

May 7, 2025

Eric Longnecker
Deputy Assistant Secretary for Technology Security
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave N.W.
Washington, DC 20230

**Re: *Comments on the Section 232 National Security Investigation of Imports of
Pharmaceuticals and Pharmaceutical Ingredients (XRIN 0694-XC120)***

Deputy Assistant Secretary Longnecker,

On behalf of Balchem Corporation and its subsidiaries (collectively, “Balchem”), we herein submit comments on the U.S. Department of Commerce’s (“Commerce”) Bureau of Industry and Security’s (“BIS”) Section 232 national security investigation of imports of pharmaceuticals and pharmaceutical ingredients.

As a U.S. producer of key nutrients and health and nutrition ingredients across the food, supplement and pharmaceutical industries in the United States, Balchem understands the importance of access to critical pharmaceuticals and pharmaceutical inputs and derivatives, including minerals, nutrients and supplements (such industries collectively referred to as the “Health and Nutrients Industries”), to meet health and nutritional needs, and supports the Administration’s commitment to ensuring that imports do not threaten the domestic Health and Nutrients Industries and U.S. national security.

However, to maintain robust domestic manufacturing across the Health and Nutrients Industries in the United States, we must ensure that these industries continue to have access to critical inputs to domestic production of products and ingredients in the Health and Nutrients Industries. Therefore, the Administration should carefully target any actions taken as a result of this investigation to ensure that U.S. manufacturing is supported and not inadvertently put at risk because it is not able to access necessary inputs.

Specifically, we believe the following is critical in ensuring that U.S. manufacturing in the Health and Nutrients Industries can be maintained without unintended consequences:

- We fully support tariffs on domestic-produced products where U.S. manufacturers can sufficiently meet the demand of such products.
- We are opposed to tariffs on foreign inputs not produced in the U.S. but necessary for U.S. production of products and ingredients in the Health & Nutrients Industries.

- We request consideration of an exclusion process for certain companies or certain products and ingredients to address any unforeseen events related to the availability of critical products and ingredients in the Health and Nutrition Industries in the U.S.
 - The Health and Nutrients Industries supply chain often involves input from a very limited number of suppliers. Therefore, if there is a supply chain disruption with a U.S. supplier, U.S. manufacturers are often forced to look outside of the U.S. for alternative suppliers until such time that the U.S. supplier can meet demand again.
- We request a phased-in approach to any actions targeting inputs not available in sufficient quantities to meet U.S. manufacturing needs to give U.S. producers in the Health and Nutrients Industries sufficient time to adjust sourcing.

We discuss the above in more detail as follows: (1) provide a brief introduction and overview of Balchem; (2) explain why a targeted approach is necessary to address national security threats posed by imports; and (3) describe why it is critical that the Administration create an exclusion process for any action taken as a result of this investigation, including taking a phased-in approach to any actions targeting inputs not available in sufficient quantities to meet U.S. manufacturing needs.

Introduction to Balchem

Balchem develops, manufactures, distributes, and markets specialty performance ingredients and products for the nutritional, food, pharmaceutical, animal health, plant nutrition, and other markets. For over five decades, Balchem has created innovative health and nutritional solutions for people and animals worldwide. Balchem is committed to making the world a healthier place by delivering trusted, innovative, and science-based solutions in the nutrition, health, and food marketplaces.

Balchem's manufacturing network in the U.S. is comprised of 16 manufacturing facilities, located in 10 states. Headquartered in Montvale, New Jersey, Balchem has U.S. manufacturing sites in Albert Lea, MN, Bridgeton, MO, Covington, VA, Defiance, OH, Faribault, MN, Green Pond, SC, Lincoln, NE, Marshfield, WI, Ogden, UT, Salt Lake City, UT, Slate Hill, NY, Sleepy Eye, MN, St. Gabriel, LA, Vancouver, WA, and Verona, MO; technology centers in Bridgeton, MO, Defiance, OH, Faribault, MN, New Hampton, NY, and Ogden, UT; and regional offices in Layton, UT, Middletown, NY, and St. Louis, MO. Balchem employs over 1,000 people across these facilities in the United States, including over 850 workers at its U.S. manufacturing facilities.

The U.S. should carefully tailor any actions taken to protect U.S. producers in the Health and Nutrients Industries

As a major U.S. producer of minerals, nutrients and supplement ingredients across the Health and Nutrients Industries, Balchem supports the Administration's Section 232 investigation into the national security concerns related to imports of ingredients in the Health and Nutrients

Industries. Imports from a limited number of suppliers can lead to vulnerabilities, especially if those suppliers are subject to foreign government control or engage in predatory trade practices that undermine the competitiveness of the U.S. industry. If not addressed, this could lead to a weakening of U.S. domestic production in the Health and Nutrients Industries, further exacerbating the risks of a global supply chain in times of global crises or geopolitical tensions.

Ensuring robust domestic production capability is crucial for maintaining the availability of ingredients and other critical inputs in the Health and Nutrients Industries, which are essential for protecting domestic public health and well-being. Strategically imposed measures will bolster domestic production and reduce dependency on foreign sources, thereby protecting U.S. national security. However, any actions should be carefully targeted to support existing U.S. production.

