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May 6, 2025

The Honorable Howard Lutnick
Secretary
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

Submitted electronically via www.regulations.gov

RE: Docket No. 250414-0065 | ID No. BIS-2025-0022 | XRIN 0694-XC120

Dear Secretary Lutnick,

On behalf of Hikma Pharmaceuticals USA Inc. (Hikma), thank you for the opportunity to provide comments on **Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients.** We are pleased to share our expertise as a leading and long-term domestic manufacturer of essential medicines. We currently operate three pharmaceutical manufacturing facilities in the U.S., including in Cherry Hill, NJ, Columbus, OH, and Dayton, NJ and are currently further expanding our manufacturing operations, in Cleveland, OH. As one of the nation's largest producers of sterile injectable and non-injectable medicines, Hikma's U.S. manufacturing capabilities help assure a steady supply of vital generic and branded medicines that serve the needs of millions of American patients and often help to solve drug shortages. Since 1991, Hikma has continuously made domestic investments and taken actions to enhance national health and security by providing a robust supply of medicines that helps ensure U.S. hospitals and healthcare providers have the medicines they need to treat their patients.

Given our expertise, our response will focus primarily on the following sections requested by the Department:

> (i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States;
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> (ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand;
>
> (iii) the role of foreign supply chains, particularly of major exporters, in meeting United States' demand for pharmaceuticals and pharmaceutical ingredients;
>
> (viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance; and

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(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security.

We also will touch on other industry-wide issues related to trade policies that affect the domestic supply of vital generic medicines and national security.

In short, for the reasons cited below, we urge the U.S. Government to abstain from tariffs on pharmaceutical finished dosages, pharmaceutical ingredients, pharmaceutical components, and pharmaceutical manufacturing machinery, and instead consider providing both immediate and long-term incentives for companies currently committed to domestic production of pharmaceutical medicines.

I. Hikma's Portfolio and Domestic Capabilities with a Secure Global Supply Chain

We would like to first answer the Department's request for input on **(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand** and **(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance.** We will conclude this section by providing an overview of **(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security.** In subsequent sections we will provide further details.

Hikma is a top-10 U.S.-based manufacturer and supplier of oral, nasal and liquid generic medicines and a top-three supplier of generic sterile injectable medicines by volume to U.S. hospitals and healthcare providers. We serve the U.S. healthcare system with a large domestic manufacturing presence, and with a diversified portfolio of more than 800 medicines across various dosage forms and strengths. Hikma is continuously increasing our domestic portfolio of medicines manufactured in the U.S. or in nearshore locations, and we continue to out-pace many generic manufacturers in U.S.-based production.

Across our facilities in Cleveland and Columbus, Ohio, and Cherry Hill and Dayton, New Jersey, and with more than 2,300 U.S. employees, we currently have domestic capacity to annually manufacture more than 12 billion finished doses. Furthermore, our distribution facility in Columbus, Ohio, can reach 60 percent of the U.S. population within a 48-hour drive.

Since 2010, Hikma has invested more than $4 billion to build and expand our domestic U.S. manufacturing, research and development (R&D), and distribution capabilities. This ongoing focus on U.S. manufacturing is why Hikma is a regular partner to the U.S. Food & Drug Administration (FDA) and trusted partner to domestic suppliers and health care practitioners.

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Our longstanding commitment to domestic manufacturing continues. Over the next five years, we plan to invest further to expand our domestic capacity to produce large amounts of high-quality, affordable medicines. Our domestic investments have contributed to establishing more reliable supply chains for U.S. hospitals and pharmacists and positioned us to be a trusted partner to the U.S. Government.

These domestic investments have enabled Hikma to be a major generic pharmaceutical manufacturer. Despite our robust U.S. manufacturing, we have concerns that tariffs on pharmaceutical components and finished doses would negatively impact the ability to offer more affordable generic medicines to patients, mitigate drug shortages and lead to more domestic manufacturing. Specifically, we are concerned about tariffs on active pharmaceutical ingredients (API), components, and specialized machinery needed to manufacture generic medicines domestically. Tariffs on these parts and ingredients would increase costs for domestic manufacturers and compound cost pressures for these already low-margin medicines, leading to further supply contraction and fewer manufacturers of essential medicines.

