

May 7, 2025

***Via Electronic Filing***

Jeffrey Kessler  
Under Secretary of Commerce for Industry and Security  
U.S. Department of Commerce  
1401 Constitution Avenue, Northwest  
Washington, DC 20230

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

The Animal Health Institute (AHI) appreciates the opportunity to submit comments in response to the Bureau of Industry and Security's (BIS) *Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, 90 Fed. Reg. 15951 (April 16, 2025) (the "Notice").

AHI represents manufacturers of veterinary pharmaceuticals, biologics, animal medical devices, diagnostics, and other essential products that safeguard the lives, health, and well-being of nearly 10 billion animals in the United States – both companion animals in American homes and food-producing livestock and poultry on American farms and ranches. Our members are committed to the President's goals of strengthening domestic supply chains and promoting American industry, agriculture, and national security.

The Section 232 investigation (the "Investigation") into pharmaceuticals was launched to assess whether pharmaceuticals and pharmaceutical ingredients, and their derivative products, "are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security." This effort is focused on ensuring reliable access to critical medicines necessary for maintaining military readiness, responding to public health emergencies, and supporting broader health infrastructure. The Investigation is part of a strategic approach to improve supply chain resilience for essential human health products, particularly in light of lessons learned from recent global supply disruptions, such as COVID-19. Additionally, President Trump signed Executive Order "Regulatory Relief to Promote Domestic Production of Critical Medicines,"<sup>1</sup> on May 5<sup>th</sup> with the goal of facilitating restoration of a robust domestic manufacturing base for prescription drugs, including key ingredients and materials. AHI believes these are laudable goals.

---

<sup>1</sup> Trump, Donald J. "Regulatory Relief to Promote Domestic Production of Critical Medicines." *The White House*, 5 May 2025

At the same time, AHI is concerned that animal health products could be inadvertently swept up under a Section 232 investigation and remedies focused on potential risks to human health. Both Executive Order 14017 on “America’s Supply Chains” and the *BIS Assessment of the U.S. Active Pharmaceutical Ingredient Industrial Base*<sup>2</sup> focus on potential concerns related to public health and the role of pharmaceuticals in treating diseases of the human body.<sup>3</sup> While animal health products are generally found within Chapter 30 of the Harmonized Tariff Schedule of the United States (HTSUS), which covers most pharmaceutical products, human health-focused products and animal health products have fundamentally different active pharmaceutical ingredients (APIs), uses, supply chains, and production processes. While a number of studies, including a report by the House Select Committee on the Chinese Communist Party have raised concerns about U.S. dependence on imports of human pharmaceuticals, we are not aware of any similar concerns that have been raised with respect to veterinary drugs. Given these considerations, we believe there are compelling reasons why animal health products should not be included within the scope of the Investigation. AHI, therefore, urges the Administration to approach each step of the Investigation through a careful and deliberate process to ensure that animal health products are not inadvertently targeted with remedies meant to address human-focused pharmaceuticals and APIs, as this could have serious unintended consequences for animal health, pet owners, and livestock production.

## **I. Executive Summary**

AHI urges the U.S. Department of Commerce to explicitly exempt veterinary medicines and related animal health products – including APIs, veterinary medicaments, biologics, and diagnostics – from any trade restrictions resulting from the investigation into pharmaceutical imports. As outlined in our full submission, applying tariffs or quotas to these products would cause widespread harm to American farmers, ranchers, and workers, undermining U.S. food security, agricultural exports, and rural economic strength. These products are not interchangeable with human pharmaceuticals and have no bearing on military readiness or emergency preparedness – core national security concerns that the investigation rightly seeks to address.

President Trump has long championed American jobs, rural prosperity, and food independence. The U.S. animal health industry generates \$608 billion in economic output through its support of livestock production, veterinary services, and pet care. Imposing restrictions on animal health inputs would raise costs for hardworking farmers, threaten livestock health, devastate pet owners, and risk disease outbreaks that could damage U.S. exports and strain American households.

