GADA
GENERIC ANIMAL DRUG ALLIANCE

Re: Investigation under Section 232 of the Trade Expansion Act of 1962, as amended. – National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

Date: May 6, 2025

Docket Number 250414-0065: CRIN 0694-XC120: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients

On behalf of the Generic Animal Drug Alliance (GADA), we respectfully submit these comments in response to the U.S. Department of Commerce's request for public input on the national security implications of the U.S. pharmaceutical supply chain. GADA represents manufacturers and distributors of FDA-approved generic animal drugs and the active pharmaceutical ingredients (APIs) used in their production. Generic animal drugs comprise an important part of the pharmaceuticals and medicated feed additives used in modern food production, and the medicines that keep livestock and pets healthy. Our shared vision in all decision making should be focused on a secure supply chain that keeps US industry, national security and animal welfare at its core.

Veterinary pharmaceuticals are integral to the security of the U.S. food supply, public and animal health, and agricultural economy. While we understand the potential for national security impacts from imports of pharmaceuticals and pharmaceutical ingredients, the realities of a global supply chain and limitations on U.S. production and manufacture of such items must also be considered. We believe the concerns around the dependence on ex-USA suppliers of the human drug pharmaceutical supply chains to be valid. At the same time, we are unaware of these same concerns applicable to animal health, and frankly do not believe the current domestic supply of FDA-approved finished dosage forms and active pharmaceutical ingredients adequate to support public and animal health from a veterinary medicine perspective.

(i) Current and Projected Demand

The US animal health industry is a robust industry forecasted for significant growth. Demand for all animal pharmaceuticals continues to grow, inclusive of generic animal drugs, in response to increasing veterinary needs, the rising cost of veterinary care, the need for cost-effective treatments for livestock, and desire for more accessibility of animal healthcare. This demand is projected to remain robust at approximately almost 8% across both companion and food-producing animal sectors through 2030.

(ii) Capacity of Domestic Production

The domestic capacity existing for manufacture of veterinary finished dosage forms, starting materials, excipients, and Active Pharmaceutical Ingredients (API) in particular, is inadequate to meet current needs. For finished dosage forms, there is an existing cohort of U.S.-based manufacturers, however it is unlikely that exclusive use of U.S. manufactured generic animal drug products would be sufficient to meet market demand. For APIs, excipients and starting materials, the vast majority of these ingredients are sourced internationally, particularly from Asia. There are simply not U.S. based options for most of these materials, at any cost. The infrastructure, labor, and cost differentials between foreign and domestic production make it unlikely that reshoring alone can fully meet current or future needs within a reasonable timeframe.

(iii) Role of Foreign Supply Chains

Foreign supply chains are an essential component of the U.S. generic animal drug industry. Given the extensive investment and time required to establish viable and compliant domestic alternatives, the U.S. will remain dependent on foreign suppliers. There is a long history of safe and effective generic animal drugs in the marketplace that have utilized foreign supply chains. While a focus must remain on enhancing the resilience, diversification, and security of these existing supply chains, it's unrealistic to think the animal health industry could be served by domestic manufacturing inputs alone.

(iv) Import Concentration and Risk

The number of suppliers of Active Pharmaceutical Ingredients for veterinary health are actually quite high, though they are geographically concentrated in China, and to some extent, India. While the countries of origin for veterinary pharmaceutical APIs are admittedly few, US supply has been proven to be consistent and robust, even during the COVID-19 pandemic. Current concerns around tariffs prove to be the biggest uncertainty regarding the consistent supply of high-quality APIs from our partners abroad. Finished dosage forms imported into the U.S. come from a range of countries/stakeholders, and it is our view that there is little risk here. The finished dosage form supply chain is highly regulated, observed by the FDA-CVM, and has proven year on year for decades to be serving public and animal health.

(v) Foreign Government Subsidies and Trade Practices

While subsidies, environmental policies, and trade practices in countries with state-supported Active Pharmaceutical Ingredient manufacturing may continue to distort global markets in regards to pricing, there are few viable, compliant options in present

day. To build this supply in the USA would require significant investment, time and regulatory oversight, not only from FDA-CVM, but from numerous Federal agencies.

(vi) Artificial Pricing and Overproduction

As an organization we are not aware of these policies in regards to pricing or overproduction being impactful to the US generic animal drug industry in present day. While foreign government artificial pricing or overproduction may have been a tool on the path to where we find ourselves at present, currently we find ourselves in a position where foreign supplied materials, especially APIs, are the only options available.

(vii) Export Restrictions and Strategic Vulnerability

The threat of export restrictions by foreign governments, whether through economic leverage or unintended supply chain shocks, could be demonstrated as a vulnerability. While a foreign government could theoretically weaponize their control over veterinary pharmaceutical supplies, there is no history of this having been conducted and if it were to be – it seems veterinary drugs would be low risk for the exposure. Complete supply chain autonomy for the USA is not feasible.

(viii) Feasibility of Increasing Domestic Capacity

Increasing domestic capacity for Active Pharmaceutical Ingredient (API), animal drug excipients, and to some degree, finished dosage form, production would require massive capital investment, long lead times, workforce development, as well as FDA approval and oversight. While not fully feasible as a near-term solution, targeted incentives and public-private partnerships could support a strategic increase in critical capacity, particularly for the most essential APIs. However, our position is that any of these efforts should be focused on defending the human health drug supply chain, and veterinary drugs should be excluded.

(ix) Trade Policies and National Security

While current trade policies could be optimized, we do not understand that further tariffs or quotas would serve the public health and/or lead to more domestic production of generic animal drugs, their APIs or excipients. A balanced approach should be taken, and there should be consideration given to excluding animal drugs from any significant changes in trade policies.

Conclusion

While GADA fully supports strengthening domestic pharmaceutical resilience, we also recognize that veterinary drugs require a different lens with which to examine the desired outcomes and risks. Veterinary drugs should not be bundled with or treated the same as human drugs in this context. Centering manufacture of veterinary drug APIs,

excipients and finished dosage forms solely in the USA, while an admirable goal, would be a severe limitation to this industry for years, if ever fully successful. We urge the Department to adopt a pragmatic, multi-pronged strategy in addressing the stated concerns, and to consider the exemption of veterinary drugs from import restrictions or tariffs.

We appreciate the opportunity to comment and stand ready to support further dialogue on this critical issue.

Sincerely,
Stephanie Batliner

Chairperson, GADA

On behalf of the Generic Animal Drug Alliance (GADA)