Furthermore, tariffs could impact some of Hikma's portfolio of medicines that we produce overseas through a strong supply chain that meets the FDA's and our high-quality standards, while also ensuring a diversified supply chain that can withstand natural disasters and other shocks. For instance, Hikma has nearshore operations in Portugal and Germany for key sterile injectable medicines – including vital oncology medicines – and we manufacture certain essential antibiotics in Jordan. Another example of our secure supply chain is our decision to source API from multiple countries across North America, Europe and parts of Asia to avoid being dependent on one location.

To protect our national security, secure our pharmaceutical supply chain, and increase access to more affordable medicines for Americans, we urge the U.S. Government to consider policies that prioritize partnerships with generic manufacturers that have invested in domestic manufacturing for decades and avoid any trade policies that could inadvertently impact domestic production and harm patients.

II. Hikma is Making Quality Medicines in the U.S. for American Patients

Hikma's manufacturing facilities have achieved an excellent long-term record of FDA quality inspections with zero major observations. Our broad portfolio and comprehensive high-quality U.S. and nearshore production capabilities enable us to deliver high-volume rapid responses to solve shortages of vital medicines and address urgent supply needs. In 2022, the Administration for Strategic Preparedness and Response (ASPR) identified 86 key medicines essential for acute patient care with no comparable alternative available, many of which Hikma manufactures.

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The Department requested input on **(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand.** Here are some of the ways Hikma is meeting demand through a strong U.S. workforce:

a) Hikma manufactures essential generic and branded oral, nasal and inhalable medicines at a state-of-the-art manufacturing facility in Columbus, Ohio, with capacity to manufacture additional products by partnering with the U.S. Government. Some of the top medicines made in Columbus include a widely used generic alternative for Advair Diskus®, a treatment for respiratory illnesses like COPD and asthma as well as an 8-mg intranasal naloxone spray to treat opioid overdoses and help combat the opioid overdose epidemic.

b) In early 2025, Hikma was the first to launch the generic medicine Mercaptopurine Oral Suspension, which treats U.S. patients diagnosed with acute lymphoblastic leukemia, as part of a combination chemotherapy maintenance routine. Due to Hikma's excellent commercial capabilities and close supplier relationships, our team was able to deliver this more affordable medicine for treatment of American patients within just 71 minutes of FDA approval.

c) Hikma's Columbus facility is also the nation's largest manufacturer of fluticasone, or generic Flonase®—helping millions of Americans who suffer from seasonal allergies.

d) In 2023, during a shortage of medicines to treat ADHD, we launched six strengths of lisdexamfetamine, a generic of Vyvanse®, made in our Columbus facility. Our supply of lisdexamfetamine helped address the domestic shortage, and Hikma is capable of helping to alleviate or solve the shortage if the Drug Enforcement Administration (DEA) increases our API supply quota.

e) Hikma's generic sterile injectable facility in Cherry Hill, New Jersey, manufactures numerous vital products with an expanding collection of high-speed manufacturing and packaging lines. Many of these sterile injectable medicines aid in surgeries, like Heparin Sodium Injection prefilled syringes, which are used to treat and prevent blood clots including during cardiac surgery and in post-operative care. Our portfolio of ready-to-administer prefilled syringes and sterile injectable medicines aid hospitals, pharmacists, doctors and nurses treat patients faster, more easily and with reduced risk.

f) Hikma also domestically manufactures a range of hospital-administrated injectable pain medicines, which were key to solving a drug shortage in 2018 when another manufacturer halted production due to quality issues. The ensuing shortage led to delayed surgical care and strained the workloads of hospital pharmacists and healthcare providers nationwide until Hikma was able to work with the U.S. Government to rapidly increase production and fill the shortage.

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g) Another example of Hikma's rapid U.S.-based response to meet urgent domestic demand for sterile injectables occurred during President Trump's Operation Warp Speed, when Hikma acted quickly to address medicine shortages during the COVID-19 pandemic, including manufacturing and supplying 12 of the most widely used medicines to treat the most severely ill patients in hospital ICUs during this time.

h) In 2022, we launched Hikma 503B in Dayton, New Jersey, which is a sterile compounding facility focused on providing high-quality, ready-to-administer injectable medicines that are customized to specific needs of patients in the U.S. Our 65,000 sq. ft., purpose-built facility leverages our decades of expertise in sterile injectable manufacturing and extensive supplier relationships to meet the needs of hospital pharmacists and healthcare providers.

