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Stephen Astle, Director
Bureau of Industry and Security,
Office of Strategic Industries and
Economic Security
Defense Industrial Base Division
U.S. Department of Commerce
1401 Constitution Avenue, NW Room 3876
Washington, D.C. 20230.

BIS– 2025–0022
XRIN 0694–XC120

Re: Comments Regarding Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Director Astle,

Cumberland Pharmaceuticals Inc. ("Cumberland") submits these comments 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. 15,951 (Apr. 14, 2025).

I. EXECUTIVE SUMMARY

Cumberland submits to the Bureau of Industry and Security ("BIS") that fostering the existing, robust global supply chain for pharmaceuticals, pharmaceutical ingredients, and derivative products supports our nation's security and the interests of all Americans. Maintaining the diversified supply chain infrastructure ensures that crucial medicines and related items are available in times of need and supports the health and wellbeing of patients in our country.

If BIS determines that pharmaceutical imports threaten national security, Cumberland suggests that it recommends action like those taken by President Trump to address the risks posed by imported uranium. Working groups or similar actions would maintain existing supply chain infrastructure, while seeking creative solutions to address any risks identified during this investigation. Additionally, promoting domestic incentive programs would be advantageous for both companies and consumers. Implementing these measures would provide a much better solution and alleviate risks caused by restrictive foreign trade policies such as tariffs or quotas.

II. SUBJECT IMPORTS DO NOT ADVERSELY AFFECT NATIONAL SECURITY SUCH THAT RESTRICTIVE TRADE MEASURES ARE NECESSARY

A. Supply Chain Stability

Understanding the global pharmaceutical supply chain is key to BIS's inquiry as to whether measures are necessary to address any national security threat posed by imports of pharmaceuticals and pharmaceutical ingredients, and related products. As discussed herein, the pharmaceuticals supply chain is highly sophisticated, robust, and internationally integrated. This integration has allowed for U.S. firms like Cumberland and others to efficiently innovate and support the development of drugs that alleviate hardship for Americans and support the health of our country's citizens.

Demand for pharmaceuticals, pharmaceutical ingredients, and their derivative products is currently high and expected to remain high. Further, and relevant for Cumberland, demand for innovative medicine has increased and is expected to continue increasing. Given that demand is currently and is expected to remain high, implementing measures that aim towards maintaining the current supply chain and growing the U.S. manufacturing portion of that supply chain allows for Cumberland and other firms in the biopharmaceutical industry to continue delivering much needed products without disruption.

It is in the best interest of the United States and domestic consumers for current supply chain infrastructure to remain in place. Pharmaceutical supply chains are internationally integrated and highly sophisticated. Certain supply partners, located in countries such as Italy and South Korea, serve as our strategic partners allowing for efficient development of new, innovative drugs for U.S. consumers. These relationships give rise to certain comparative advantages that benefit U.S. consumers.[1]

We partner with companies in South Korea and in Europe to manufacture and supply our medicines needed for the U.S. The products they supply to us include Vibativ® – our potent antibiotic which can be a life-saving treatment for serious infections, and Acetadote® – which treats the leading cause of poisoning in the U.S. and is also a life-saving treatment.

Further, these supply arrangements enable us to export our products to other countries including China which is becoming a growing segment of our business. By maintaining these relationships, Cumberland is able to allocate our resources towards developing innovative new medicines that address unmet medical needs, while also providing affordable and reliable, state-of-the-art medicine for American patients.

Beyond this, by having foreign trade partners, the pharmaceutical supply chain can be sufficiently diversified, which mitigates risk related to over-reliance on one country. If the pharmaceuticals

[1] As a potential solution to further integrate with allied nations, BIS could also recommend entering into strategic, product specific multilateral trade agreements as it did in its report on the titanium sponge Section 232 investigation, discussed *infra*.

supply chain was over-reliant on one country—even the U.S.—were some unforeseen event to occur, Americans would be without our necessary lifesaving treatments. Instead, by engaging in strategic partnerships with organizations located in trusted nations, the overall supply chain efficiently and effectively allocates risk. Doing so avoids potential drug shortages and bottlenecks caused by over-reliance on one country.

The global pharmaceuticals supply chain is also not overconcentrated on a small number of suppliers. Choices are available. The global pharmaceuticals supply chain has reached a level of complexity that forecloses overconcentration. Additionally, the foreign strategic partners with high-market shares do not pose substantial risks to U.S. pharmaceuticals manufacturing or consumers because many are located within the borders of historic allies that can be trusted with respect to our national security.

