May 7, 2025

SENT VIA FEDERAL eRULEMAKING PORTAL

Department of Commerce
Bureau of Industry and Security
1401 Constitution Ave NW
Washington, DC 20230

Re: BIS-2025-0022/XRIN 0694-XC120 Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Sir/Madam:

These comments are submitted by, Curium US LLC ("Curium") in connection with the notice of the Section 232 National Security Investigation into imports of pharmaceuticals and pharmaceutical ingredients initiated by the Department of Commerce's Bureau of Industry and Security ("BIS") on April 16, 2025 ("Notice").[1] Specifically, Curium's comments relate to the invitation to provide comments on the following issues outlined in the Notice:

- The extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;
- The role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceuticals ingredients; and
- The feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance.

As detailed below, the supply chain for Curium's products is fragile due to high expenses associated with domestic production, a limited number of suppliers, intellectual property rights held by foreign producers for key ingredients and the short shelf life of finished products (e.g., quickly decaying radionuclides). The imposition of tariffs on these products will increase the cost of care to U.S. patients, will force medical providers to ration care, use inferior diagnostic and treatment methods, and jeopardize patient care.

[1] *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15951 (April 16, 2025).

Curium
111 West Port Plaza, Suite 800
Saint Louis, MO 63146, United States T +1 314 384 8009 E NuclearMedicine@curiumpharma.com W curiumpharma.com

Introduction

Curium is the world leader in radiopharmaceuticals focused on diagnostic and therapeutic products, including products used in the early detection of cancer, heart disease, and other life-threatening diseases. Curium's operations include its headquarters in St. Louis, Missouri which employs over 500 employees, its nuclear medicine manufacturing site in Maryland Heights, Missouri, and a manufacturing facility in Noblesville, Indiana. Curium's international affiliates also have several facilities in Europe, including a facility in Petten, the Netherlands which employs approximately 400 employees, a facility in Saclay, France which employs about 450 employees as well as two facilities in Finland and one in Turkey.

Nuclear medicine is a branch of medicine that employs small amounts of radioactive isotopes to help diagnose, determine the severity of, or treat a variety of diseases, including certain types of cancers, heart disease, gastrointestinal, endocrine, neurological disorders and other abnormalities within the body. Radiopharmaceuticals are drugs regulated by the U.S. Food and Drug Administration (FDA) while the radioactive nature of its ingredients is regulated by the U.S. Nuclear Regulatory Commission (NRC). Curium's products provide diagnosis or therapy for more than 10 million U.S. patients annually.

Despite continuing efforts by the U.S. industry with the support of the U.S. government, United States-based suppliers have not established a robust or reliable domestic supply of the required components. For example, molybdenum-99 (Mo-99) is the key medical radionuclide (key precursor isotope) used in technetium-99m (Tc-99m) generators. Tc-99m is used by nuclear medicine physicians in about 85% of all diagnostic nuclear medicine studies. Currently, 100% of the Mo-99 used in the U.S. is produced in and imported from the European Union, South Africa and Australia. The Department of Energy (DOE), under the American Medical Isotope Production Act of 2012[2] initiated a program to encourage domestic production of Mo-99. The DOE has spent more than $600M to fund domestic production efforts for Mo-99, which has been matched by more than $600M of private investment in the U.S. Thirteen years later, there is still no reliable domestic source of Mo-99. This illustrates the costliness and complexity of establishing domestic production of medical isotopes.

Curium Operations

Curium also produces strontium-82 (Sr-82) in its Noblesville, Indiana facility. Curium ships the Sr-82 to a customer in Canada to use in producing its rubidium-82 (Rb-82) generators. Sr-82/Rb-82 generators are then shipped back to the U.S. to be used by nuclear medicine physicians in nuclear cardiology studies. A similar product, germanium-68 (Ge-68), is produced by Curium at its Maryland Heights, Missouri facility. Curium ships Ge-68 to customers in Belgium to produce a gallium-68 (Ga-68) generator. These generators are shipped back into the U.S. to be used by nuclear medicine physicians for several cancer diagnostic studies. These are two examples of the complexity of the nuclear medicine supply chain.

[2] https://www.congress.gov/bill/112th-congress/senate-bill/99

Curium
111 West Port Plaza, Suite 800
Saint Louis, MO 63146, United States T +1 314 384 8009 E NuclearMedicine@curiumpharma.com W curiumpharma.com

Curium also manufactures a key active product ingredient (API) at its facility in Saclay, France. That API is imported into the U.S. and is used to manufacture a product under current Good Manufacturing Practices (cGMP) in our Maryland Heights, Missouri facility. That product is used by nuclear medicine physicians for lung perfusion studies to help with the determination of pulmonary emboli. The production of this API is extremely complex. To onshore to the U.S., Curium would need to invest in significant infrastructure, perform a complex technology transfer, perform exhaustive quality and regulatory testing to ensure compatibility with the existing process, collect clinical data, write and file a new Drug Master File (DMF), and amend its New Drug Application (NDA) with FDA. To complete all these steps to effectuate the onshoring of this single API component would be costly, require a great deal of complex development work and take at least 24 months to complete and obtain FDA approval.