---

<sup>2</sup> Commerce Department, “BIS To Conduct Assessment Of U.S. Active Pharmaceutical Ingredient Industrial Base” (July 9, 2024) at <https://www.bis.gov/press-release/bis-conduct-assessment-u.s.-active-pharmaceutical-ingredient-industrial-base>

<sup>3</sup> The BIS Survey defines an Active Pharmaceutical Ingredient as: “Any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.”

Instead of broad measures, AHI recommends a targeted, pro-growth strategy: (1) exempt animal health products using specific HTS codes; (2) coordinate with veterinary and agricultural stakeholders to incentivize reshoring of critical inputs; (3) streamline FDA and USDA regulatory approvals to speed domestic production; (4) prioritize sectoral trade deals that open markets for Made-in-America veterinary products; and (5) if tariffs are imposed, provide exemptions for U.S. content or foreign inputs used in U.S. manufacturing.

AHI supports President Trump's vision of a secure, self-reliant America. But trade restrictions or tariffs on animal health products or inputs would backfire – harming the very communities he aims to defend. We urge an approach that protects American agriculture, workers, families and pets, thus strengthening national security.

## **II. The Animal Health Industry is Committed to Creating Good-Paying Jobs and Strengthening America's Economy**

### **a. Animal Health Industry is A Foundation for Rural Economic Growth in the United States<sup>4</sup>**

The animal health industry contributes directly to the U.S. economy through jobs, wages, exports, and taxes. Animal health products also support and enable other industries and enhance the quality of life for millions of Americans. Animal health companies produced \$11.4 billion of medicines in the U.S., of which nearly \$9.0 billion was sold domestically and \$2.4 billion was exported. The economic impact of the industry plus the industries that depend on animal health – veterinary services, pet services, and meat and dairy production – generated about \$608.1 billion in output. Notably, the animal health sector consistently outperforms the broader U.S. manufacturing industry across key economic indicators, reflecting its strong commitment to innovation and sustained economic growth.

Farmers and ranchers use medicines to ensure the health of food-producing animals, protect public health, and protect the food supply. As of January 2024, the U.S. had 87.8 million cattle and 74.97 million swine stock, according to the U.S. Foreign Agricultural Service's Livestock and Poultry: World Markets and Trade report. Farmers and ranchers generated over \$184 billion in output, raising cattle, pigs, chickens and other animals. Healthy livestock are used to produce meat, eggs, and dairy products purchased by consumers in the U.S. and abroad, which contributes to the U.S. economy and supplies consumers with healthy, safe, and affordable food.

Companion animals play important roles in lives of American families. They play an important economic role as well. More than 67% of American households own pets, totaling nearly 400 million pets, including dogs, cats, horses, birds, fish, horses and more. Americans spent over \$75.5 billion on their pets in 2016, with an average total household spend of \$892 on pet food, veterinary services, supplies, and other services. The median lifetime expenditures for medicines are \$5,154 for a dog and \$5,325 for a cat.

---

<sup>4</sup> Pham, N., & Donovan, M. (2022). *The Economic and Social Contributions of the Animal Health Industry*. ndp | analytics. Retrieved from <https://ahi.org/animal-health-industry/>

## **b. U.S. Economic and Manufacturing Footprint**

Animal health manufacturers operate at sites across the United States to make vaccines and pharmaceuticals to treat a wide array of conditions for food producing and companion animals. As of August 2022, there were 146 facilities producing animal health products, of which 68% manufacture the products, 34% are involved in labeling, 27% package products for distribution, and 22% conduct analysis. In addition to these operations, another 691 facilities use animal health products to manufacture medicated animal feed. In total, these 837 facilities operate across 41 states with the largest presence in the primarily rural region of the Mid-West and the South. Further, the industry's products are key inputs into U.S. farming and ranching operations, bolstering the economic returns to U.S. rural communities and ensuring a safe, resilient food production system.