In addition to our strong and growing domestic manufacturing and development capabilities, Hikma's expertise extends to answer the Department's request on **(iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients.** Hikma's U.S. manufacturing capabilities are bolstered by its nearshore manufacturing operations and select commercial partnerships. Collectively, our dedication to serving the U.S. healthcare system and millions of American patients with high-quality medicines through domestic and nearshore manufacturing and commercial licensing, allows us to meet domestic demand through our foreign supply chains in several crucial areas:

a) Hikma's FDA-inspected facilities in Portugal and Germany provide relief for American patients that need a range of sterile injectable medicines, including oncology medicines, many of which are in shortage and not manufactured in the U.S. by Hikma or our competitors.

b) Our nearshore facilities also manufacture a range of vital antibiotic medicines for U.S. patients. For instance, during the 2022-2023 Winter season there was a surge in demand for amoxicillin, a common antibiotic used to treat infections, leading to a nationwide shortage affecting children and families. As one of the top producers of this essential, affordable medicine for American patients, we operated 24/7 to produce more amoxicillin faster. We also implemented several measures to help solve this shortage faster, including working directly with the FDA and changing our shipping method to prioritize more rapid delivery and decreasing wait times for U.S. patients.

c) Hikma recently launched—as the first U.S. pharmaceutical company to do so—a generic version of Victoza®, Liraglutide Injection, a Glucagon-Like Peptide-1 (GLP-1) product to treat diabetes more affordably for U.S. patients. At this time of writing, only one other generic manufacturer who received FDA approval has launched this medicine, and no one is producing the generic GLP-1 domestically. To achieve this, Hikma must rely on advanced technology that was developed in China and is not yet available in the United States. To provide a more affordable and high-quality version to Americans, Hikma entered

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into a commercial license after confirming its own high standards are met by its partner's FDA-approved facility in China. Importing this medicine enables the United States to benefit from innovations that occur outside of our borders, and we believe this also helps drive competition and innovation to offer high-quality and more affordable medicines for patients.

III. Most Generic Manufacturers Left the U.S.; Hikma Invested More

The Department also requested guidance on **(i) the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States** and **(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance.**

Generic drugs account for approximately 90 percent of all U.S. prescriptions filled but receive only 13 percent of the dollars spent annually on medicines. As the U.S. Government aims to lower the cost of healthcare, it's no surprise then that demand for generic medicines, especially sterile injectables, is high.

Generic drugs comprise the majority of medications in shortage at any given time in the U.S., making up as much as 84 percent of all shortages. Shortages are even worse among generic injectable medicines. Generic drug shortages can be caused—or worsened—by several factors, most notably by a race to the bottom on pricing. These challenging pricing pressures are happening because of extreme competition caused by fewer purchasers controlling the market and because many generic pharmaceutical manufacturers are moving operations overseas to reduce their costs. This significant and ongoing move away from U.S. production allows our competitors to find cheaper labor while Hikma continues to invest locally and pay U.S. salaries and benefits.

While many of our competitors left the U.S. years ago, Hikma's U.S. investments have consistently grown and have recently exceeded more than $4 billion to build, acquire and expand R&D, manufacturing and distribution capabilities. Some notable investments and partnerships in the U.S. include:

a) Our 2021 acquisition of Custopharm, which added 13 new sterile injectable medicines to our growing injectables portfolio and helped us further expand our R&D pipeline.

b) Hikma's 2022 launch of a sterile compounding business in New Jersey to produce medications in ready-to-administer formats for healthcare providers to quickly address specific patient needs.

c) Hikma's recently completed acquisition of Xellia Pharmaceuticals, a new investment in U.S. manufacturing in Cleveland, Ohio, which will increase our domestic capacity to produce sterile injectable generic medicines for U.S. patients with new high-speed equipment. To bring this new facility to Hikma's standards, we are currently importing

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machinery to upgrade and expand this facility, among other investments we are focused on in the U.S.

Hikma's facilities in New Jersey and Ohio have immediate and meaningful capacity to increase production of generic sterile injectables and other generic medicines. If requested by the U.S. Government, Hikma can quickly prioritize manufacturing schedules to address urgent needs with our available capacity to produce 2.7 billion additional finished doses. We have plans in place for more investments in these campuses, which will enable Hikma to manufacture billions of additional doses of essential medicines annually. Through our ongoing expansion and investment in our U.S. facilities, we expect to have new capacity to manufacture an additional 6.4 billion finished doses of essential medicines by 2028.

