May 7, 2025

BY ELECTRONIC FILING

Secretary Howard Lutnick
U.S. Department of Commerce
Bureau of Industry and Security
Office of Strategic Industries and Economic Security
1401 Constitution Avenue NW
Washington, DC 20230

Re: **Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients** {XRIN 0694-XC120; Docket No. 250414-0065; Notice BIS-2025-0022}

Dear Secretary Lutnick:

On behalf of Octapharma USA, Inc. ("Octapharma USA"), thank you for the opportunity to respond to the Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients issued on April 16, 2025 ("Section 232 Investigation"). Octapharma USA supports the Trump Administration's efforts to mitigate national security threats by centralizing the pharmaceutical supply chain around U.S.-origin active pharmaceutical ingredients ("API") and key starting material(s) ("KSM"). Octapharma USA looks forward to engaging, alongside the industry, with the Administration regarding how these issues can most effectively and efficiently be addressed.

Recognizing the importance of reducing U.S. reliance on foreign pharmaceutical inputs and finished products, we urge the Administration to consider domestic measures to facilitate the reshoring of manufacturing for plasma-derived products. Import restrictions, including tariffs, could lead to loss of U.S. dominance in collection and shortages in the national stockpile. These concerns are of particular importance to companies like Octapharma USA that specialize in the production of human plasma-derived medicinal products, which are treated differently under U.S. law than other pharmaceutical products for a number of key reasons outlined below.

<u>Octapharma USA: Saving the Lives of the American People and the U.S. Military</u>

Octapharma AG is a private, independent plasma fractionator that develops life-saving medicines comprised of high-quality human proteins sourced from human plasma and cell-lines. Octapharma AG employs approximately 5,000 workers in the U.S., either through Octapharma USA or its sister company, Octapharma Plasma, Inc. ("OPI"), which alone operates 181 U.S. plasma donation centers across the country. Octapharma USA is a wholly owned subsidiary of privately held Octapharma AG ("Octapharma AG"), headquartered in Lachen, Switzerland. Octapharma USA

works with various U.S. government agencies to develop and provide critical medicines for both military and civilian use.[1]

Octapharma USA's plasma products treat patients across three main therapeutic categories: hematology, immunotherapy, and critical care. More specifically, our medicines help patients with bleeding disorders, immune mediated diseases, and volume or clotting dysfunction arising from emergency medical situations. Octapharma USA has a long history of partnering with the U.S. government to meet American patient needs. For example, we have the only U.S. Food & Drug Administration ("FDA")-approved fibrinogen concentrate, *Fibryga*, for acquired fibrinogen deficiency due to major bleeding. Fibrinogen is essential to the formation of stable blood clots to stop this bleeding.

Octapharma USA was also recently granted an Emergency Use Authorization ("EUA") to facilitate supplying our lyophilized plasma for transfusion to the U.S. Department of Defense, specifically assisting the Biomedical Advanced Research and Development Authority ("BARDA"), in developing dried plasma for both military and civilian use following major emergencies or mass casualty events. Dried plasma is a potentially lifesaving therapeutic for injured soldiers on remote battlefields experiencing major trauma or bleeding, and as such has remained a significant priority of the U.S. military for years. BARDA, on behalf of our industry, continues to engage the U.S. government and prominent research institutions on the development of such life-changing medicines for both military and civilian uses.

I. Octapharma USA Helps Meet Domestic Demand and Bolster the National Stockpile of Life-Saving Drugs

Addresses criteria (i), (ii), and (viii) in the Federal Register Notice of Request for Comments

Plasma-derived medicinal products are lifesaving medicines used to treat emergency trauma, autoimmune diseases, rare disorders, and other complex conditions. The U.S. has the most robust and safe plasma collection system in the world and is the largest collector of human plasma. Even still, there are only five major companies operating within the plasma-derived medicines market in the United States, all of which are needed to produce enough medication to meet patient demand domestically. Demand for plasma-based therapies has been steadily rising each year, and the manufacturing process is complex and can take 7-12 months. There have also been recent shortage concerns of plasma products, prompting the U.S Department of Health & Human Services ("HHS") under President Trump's first term to launch a national public awareness campaign to promote plasma donations in June 2020.

Octapharma USA also contracts with the U.S. government to provide our products. For example, as mentioned previously, we were recently granted an Emergency Use Authorization ("EUA") to facilitate supplying our plasma products to the U.S. Department of Defense. We will in turn become a key supplier to the federal government based on this EUA and our medicines will save the lives of American soldiers. According to the U.S. Food and Drug Administration and the U.S.

[1] Learn more at https://www.octapharmausa.com/.