The Administration should take action to address national security concerns related to imports of ingredients in the Health and Nutrients Industries

For products where U.S. production can meet demand, U.S. producers are facing significant pressure from imports. U.S. producers often have to compete against low-priced products, leading to a loss of sales or revenue due to competition from imports. This, in turn, impacts the financial performance of U.S. manufacturers and prevents U.S. producers from reinvesting in their manufacturing facilities and be able to compete in the U.S. market. This exposes the United States to national security concerns related to accessing adequate supplies of domestically produced products and ingredients in the Health and Nutrients Industries.

For this reason, the United States should focus on setting tariffs that strategically target products produced in the United States in sufficient quantities to meet U.S. demand. This includes, for example:

- Choline, properly classified under HTSUS subheading **2923.10.00** is an essential nutrient for health and well-being in both humans and animals. Balchem has sufficient capacity at multiple U.S. manufacturing sites to handle all current demand of various forms of choline, including but not limited to choline chloride, choline L(+) bitartrate, and choline dihydrogen citrate. Balchem's choline products are critical components used in a myriad of products for human nutrition. For example, choline is an essential nutrient in infant formula and pre- and post-natal dietary supplements.
- Methylsulfonylmethane ("MSM"), properly classified under HTSUS subheading **2930.90.92**. Balchem has sufficient capacity at its manufacturing site in the State of Washington (Vancouver, WA) to meet current demand and could expand to meet additional demand.
- Certain minerals and glycinates, properly classified under certain HTSUS subheadings in Chapter 29, including **2922.49**, **2922.50**, **2925.29**, and **2918.19**. For example:
 - **2922.49.80**: Balchem production at its manufacturing facility in Ogden, UT is sufficient to handle all current U.S. demand for spray-dried listed items.

- **2922.50.50:** Balchem production at its manufacturing facility in Ogden, UT is sufficient to handle all current U.S. demand for spray-dried listed items.

If the Administration determines it is necessary to take action pursuant to this Section 232 investigation, it should target inputs of those products where there is sufficient U.S. production to meet U.S. demand.

The Administration must ensure any actions taken do not have a counterproductive effect

The national security concerns discussed above are not an issue for products where U.S. production is *insufficient* to meet demand, and taking action against inputs into downstream products produced in the United States could have the opposite effect intended. If U.S. producers need to rely on imports because they cannot obtain sufficient inputs from sources in the United States, the Administration should not include these products in any actions taken pursuant to this investigation.

For example, Balchem relies on imports of the following products that are not produced in the United States, have no significant domestic source in the United States, or are not available at the required specifications:

- Vitamins K2 Alpha and MK7, properly classified under HTSUS subheading **2936.29.50**.
- Magnesium oxide, properly classified under HTSUS subheading **2519.90.50**.
- Certain minerals properly classified under Chapter 29, including the following:
 - Chromium, properly classified under HTSUS subheading **2827.39.90**.
 - Zinc sulfate, properly classified under HTSUS subheading **2833.29.45**.
 - Niacin, properly classified under HTSUS subheading **2936.29.16**.
- Optifolin (FG), properly classified under HTSUS subheading **2936.29.20**.
- Lysine, properly classified under HTSUS subheading **2922.41.00**.

Because there is no reliable supply of these inputs from sources in the United States, any action targeting imports of these products pursuant to the Section 232 investigation would have an effect counter to the Administration's objectives. The Administration should therefore exclude them from any actions taken as a result of this investigation. At the very least, the Administration should stagger the implementation of any actions taken targeting inputs that do not have a source within the United States to give manufacturers of products and ingredients in the Health and Nutrients industries sufficient time to develop domestic sources for inputs.

The Administration should provide for an exclusion process for any action taken as a result of its investigation

Finally, the Administration should provide for an exemption process to address any unforeseen events that might impact national security concerns related to the availability of critical products and ingredients in the Health and Nutrients Industries in the United States. Because it is impossible to foresee or anticipate all events that might impact supply chains in the Health and Nutrients Industries, the Administration should provide for a mechanism through which it can grant exemptions to any actions taken.

Conclusion

Balchem supports this Administration's efforts to address national security concerns related to products and ingredients in the Health and Nutrients Industries, and ensure domestic production of critical health, nutrients and dietary supplement products and ingredients. In so doing, Balchem encourages BIS to take into account the realities of the supply chains in the Health and Nutrients Industries and the importance of ensuring domestic public health and well-being – and consider the following:

- Set tariffs on domestic-produced products where U.S. manufacturers can sufficiently meet the demand of such products.
- Do not set tariffs on foreign inputs not produced in the U.S. but necessary for U.S. production of products and ingredients in the Health & Nutrients Industries.
- Consider an exclusion process for certain companies or certain products and ingredients to address any unforeseen events related to the availability of critical products and ingredients in the Health and Nutrition Industries in the U.S.
- Take a phased-in approach to any actions targeting inputs not available in sufficient quantities to meet U.S. manufacturing needs to give U.S. producers in the Health and Nutrients Industries sufficient time to adjust sourcing.

Balchem appreciates your consideration of its comments and stands ready to provide further information, as necessary. Please do not hesitate to contact the undersigned with any questions.