Submitted via Regulations.gov

May 7, 2025

Stephen Astle
Director, Defense Industrial Base
Division Office of Strategic Industries and Economic Security Bureau of Industry and Security
United States Department of Commerce

Re: Docket No. 250414-0065; XRIN 0694-XC120; Request for Public Comments on Section 232

Dear Director Astle:

Nutricia North America ("Nutricia" or "we") is providing this comment in response to the "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 Fed. Reg. 15951 (Apr. 16, 2025)." Nutricia endeavors to improve the quality of human life through medical nutrition. It is this ambition that drives our purpose to pioneer nutritional discoveries that help people to live longer, healthier lives.

Nutricia is a market leader in the United States and globally in the production of medical foods. Medical foods are a specialized category of FDA-regulated products defined in the Orphan Drug Act to refer to nutrition products specially formulated for the dietary management of a disease or condition or to meet the nutritional needs of specific patient populations. Despite managing diseases, and often being the primary therapy for some conditions, medical foods are separate and exempt from the definition of "drugs" in the Food, Drug, and Cosmetic Act.

The medical foods category includes, for example, products for the management of rare inborn errors of metabolism ("IEM"), such as phenylketonuria ("PKU"). Patients with an IEM are born with genetic disorders caused by abnormalities in their DNA. The incidence rate of IEMs is quite rare. PKU, the most prevalent and well-known IEM, has an incidence rate of 1 in 10,000-15,000 births. As a result of the genetic error in PKU patients, their bodies cannot break down phenylalanine, an essential amino acid present in all protein. If patients with PKU consume too much phenylalanine, it builds up in the bloodstream and brain and can lead to toxic effects on the nervous system resulting in intellectual disabilities, lower IQ, behavioral and mood disorders, seizures, and/or developmental delays. The primary medical therapy for PKU patients, starting at birth, is to carefully control the intake of very low levels of phenylalanine.

Because phenylalanine is present in all protein, patients can only eat a very low protein diet. To obtain the protein PKU patients need to live, they consume formulas that have no whole protein but instead supply all essential amino acids individually, leaving out phenylalanine. PKU is a

lifelong condition. Patients are identified at birth through a blood test – pin prick to the heel. PKU is a lifelong condition. There is no cure for PKU. Two drug products exist that can help a minority of PKU patients eat normal diets, but most will need to follow a phenylalanine-restricted diet for the rest of their lives, utilizing PKU medical food formulas formulated with little to no phenylalanine. Nutricia is one of the very few manufacturers that produce PKU medical foods and is the leader in this space, as well as the leader in PKU infant formulas. Replacement products are often not readily available — formulations are unique and patients can react poorly to changes in formula. As such, any disruption to the supply chain for such critical food products will likely have an almost immediate impact on patient health and quality of life.

Nutricia's manufacturing facilities are in Europe and the United Kingdom; Nutricia has decades of experience manufacturing medical food products in these facilities. The manufacturing process for these products is highly specialized and it takes years to establish a new medical food manufacturing facility and to safely develop products in the new facility. Medical foods and infant formula medical food facilities are subject to heightened manufacturing standards and regular FDA inspection. Many of the ingredients are highly specialized and cross-contamination and sanitation controls exceed those of normal food production. Because the incidence of IEMs and other medical food conditions is rare, batch sizes are small and carefully controlled. For patient convenience, the formulas are often designed to have long shelf lives and be shelf stable. Ensuring product safety, efficacy, and stability requires extensive testing that itself can take years.

For medical food infant formulas, any changes to production facilities, processes, ingredients or packaging, require notification to FDA before the product can be distributed in the United States. Preparing the FDA notification can take months, or even longer if the changes dictate that new shelf life testing or clinical studies be conducted. FDA's notification review, which occurs after manufacturing facilities and processes are established and products are developed, can take anywhere from 6-months to well over a year. For these reasons, transfer of overseas production to the United States would require significant time.

Nutricia has taken the position that medical foods should be classified as "medicaments" under HTS Chapter 30. Currently, they are classified by U.S. Customs and Border Protection under a general food classification in HTS Chapter 21. As a result of not having a specific tariff classification and being lumped in with general foods, impacts on medical foods (which may negatively affect patients) are often overlooked in tariff policy. Because of the specialized use of these products as a primary therapy for disease, Nutricia maintains that Chapter 30 is more appropriate to better situate the products with other disease-therapy products in making tariff policy decisions.

Further, PKU formulas, and many other medical foods, are comprised primarily of individual amino acids and vitamins and minerals sourced globally. Amino acids, vitamins, and mineral ingredients are all classified under HTS Chapter 29; many do not currently have sufficient domestic production. Global sourcing is necessary because vitamin production, for example,

requires highly specialized processes and unique waste management facilities. Relocating the production of these products and ingredients to the United States to meet medical food needs is not currently feasible. Tariffs on amino acids, vitamins, and minerals would therefore impact the cost of production of domestic medical food products necessary for medical food patients. As noted above, it would take years to shift overseas medical food production to domestic facilities to meet domestic needs; however, even if a sufficient supply of domestic medical foods is achieved, the cost of production would remain significantly impacted if there is insufficient domestic supply of the necessary amino acids, vitamins and minerals.

For the above reasons, we are concerned that tariffs aimed at pharmaceutical products, vitamins, minerals, or amino acids could inadvertently cause supply chain disruptions to critical medical food products. Such disruptions could negatively impact patient health for infants, children, and adults dependent on these products as primary therapy for their medical conditions.

Accordingly, Nutricia North America strongly requests that any pharmaceutical sector-specific tariffs under Section 232 not include medical foods or their ingredients.

We appreciate your review of this request. Please contact Madeline Seeburger at madeline.seeburger@danone.com if you have any questions.

Sincerely,

Miguel H. Del Toro

Miguel H. Del Toro
VP and Associate General Counsel
Nutricia North America, Inc.