
29329990	Nonaromatic heterocyclic compounds with oxygen hetero-atom(s) only, nesoi
29339912	6-Bromo-5-methyl-1H-imidazo-(4,5-b)pyridine; 2-sec-butyl-4-tert-butyl-6-(benzotriazol-2-yl)phenol; 2-methylindoline; and other specific
29362100	Vitamins A and their derivatives, unmixed, natural or synthesized
29362200	Vitamin B1 (Thiamine) and its derivatives, unmixed, natural or synthesized
29362300	Vitamin B2 (Riboflavin) and its derivatives, unmixed, natural or synthesized
29362401	Vitamin B5 (D- or DL-Pantothenic acid) and its derivatives, unmixed, natural or synthesized
29362500	Vitamin B6 (Pyridoxine and related compounds with Vitamin B6 activity) and its derivatives, unmixed, natural or synthesized
29362600	Vitamin B12 (Cyanocobalamin and related compounds with Vitamin B12 activity) and its derivatives, unmixed, natural or synthesized
29362700	Vitamin C (Ascorbic acid) and its derivatives, unmixed, natural or synthesized
29362800	Vitamin E (Tocopherols and related compounds with Vitamin E activity) and its derivatives, unmixed, natural or synthesized
29362910	Folic acid and its derivatives, unmixed
29362916	Niacin and niacinamide
29362920	Aromatic or modified aromatic vitamins and their derivatives, nesoi
29362950	Other vitamins and their derivatives, nesoi

29369001	Vitamins or provitamins (including natural concentrates) and intermixtures of the foregoing, whether or not in any solvent
30019001	Glands and other organs for organotherapeutic uses, dried, whether or not powdered
32030080	Coloring matter of vegetable or animal origin, nesoi
39123100	Carboxymethylcellulose and its salts
39129000	Cellulose ethers, other than carboxymethylcellulose and its salts, in primary forms