## **c. Projected Growth**

The U.S. animal health industry is projected to experience strong growth driven by rising pet ownership, innovation in therapeutics and diagnostics, and expanded veterinary services. The U.S. animal health market size was valued at USD \$12.65 billion in 2024 and is expected to grow at a compound annual growth rate (CAGR) of 7.97% from 2025 to 2030 putting the revenue forecast in 2030 at \$19.77 billion. The pharmaceuticals segment accounted for the highest revenue share of 61.21% in 2024. The biologics segment is anticipated to grow at the fastest CAGR of 9.36% over the forecast period due to increasing animal health expenditure, availability of veterinary medicines, R&D activities, and growing product launches. The companion animal segment is anticipated to grow at the fastest CAGR of 8.54% from 2025 to 2030. This can be attributed to the steady rise in the population of pet dogs & cats in key markets.<sup>5</sup>

Anticipated growth in the animal health sector is driven by advancements in animal healthcare, increasing pet ownership, and heightened demand for animal protein. Because of our modern and efficient system of meat production and the high value American families put on household pets, the United States is a global leader in veterinary medicine and innovative veterinary drugs. However, it is important to note that prevailing market conditions, such as regulatory modernization (or the lack thereof) and economic shifts, can significantly affect these projections. Additionally, animal health in the United States is a mature market. Farmers and ranchers have a long history of using diagnostics and working with veterinarians to properly utilize drugs and vaccines to keep their animals healthy. That means that a significant growth potential exists in other markets. Growing international markets will support U.S. jobs and U.S. manufacturing.

The animal health industry is not only vulnerable to the effects of U.S. tariffs, but also to the negative effects of retaliatory tariffs that would hinder our ability to export to these growing international markets. In order to best support the U.S. domestic animal health industry, the Administration's focus should be on opening new export markets for U.S. products. Excluding

---

<sup>5</sup> Grand View Research. *U.S. Animal Health Market Size, Share & Trends Analysis Report by Animal Type (Production Animal, Companion Animal), by Product, by Type of Vaccine, by Disease, by Route of Administration, by Distribution Channel, and Segment Forecasts, 2025–2030*. 2024. Grand View Research, <https://www.grandviewresearch.com/industry-analysis/us-animal-health-market-report>.

animal health products from the scope of the Investigation would insulate this critical sector from inadvertent adverse consequences, including higher marginal costs and potential retaliatory restrictions in global markets. Continued investment in research and development, as well as supportive trade policies aimed at opening growing export markets for U.S. companies and veterinary medicines, will be critical to maintaining U.S. leadership in this globally competitive sector.

**d. The Majority of the Animal Health Products Manufactured in the United States are Consumed Domestically**

A significant amount of the animal health products consumed in the United States are sourced from manufacturing sites within the United States (approximately 73% of domestic production is consumed in the United States). Meanwhile, U.S. manufacturing sites are also responsible for exporting millions of dollars of product to other countries, bringing important revenue into the United States that can be used towards more research and development, more capital investments, and more good paying U.S. jobs. In fact, the animal health industry currently creates over 24 thousand direct jobs and nearly 1.5 million indirect jobs that paid \$74.5 billion in wages in 2021. This balance between domestic consumption and export highlights the critical role U.S. production plays in both supporting local market demands and contributing to international supply chains.

**III. It is Important for Farmers and Ranchers to be Able to Afford Animal Health Products**

Animal health products are essential to maintaining the health of U.S. livestock and protecting public health. The U.S. animal health market lacks third-party payers; the full cost of development, regulation, and manufacturing is borne directly by U.S. veterinarians, farmers, and pet owners. The imposition of tariffs on these products would increase the potential for cost increases that would directly take away from U.S. companies' ability to invest further in U.S. manufacturing or R&D, or the increase in cost would have to be passed down the supply chain, raising costs and decreasing availability.

The U.S. animal health industry invests over \$1 billion annually in R&D, amounting to roughly 7% of total industry sales – compared to an average of 3% in other sectors.

Additionally, customers of animal health products are extremely sensitive to price. Because of this high elasticity of demand, tariffs on veterinary pharmaceuticals and ingredients would have detrimental effects on industry, farmers, and consumers. Higher costs for livestock medicines would limit farmers' ability to afford preventive measures, potentially leading to widespread disease outbreaks and economic losses. For example, raising the prices of vaccines and therapeutic drugs could limit the ability of farmers and ranchers to manage disease outbreaks, such as the devastating incidences of avian flu among U.S. poultry operations, which has had the unintended consequence of sending egg prices through the roof and putting pressure on the Administration. Likewise, significant price increases in pet vaccines due to tariffs could have the unintended consequence of reducing vaccination rates, increasing the risk of disease outbreaks among pets.