Cumberland has taken advantage of these circumstances and strategically diversified its supply chain by transacting with partners within trusted nations. Cumberland manufactures its products in Europe and South Korea. Cumberland leverages relationships with suppliers in these countries because they offer advanced manufacturing and reliable solutions. Manufacturing of subject merchandise is not overconcentrated within these regions. Instead, the current environment allows for adequate risk-spreading through diversification supported by partnerships grounded in trust through decades of integration. The market dynamics of these producing countries along with the diversification of production across the world prevents Cumberland's partner companies and their respective governments from weaponizing their position in the pharmaceuticals manufacturing supply chain or otherwise exerting control over the market.

In conducting its analysis, the BIS must consider that trade measures such as tariffs or quotas may adversely affect the global supply chain that can lead to drug shortages. Working groups or other alternative, proactive measures—such as those taken as a result of the section 232 investigation—that that examine ways for the U.S. to fortify infrastructure could productively address any potential national security risks, while maintaining productive and efficient supply chains.

B. Domestic Manufacturing

Reliable supply chain infrastructure includes the promotion of domestic production. Cumberland sources products from a variety of jurisdictions including the United States. Our partner organizations that manufacture in the U.S. in turn rely on dependable supply chain solutions that would be at risk if restrictive measures were adopted. Instead, alternative solutions that support domestic manufacturing could be adopted. For example, other measures, such as subsidies for purchasing or investing in domestic manufacturing facilities or domestic content requirements for government procurement such as enhanced Buy American Act rules, provide domestic producers with incentives to scale manufacturing domestically.

Such recommendations are within BIS' toolkit and have been leveraged before. For example, in the Section 232 investigation evaluating the effects of titanium sponge imports, BIS recommended two potential domestic initiatives to address national security risks. These recommendations included entering a government procurement program under the Defense Production Act of 1950 and expanding the National Defense Stockpile to include titanium sponge. Like solutions could be

leveraged in the pharmaceutical context. These recommendations, if implemented, would incentivize increased domestic production capacity.

Cumberland also suggests that the scope of potential measures could be narrowed, which would positively affect domestic manufacturing while supporting research, innovation, and advancement of pharmaceuticals technology. Cumberland invests substantial resources in the United States towards innovation and providing state-of-the-art pharmaceutical products for American patients. By imposing blanket tariffs or quotas on all pharmaceuticals, pharmaceutical ingredients, and derivative products, innovation may be stifled due to rising costs. To continue supporting innovation and availability of high-quality drugs, while simultaneously bolstering domestic manufacturing, future measures could apply only to certain APIs and/or other inputs that are readily available in the United States.

By narrowing future measures to apply only to select APIs and other inputs, U.S. manufacturing will increase capacity with respect to these raw materials needed for pharmaceutical products. These actions would, in turn, increase the number of domestic producers able to meet current and future demand for these components.

Cumberland believes initiatives such as domestic subsidies, tax-breaks, or government procurement programs can positively incentivize domestic manufacturing while maintaining supply chain stability. Further, working groups to address ongoing concerns beyond expiration of the investigation can continue to monitor developments and address any persisting national concerns. Multilateral negotiations with trusted trade partners could also support long-term domestic manufacturing.

C. Unfair Practices by Foreign Trade Partners

As Cumberland discussed above, the global supply chain for pharmaceuticals and derivative products is highly sophisticated and collaborative. Cumberland's experience is that our supply partners' governments do not provide significant subsidies to organizations within their borders. Generally, policies within foreign jurisdictions favor low trade barriers which allow for efficient, low-cost integration with Cumberland and other U.S. purchasers and producers. Cumberland's trade partners are market-driven companies that do not have any incentive to artificially lower prices.

This landscape has allowed Cumberland to focus on developing high-quality, innovative pharmaceutical products. By developing a supply chain based on components and other upstream articles that are produced efficiently in other countries, Cumberland has been able to allocate domestic resources to creating state of the art medicine that Americans need. Reliance on close trade partners has also allowed Cumberland to lower prices for U.S. consumers by lowering the price of components such as APIs. This would not be possible if the foreign trade partners were engaging in unfair trade practices.

III. CONCLUSION

Americans need dependable, rapid, and market-driven access to pharmaceuticals, pharmaceutical ingredients, and derivative products in order to stay healthy and thrive. Because these articles are so important, decades of innovation and integration have fostered a highly sophisticated, robust international supply chain to support access to these goods. Maintaining this supply chain is in the best interest of all Americans.

If BIS finds that imports from certain jurisdictions impair or threaten to impair national security, it should recommend measures that do not disrupt the current supply chain environment. Domestic incentive programs or working groups to formulate long-term solutions as opposed to across-the-board tariffs or other restrictive trade measures can accomplish this goal. Alternatively, BIS could recommend narrow tariff measures that maintain Americans' access to innovative, state-of-the-art pharmaceutical products manufactured abroad, then engage in multilateral negotiations. Ensuring access is most important; implementing measures that support the existing system is the most efficient way to ensure such access.