Department of Defense's ("DoD") Office of Health Affairs, the supply of dried plasma is the first priority for the U.S. military, and we want to acknowledge that the previous Trump administration was instrumental in enacting Public Law 115-92 to address this need.[2]

Certain trade policies and import restrictions, such as tariffs, risk increasing costs throughout the supply chain, passing through to American consumers, and ultimately decreasing the overall supply of plasma products for the U.S. national stockpile. Currently, Octapharma USA conducts 100% of all plasma collection, through OPI, in the United States, as well as all sales, marketing, and distribution efforts with Octapharma USA partners. Increased costs resulting from new levies risk driving this plasma collection to third party nations, disadvantaging the hundreds of plasma donation businesses across the U.S. and impacting thousands of jobs.

Of note, Octapharma USA has had several discussions with representatives of the DoD regarding the construction of a manufacturing facility on U.S. soil that would manufacture the lyophilized plasma product for the military, as well as plasma derived products to meet the increasing demand in the United States. These discussions are in the preliminary stage, however, Octapharma USA has identified a potential greenfield location in Charlotte, North Carolina on the same property where OPI's headquarters are located.

II. The U.S. Regulatory Landscape Protects Plasma-Derived Therapies and Provides Opportunities for Enhanced Trade Practices

Addresses criteria (ix) in the Federal Register Notice of Request for Comments

Unlike other types of pharmaceutical products, some plasma-derived medicines have very low margins and, for many reasons, have been recognized repeatedly in U.S. law as distinct from other pharmaceuticals. Specifically, because plasma-derived medicines are essential lifesaving therapies that rely on human plasma and cannot be substituted with synthetic versions, U.S. law has historically treated them differently than other pharmaceutical products in the United States. Additionally, the Social Security Act ("SSA") and Medicare regulations facilitate reimbursement under specified payment provisions for "blood and blood products," "clotting factors," "intravenous immune globulin" ("IVIG"), and other drugs and biologicals that fall within Octapharma's product mix. SSA § 1842(0)(1); 42 CFR 414.904.

The majority of the value of our goods are of U.S.-origin. Over 65% of the total cost of manufacturing these products relates to the collection of plasma in the U.S., making the final value of these products substantially of U.S. origin. This is true because all plasma collection is done in the United States and is not mixed with other sources when exported abroad for fractionation. As previously mentioned, four of the five players in this segment of the broader pharmaceutical industry in the United States rely on European counterparts for a small portion of their production process. There is no Chinese or Indian content in the supply chain for these products. Building a pharmaceutical manufacturing plant in the United States is a complex and lengthy process. We can

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[2] *FDA and DoD launch program to expedite availability of medical products for the emergency care of American military personnel*, U.S. Food and Drug Administration (Jan. 16, 2018), https://www.fda.gov/news-events/press-announcements/fda-and-dod-launch-program-expedite-availability-medical-products-emergency-care-american-military.

expect it to take 5 to 7 years to complete. This timeframe includes the construction of the facility, obtaining necessary regulatory approvals, and ensuring all quality control systems are in place. Alternative polices that prioritize research and development, and acquiring and developing the requisite manufacturing equipment, while providing the industry a transition period to evaluate the practicalities of reshoring our production, would stimulate growth and prevent increased costs or operational delays of life-saving medicines.

Plasma derived medicines, classified under the Harmonized Tariff Schedule ("HTS") as codes 3002 and 3004, are not currently subject to tariffs because they serve critical healthcare needs for the American people and plasma donation supports American jobs and companies. While Octapharma supports the Administration's goals of incentivizing domestic production of critical pharmaceutical supply chains, we are concerned that the imposition of tariffs on plasma-derived products could pose significant economic and national security costs on U.S. producers. Specifically, it could lead to the shutdown of hundreds of plasma donation centers across America, eliminate thousands of American jobs, incentivize increased foreign plasma collection, and threaten our country's role as the global plasma industry leader.

III. Conclusion

Octapharma USA appreciates this opportunity to comment on the Administration's request regarding national security threats present throughout the pharmaceutical supply chain, and we encourage the U.S. Department of Commerce to consider the unique nature of plasma-derived medicines as it implements broader measures to support U.S. growth and national security. Octapharma looks forward to engaging with the government to implement policies that most effectively serve the nation's best interests in mitigating national security risks, remedying unfair trade practices that harm the American people, and stimulating domestic production in this space, while continuing to facilitate the provision of life-saving medicines to the U.S. military and civilian population.

Respectfully submitted,

/s/ Flemming Nielsen

Flemming Nielsen, President

Octapharma Inc. USA