## **IV. Tariffs Could Hurt, Not Support, the Animal Health Supply Chain, Potentially Impacting U.S. Food Security and Agricultural Exports**

### **a. Animal Health Products Keep U.S. Animals Healthy and Productive**

Any concerns regarding the U.S. ability to effectively respond to a disease outbreak could detrimentally harm U.S. exports of these products. Due to the existential and systemic risk associated with animal disease outbreaks, a single animal health event could result in substantial economic harm, likely to the detriment of U.S. national security.

Veterinary tools such as diagnostics, vaccines, and biosecurity inputs are America's first line of defense against animal disease threats. Weakening or disrupting access to these tools is a national security risk. Examples of these sweeping negative impacts include the risk of foreign animal disease or continued epidemics of infectious disease:

- A single outbreak of African Swine Fever could result in over \$80 billion in economic U.S. losses and the loss of 60,000 American jobs in the pork sector. Exports accounted for 30.3% of total U.S. pork and pork variety meat production in 2024. This equated to an average of \$66 in value from each hog marketed. This could immediately be lost.
- During the 2022 Highly Pathogenic Avian Influenza (HPAI) outbreak, over 105 million U.S. birds were impacted, resulting in losses to U.S. producers and foreign trade bans from key export markets.
- Exports of U.S. beef – worth \$10.58 billion in 2021 – would be devastated overnight if there were an outbreak of Foot and Mouth Disease (FMD), a highly contagious, viral disease impacting cloven-hoofed livestock including cattle, sheep, and pigs, and wildlife species like deer. Morbidity can reach 100% in susceptible populations, and mortality can reach 20% or more in young calves, lambs, and piglets.

America's veterinarians, pet owners, farmers and ranchers rely on access to animal health products and prioritize continued access to these important products. On numerous occasions these important stakeholders have trumpeted the importance of such access:

*APPA supports the efforts of AHI to explicitly exempt veterinary medicines and related animal health products from any trade restrictions resulting from the investigation into pharmaceutical imports. The U.S. animal health industry is projected to experience strong growth driven by rising pet ownership and imposing tariffs on imports of Pharmaceuticals and Pharmaceutical Ingredients, may negatively impact this anticipated growth. The imposition of tariffs on these products would also increase the potential for veterinary cost increases and thus raising the cost of pet ownership which might hinder the growth of the pet industry as a whole which is projected to reach \$157 Billion in spending in 2025. American Pet Product Association (APPA) is the leading trade association within the pet industry representing over 1,000 manufacturers, suppliers, retailers.*

The American Veterinary Medical Association (AVMA) has said, “*Veterinarians need more FDA-approved animal drugs (both pioneer and generic) at a reasonable cost, so that our clients can afford treatment for their animals when these products are needed. ... The needs of veterinarians are unique in that we treat a multitude of species across an incredible range of sizes for a variety of diseases and conditions*”<sup>6</sup>

Furthermore, the use of animal health products is important for maintaining the productivity of American herds and the prosperity of US farms:

The National Milk Producers Federation highlights the need for diagnostics and medical therapies stating, “*Sick animals need to be rapidly diagnosed and treated accurately and consistently. An effective Herd Health Plan emphasizes prevention, rapid diagnosis, and quick decision-making on the necessary treatment of all sick animals. A licensed veterinarian should help a dairy farmer develop and implement a Herd Health Plan.*”<sup>7</sup>

National Pork Producers Council has said, “*...the industry must remain diligent in its efforts to prevent an outbreak of African swine fever (ASF), Foot and Mouth Disease (FMD), or any other foreign animal disease in the United States. Such an outbreak would be a devastating animal health crisis with extremely negative implications for market prices, export opportunities and the overall economy.*”<sup>8</sup>