Potential Tariff Impact on Nuclear Medicine and Patient Care

Curium believes patient access to the best available healthcare is paramount. Tariffs on products will increase the cost of care to U.S. patients, force medical providers to ration care, use inferior diagnostic and treatment methods, and jeopardize patient care. The diagnosis and therapy required by patients utilizing Curium's products acute care, meaning that a diagnosis is needed as soon as a physician orders it, and the subsequent therapy must begin as soon as possible.

Tariffs on nuclear medicine products or key inputs would disrupt access to necessary products, increase costs, and result in a drug shortages jeopardizing acute patient care.

The nuclear medicine industry has undergone a significant resurgence within the last few decades, led by U.S. based innovation and investment. This resurgence has resulted in more research and development for innovative diagnostic and therapeutic treatments which will ultimately improve patient care. Newly approved radiopharmaceutical treatments for neuroendocrine tumors and prostate cancer have shown important efficacy for patients in which it is considered appropriate to delay taxane-based chemotherapy or who have received prior taxane-based chemotherapy but still had progression.[3]

Tariffs on nuclear medicine products and key inputs would stymie this momentum in innovation by making critical components of nuclear medicine cost-prohibitive for research purposes. As a result, U.S. companies, like Curium, will be forced to allocate more resources toward increased costs to obtaining products and inputs for its existing products—reducing available funding for innovation, research and development.

Requested Exemptions or Deferrals

[3] https://pmc.ncbi.nlm.nih.gov/articles/PMC7700749/; https://pmc.ncbi.nlm.nih.gov/articles/PMC9989419/; www.novartis.com/us-en/sites/novartis_us/files/pluvicto.pdf

For these reasons, Curium respectfully requests that the administration defer or exempt any tariffs on radiopharmaceutical products, medical isotopes, APIs, precursors, and key radiopharmaceutical processing specialty equipment. Specifically, Curium requests that the products classified under the following Harmonized Tariff Schedule ("HTSUS") subheadings be exempt from any contemplated Section 232 tariffs and that the administration strongly consider making the exemptions outlined in Annex II permanent and defer or exempt such products from the reciprocal tariffs imposed pursuant to the International Emergency Economic Powers Act of 1977 (IEEPA).[4] All of the below tariff subheadings cover products that are critical to the U.S. radiopharmaceutical industry. The HTSUS classifications for which Curium proposes a deferral or exemption are as follows:

2804.50.0020	2933.19.3500
2804.29.0055	2937.19.0000
2805.19.2000	2940.00.6000
2805.19.9000	2942.00.5000
2844.20.0050	3002.90.5250
2844.43.0021	7508.9050
2844.43.0028	7907.00.6000
2844.43.0050	8007.00.5000
2845.90.0100	8112.59.0000
2932.19.5100	8112.99.9100

In addition, any Section 232 tariffs should not include products classified under the following HTSUS subheadings:

1702.11.0000
2615.10.0000
2844.42.0000
2844.42.0021
2918.15.1000
2926.90.5050
3822.00.6000
3822.19.0080
3926.90.9910
8309.90.0000

These subheadings are not listed in Annex II and should not be added to any remedy imposed under Section 232. Moreover, the administration should defer or exempt such products from the reciprocal tariffs imposed pursuant to the International Emergency Economic Powers Act of 1977 (IEEPA).[5]

Conclusion

[4] See Annex II to *Executive Order 14257: Regulating Imports with a Reciprocal Tariff To Rectify Trade Practices That Contribute to Large and Persistent Annual United States Goods Trade Deficits*, 90 Fed. Reg. 15041 (April 2, 2025).
[5] Id.

Curium
111 West Port Plaza, Suite 800
Saint Louis, MO 63146, United States T +1 314 384 8009 E NuclearMedicine@curiumpharma.com W curiumpharma.com

Curium appreciates your time and attention to this matter. To the extent there are any questions about the information provided herein, please do not hesitate to reach out to the undersigned.

Sincerely

Roy W. Brown
Vice President, Government Affairs & Strategic Alliances

cc:

Burke Miller, Legislative Assistant, Burke_Miller@Young.Senate.gov
Robert Orr, Economist, Robert_Orr@hawley.senate.gov
Zachary Northcutt, National Security Fellow, Zach_Northcutt@schmitt.senate.gov
Luis Reyes, Military Legislative Assistant, Luis_Reyes@schmitt.senate.gov
James Hart, National Security Advisor, James_Hart@schmitt.senate.gov
Emmett Jamieson, Legislative Aide, Emmett_Jamieson@schmitt.senate.gov
Hilary Pinegar, Legislative Director, hilary.pinegar@mail.house.gov

Curium
111 West Port Plaza, Suite 800
Saint Louis, MO 63146, United States T +1 314 384 8009 E NuclearMedicine@curiumpharma.com W curiumpharma.com