May 7, 2025

Stephen Astle
Director, Defense Industrial Base Division
U.S. Bureau of Industry and Security
Office of Strategic Industries and Economic Security
U.S. Department of Commerce

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

Subject: Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Dear Mr. Astle,

Alora Pharmaceuticals LLC is pleased to submit our comments regarding the Section 232 National Security Investigation on the imports of pharmaceuticals and pharmaceutical ingredients. As the parent company of six subsidiaries that manufacture and market both branded and generic pharmaceutical products, Alora Pharmaceuticals is based in Alpharetta, GA, with manufacturing facilities located in Marietta, GA, and Fort Worth, TX.

Founded in 2007, Alora Pharmaceuticals is a U.S. owned, privately held company with over 600 employees dedicated to research, development, manufacturing, and sales of more than 98 branded and generic pharmaceutical products. Our products span various therapeutic areas, including Neurology, Women's Health, Endocrinology, Pain Management, Cough & Cold, and ADHD. With advanced manufacturing capabilities, we produce a broad range of assets, including topicals, unit dose, oral solid dose, and liquid products, serving both human and companion animal health markets.

Our expertise encompasses sourcing and procuring pharmaceuticals and pharmaceutical ingredients globally to support our product pipeline. Our comments focus on the following key areas outlined in the Request for Information by the U.S. Bureau of Industry and Security:

1. ***Current and Projected Demand for pharmaceuticals and pharmaceutical ingredients in the U.S.***
   We anticipate continued growth in the pharmaceutical market within the U.S., particularly for generics and branded medicines. Alora Pharmaceuticals currently manufactures over 98 branded and generic products.

2. ***The extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand.***
   Currently, there is limited US domestic production of starter materials, with most Active Pharmaceutical Ingredients (API) sourced from overseas, including India, the EU, and China. The shift towards onshoring API production will require years of development, alongside changes to EPA regulations to allow for sustainable production practices. Additionally foreign suppliers have a lower employee cost base from which they operate. In some cases, the industry is losing manufacturers of generic drugs due to their inability to compete from a cost basis with Indian and Chinese manufacturers. In addition, China and India control a significant portion of pharmaceutical desiccant market. Any disruption to this could significantly impact the US pharmaceutical marketplace.

   Finished dose forms (FDF) are primarily made in India. Making it extremely challenging to compete in manufacturing solid, liquid, and other formulations of pharmaceuticals. Predatory pricing practices are driving prices below a level at which companies can compete. **Injectable products in the US are manufactured at a level of 3x to 10x cost versus the cost of products made in India**.

   This forces US manufacturers to outsource production for these types or products. This drives out competition, forcing companies to leave the market and thus creating drug shortages. Today, the majority of common generic medicines have no US source of active pharmaceutical ingredient (API), the component of the medicine providing therapeutic benefit. Some recent studies have highlighted the current situation[1]: Greater than 80% of APIs for FDA-defined essential medicines and over 90% of top antibiotics and antivirals have no US manufacturing source. Less than 5% of large-scale API sites, globally, are located in the US – the majority of large-scale manufacturing sites are in India and China. India and China have the greatest number of API facilities supplying the US market and over ten percent of these facilities have an FDA Warning Letter[3]

3. ***Role of Foreign Supply Chains, particularly of major exporters in meeting US demand for pharmaceutical product and pharmaceutical ingredients***
   Foreign manufacturers are integral to maintaining international supply chains, and disruptions can lead to significant gaps. Any restrictions imposed by countries like

[1]https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program data/index.html 2 Shivdasani, et. al., 2021. 3 The Geography of Prescription Pharmaceuticals Supplied to the USA: Levels, Trends, and Implications. Journal of Law and Biosciences. Jan-Jun.

China and India on API and starter materials or Finished Dose Formulations (FDF) could severely impact the U.S. market.

4. ***Concentration of U.S. imports of pharmaceutical products and pharmaceutical ingredients from a small number of suppliers and associated risks***.
   Reliance on a small number of suppliers/foreign manufacturers poses risks that may impact supply chains. If one of those producers exit the marketplace due to foreign business practices. It places incredible pressure on the market for supply. Increasing the diversity and number of API and finished product manufacturers would allow for greater access of API and starter materials. This could also raise concerns regarding the consistency of manufacturing and quality of API and starter materials. More producers create an impossible task for the FDA to qualify all of those producers for a given product.