IV. Impact of Tariffs on Domestic Pharmaceutical Manufacturers

Finally, we will offer our experience of **(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security.**

The U.S. Government is rightly focused on strengthening our pharmaceutical supply chain with U.S.-produced medicines, and we believe it is vital to provide incentives for companies currently committed to domestic production of finished doses. Financial incentives could include:

a) Tax incentives that prioritize generic pharmaceutical companies that have a demonstrated commitment to U.S. investments and already have a reputation for high-quality manufacturing of essential medicines domestically, which will speed U.S. production and support national security.

b) The U.S. Government should consider long-term fixed-price guaranteed contracts with domestic manufacturers to ensure long-term availability of essential medicines and to avoid sudden requests for medicines facing shortage that take time to produce. This will guarantee a reliable and consistently available supply of these medicines are always available for use by U.S. hospitals and healthcare providers.

c) All federal agencies should consider additional prioritization for domestic manufacturers, especially those making essential medicines that are at risk of, or actively in shortage. For instance, as companies seek higher aggregate production quotas for medicines subject to DEA oversight, like lisdexamfetamine that treats ADHD, the Administration could offer higher quotas for API supply to companies manufacturing the medicine in the U.S.

This domestic prioritization can ensure generic medicines are made here and are ready to quickly and easily reach patients while also supporting our local communities with well-paying jobs and related employee benefits. These incentives could also bring some of the fastest action to build a more robust U.S. pharmaceutical supply chain and solve drug shortages. It is our strong request that the U.S. Government consider ways to incentivize generic manufacturers like Hikma that have consistently invested in U.S. manufacturing for decades.

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Any trade policies that add tariffs to pharmaceuticals or pharmaceutical ingredients could create unintended consequences that disincentivize domestic manufacturing and investment. Furthermore, current trade policy is creating an unlevel playing field by exempting imported finished doses from tariffs, while placing tariffs on the pharmaceutical components and machinery we require to manufacture essential medicines domestically. This policy could harm domestic pharmaceutical manufacturers like Hikma while ex-U.S. pharmaceutical manufacturers that have taken operations overseas would receive a significant tariff-related financial advantage. Current trade policies could have the following effect:

a) If tariffs are placed on manufacturing components like excipients (included in 93 percent of medications), vials, stoppers, filters, other packaging materials, and the expensive specialized pharmaceutical machinery Hikma plans to purchase to further invest in our U.S. capabilities, our cost per finished dose produced in the U.S. may rise significantly.

b) There are cases where Hikma imports high-quality finished products made at our near-shore facilities or by international partners who have arranged for us to sell their FDA-approved medicines to meet domestic demand. Tariffs could cause these medicines, many of which are not manufactured in the U.S., to become unavailable or more expensive for patients.

c) Finally, Hikma sources API from U.S.-based suppliers when possible and through a diversity of suppliers globally. However, API supply is still concentrated outside the U.S., and we would like to see the U.S. Government work to reshore or nearshore API supply. Importantly, removing tariffs from imported API will not solve the full issue. API suppliers will face similar pricing challenges and competition as domestic generic manufacturers face; therefore, we encourage further considerations to incentivize and make domestic API supply competitive.

Hikma's mission is to create high-quality medicines and make them accessible to the people who need them. We are one of only a few generic pharmaceutical manufacturers to consistently invest large sums in the U.S. over the years, and therefore we are well-positioned to continue to serve American hospitals, healthcare providers and patients. **To continue providing U.S. healthcare system with accessible medicines, significantly investing in our U.S. capabilities and purchasing the necessary components and specialized production machinery from trusted nearshore and global partners that enables our domestic manufacturing, we strongly urge the U.S. Government to abstain from tariffs on pharmaceuticals, pharmaceutical ingredients, components and machinery, and instead consider incentives.**

We would like to continue this conversation and avail our subject matter experts to you for any further discussion about strengthening the U.S. pharmaceutical supply chain. If you have any questions regarding our comments or require additional information, please contact Steve Weiss, US Head of Government Affairs at sweiss@hikma.com.

Thank you for your consideration.

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Sincerely,

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CC: Eric Longnecker, Deputy Assistant Secretary for Technology Security