5. ***Impact of Government subsidies and predatory trade practices on US pharmaceutical industry competitiveness***.
   Predatory pricing by foreign entities can undermine U.S. competitiveness. The FDA currently has a backlog of over 2,000 inspections since COVID-19. This backlog exacerbates these challenges, reducing competition and placing U.S. firms at a disadvantage due to the cost differential for FDA filings and inspections. These do not substantially favor US Corporations. COVID-19 created a significant demand shock to the US drug supply chain revealing the United States' significant reliance on foreign production of essential drug active pharmaceutical ingredients. The FDA's Center for Drug Evaluation and Research (CDER) shared that as of August 2019, 72% of FDA-approved API manufacturing facilities were outside of the US. A recent 2021 deeper dive revealed that approximately 75% of COVID-19 related drugs, 97% of antibiotics, 92% of antivirals, and 83% of the top 100 generic drugs consumed have no US-based source of APIs. **Even common over-the-counter products are dependent on overseas producers, for instance, 80% of the global supply of PAP, a precursor material for acetaminophen, is only available from China**. Notably, COVID-19 highlighted this operational and geopolitical vulnerability as 44 pharmaceutical companies were rendered inoperable in China and the government of India ceased the export of 26 medicines, including acetaminophen and antibiotics, by rule.[4]

   The market for Venlafaxine ER tablets is extremely competitive, with low price points set by Indian competitors. This makes it challenging for U.S.-based manufacturers like Alora to compete, leading to a reduced market share. Indian competitors can sell this product for $0.75-$2.00 per 100 count bottle, where US companies may

only be able to sell the same quantity for $5.00-$9.00 per 100 count bottles. This is far below the finished good cost from a US manufacturer (Alora) Dexcel (Israeli based). These are the only non-Indian or Chinese producers of this product. Currently there is only one US manufacturer for this product (Alora).

6. **Economic Impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state sponsored production**
   Artificially low cost of API, starting material and finished product prices drive U.S. generic manufacturers out of business market. Foreign manufacturers benefit from lower material costs, employment costs and lower costs of entry making it difficult for U.S. companies to compete.

7. **The potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over foreign pharmaceutical supplies**
   Tariffs or restrictions on pharmaceutical products or pharmaceutical materials could significantly impact the availability of lifesaving products in the U.S. market. In addition, onshoring and increasing domestic production may need a corresponding relaxing of regulations and EPA restrictions.

8. **The feasibility of increasing domestic capacity for pharmaceutical and pharmaceutical ingredients to reduce import reliance**

   US Pharmaceutical companies need some level of support to drive stability and sustainability for US manufacturing by US owned companies. This can be achieved through 100% tax credit for bringing manufacturing back to the US and incentivizing US companies to produce more products in the US. In addition, regulations and EPA regulations/restrictions will need to be reviewed and adjusted.

Additional Information

- **Generic Customer Tariff Discussions**: Several generic customers (wholesalers) have expressed concerns about the potential impact of recently implemented tariffs. Although these customers have taken no definitive actions, as of now, they are aware of possible impacts on finished goods, APIs, KSMs (key starting materials), and raw materials. Some suppliers have indicated the need to raise product prices due to these potential tariffs. Unfortunately, due to contractual obligations US Manufacturers may not be able to raise their price due to previously agreed upon terms.

- **Failure to Supply**: US contractual provisions with several generic customers (wholesalers) could result in penalties if we fail to supply finished goods due to

tariff-related disruptions. Penalties can range from replacement costs to our WAC price, depending on the duration of the supply disruption. These penalties can be in place for 30-60 days. As a manufacturer, if we cannot get API, starter materials or finished products due to tariffs we as a company will be in a "Failure to Supply" situation that will result in our company paying penalties due to current contractual commitments.

- **Predatory Pricing Example**: The market for Venlafaxine ER tablets is extremely competitive, with low price points set by Indian competitors. This makes it challenging for U.S.-based manufacturers like Alora to compete, leading to a reduced market share. Indian competitors can sell this product for $0.75-$2.00 per 100 count bottle. This is far below the finished good cost from a US manufacturer (Alora) Dexcel (Israeli based) usually between $5.00-$9.00 per 100 count bottle. These are the only non-Indian or Chinese producers of this product. Currently there is only one US manufacturer for this product (Alora). Also see additional response in question #5
- **Generic Customer Market Dynamics**: large generic customer groups (Wholesalers) dominate the distribution market, leading to intense competition and depressed pricing. These customers are driven solely by cost and they do not care if they obtain their products from a US company or foreign entity. This environment makes it difficult for many manufacturers to sustain operations. 3 companies make up 92% of the overall market (Red Oak Sourcing- Cardinal/CVS, WBAD – Cencora and Walgreens, ClarusOne-McKesson, Walmart & Rite Aid). These 3 companies do not necessarily do what is best for the patient but what is best for their shareholders when it comes to product acquisition and product pricing. In the generic marketplace it is exceedingly difficult for manufacturers to exist, pressure on API suppliers, starting materials etc. creates very thin margins, forcing companies to drop out of a particular product market. It is important to note that the 3 companies mentioned above control 92% of the overall market. These top 3 companies are owned by the largest PBMs (Pharmaceutical Benefit Managers).

Factors that contribute to price erosion, including shorter product lifecycles, budget constraints, and increasingly sophisticated buyers. The number of generic pharmaceutical manufacturers serving the US market has risen 50% since 2014 [2]. Manufacturers are vying for the business of fewer buyers – three buying groups make

[2] FDA, "Facts About Generic Drugs"; https://www.fda.gov/media/83670/download 4 FDA, "Estimating Cost Savings from New Generic Drug Approvals in 2018,2019, and 2020" CDER, page 4; https://www.fda.gov/media/161540/download

92% of the wholesale generic purchases in the US[3] . Consolidation has accelerated that price-based competition, with frequent bidding cycles used to lower the price for a given generic . The bidding cycles require manufacturers to update supply price reduction within a matter of weeks at the request of the wholesalers. The wholesalers are then free to move volume to the lowest bidder at the end of the cycle. While the bidding cycles ensure supply at the best market price, it also results in no long-term guarantee or certainty of demand for manufacturers despite significant capital investments. Industry interviews with generic companies as part of this research indicate that it is not uncommon for a generics drug supplier to have their entire business up for bid through the course of a calendar year creating significant risk in the financials of the business. These cost reduction trends continue year after year, in what has been referred to as the 'race to the bottom,' squeezing generic manufacturer's margins further and further degrading the economic viability of the manufacturing supply base.

FDA Fees and Inspections

US owned company fee structure vs foreign owned pharmaceutical Companies.

- Under GDUFA, the fee for a facility inspection outside the U.S., its territories and possessions shall not be less than $15,000 and not more than $30,000 higher than the amount of the fee paid for a facility located within the U.S. [4]

FDA Inspection Process

The frequency of inspections by the FDA varies for U.S.-based and foreign pharmaceutical companies.

- U.S.-Based Pharmaceutical Companies: The FDA typically inspects U.S. facilities every two years, and these may last several weeks. This can vary based on the company's compliance record and the nature of the products manufactured. For foreign manufacturers, foreign pharmaceutical companies tend to receive advance notice with inspections lasting typically one week. In the US the FDA provides US companies usually have no advanced notice, and inspections may extend months.
- Foreign Pharmaceutical Companies: The FDA inspects foreign firms less frequently, generally every three years. However, the schedule can be influenced by several

[3] FDA, "Generic Competition and Drug Prices" CDER, page 2; https://www.fda.gov/media/133509/download 6 IBIS, "Generic Pharmaceutical Manufacturing in the US" Generic Pharmaceutical Manufacturing in the US - Number of Businesses | IBISWorld 7 AAM, "AAM calls out threat of consolidation among purchasers" 2022; AAM Calls Out Threat Of Consolidation Among Purchasers :: Generics Bulletin (informa.com)
[4] Federal Register docket NO. FDA-2013-N-0007 "Generic Drug User fee

factors, including risk assessments, past inspection results, and the type of products being produced and the number of manufacturing sites a company may have. Foreign companies are notified in advance of the inspections, and inspections typically last a week/weeks.

- **Facility Inspection Fees**[5]

    1. **Domestic FDF Facility Fee** **$175,389**
    2. **Foreign FDF Facility Fee** **$190,389**
    3. **Domestic API Facility Inspection Fee** **$26,458**
    4. **Foreign API Facility Inspection Fee** **$41,458**

- **FDA Facility Inspection Backlog**[6]

Analysis by the Associated Press (AP) report on FDA inspections highlights that there is a backlog of 2,000 facilities located within the U.S. have not had FDA inspectors return to complete facility inspections since the pandemic.

The U.S. pharmaceutical industry is among the most advanced in the world, contributing significantly to both the economy and healthcare advancements. However, the current fee structure may deter U.S. companies from investing in the development of new drugs, potentially slowing the pace of innovation and leading to fewer treatment options for patients. In contrast, foreign companies might benefit from lower fees, allowing them to undercut U.S. companies on price while still accessing the U.S. market. In addition, they benefit from less frequent facility inspections.

Possible Solutions

- Consider exempting API and starter materials from tariffs until US Manufacturers have the ability to manufacture under US regulations. Tariffs should be implemented in a staged approach to give the market time to prepare.
- Prioritize TAA-compliant countries as preferred providers to potentially reduce costs and restrict production from China and India. Providing manufacturing credits and relaxed EPA regulations may in the end reduce costs while maintaining a robust supply chain.

---

[5] FDA Frequently asked Questions- FDA website

[6] Analysis by the Associated Press on FDA Facility Inspection backlog, AP, September 6,2024 Perrone, M and Forster, N

- Support for U.S. pharmaceutical companies through tax credits and regulatory adjustments for manufacturing will be crucial for stability and sustainability.
- Continue and push for PBM reform that will eliminate anticompetitive business practices with US pharmaceuticals.
- Make US owned pharmaceutical companies a priority vs. foreign owned pharmaceutical companies that have a US presence a priority.

The impact of current trade policies necessitates exploring additional measures, including tariffs or quotas, to protect national security. We believe these strategies could foster a more balanced competitive landscape and enhance U.S. pharmaceutical production.

Thank you for considering our input on this critical matter. Senior Leadership of Alora Pharmaceuticals would be available for further clarification and discussion if requested.

Sincerely,

Harold Arthur Deas, Jr.

CEO
Alora Pharmaceuticals

For more information, please reach out to:

Brad Harmon

Alora Corporate Affairs

Bharmon@alorapharma.com

201-919-8614