“*Across our industry, turkeys are raised in environments that help protect them from disease and predators. However, no situation is completely sterile and as such, illness and disease will occur. When that happens, just as in human medicine, we rely on trained, experienced professionals to prevent and treat disease; this care by veterinarians includes the judicious use of antibiotics for preventions, control and treatment... The antimicrobials used for this purpose are vital to the maintenance of an animal’s overall health status. An animal that is unhealthy is more susceptible to additional infections, some of which could have food safety implications. Judicious use of antibiotics for prevention must continue to be an option for a veterinarian attempting to prevent animal suffering from disease.*” said the National Turkey Federation.

The US Beef Quality Assurance Program states that “*Healthy animals are important for the economic prosperity of farmers and ranchers. For example, pre-conditioning calves which involves administering [the proper deworming medication and vaccines] is a key to financial success because it improves the rate of gain, feed efficiency, and carcass quality of the cattle. This means a greater rate of return for farmers.*”

---

<sup>6</sup> Donlin, Janet D. Letter to Eric Nelson regarding the Animal Drug User Fee Act (ADUFA). 1 Dec. 2022. American Veterinary Medical Association. Letter.

<sup>7</sup> National Milk Producers Federation. Animal Care Reference Manual 5. National Dairy FARM Program, July 2024–June 2027, p. 56. <https://nationaldairyfarm.com/wp-content/uploads/2024/09/FARM-14787-2023-Animal-Care-Standards-Reference-Manual.pdf>.

<sup>8</sup> National Pork Producers Council. (2024, June 28). U.S. economic contribution report. <https://nppc.org/wp-content/uploads/2024/06/U.S.-Economic-Contribution-Report-6.28.24.pdf>

Broad tariffs would do nothing to boost supplies of veterinary drugs and risk weakening national security rather than strengthening it. Therefore, animal health products should be excluded from the scope of the Investigation or, in the alternative, be accounted for through specific non-tariff remedies under Section 232, including greater domestic capacity investment and negotiating market-opening trade deals.

**b. Ensuring Reliable Access to Animal Health Products Through a Balanced Global and Domestic Supply Chain Strategy**

The U.S. animal health supply chain is a globally integrated system that ensures efficient import and export of critical veterinary pharmaceutical products and inputs. This structure enables the steady, affordable availability of essential medications, supporting both animal care and broader public health and national security priorities. While domestic production is a crucial component of this supply chain – accounting for an estimated 73% of animal drug manufacturing – relying solely on U.S.-based production is neither economically viable nor sufficient to meet national demand.

Abrupt or broad-based tariff increases on key inputs, such as active pharmaceutical ingredients (APIs) and critical diagnostic components, could unintentionally undermine the resilience of the U.S. animal health supply chain. Attempting to decouple from global production and shift to a domestic-only manufacturing model would significantly raise costs, reduce efficiency, and risk discontinuing vital products. Transitioning manufacturing practices, such as changing API sources, often requires several years due to extensive FDA and USDA regulatory oversight. In some cases, relocating production facilities to the United States could take more than eight years and cost up to \$600 million per facility, largely due to regulatory and permitting hurdles. Reconstructing the entire supply chain domestically would require billions of dollars, making critical veterinary treatments unaffordable for many ranchers, farmers, and pet owners.

Moreover, many imported components are sourced from U.S. allies or other low-risk trading partners. This so called “friend-shoring” is an important tactic for reducing industry reliance on adversarial countries. Imposing tariffs on these inputs would not only penalize these trusted partners but also harm U.S.-based manufacturers that depend on them.

Finally, for certain animal health products, domestic production is simply not economically feasible due to specialized manufacturing requirements, high operational costs, or market-specific factors such as disease prevalence or animal population size. A rigid domestic-only approach would strain the system and reduce access to essential animal health solutions.

**c. Supporting growth in the animal health industry through Sectoral Agreements to support U.S. exports of Made-in-America veterinary products**

In Section 2(g) of his “American First Trade Policy Memorandum,” President Trump directed the U.S. Trade Representative (USTR), in conjunction with the Secretary of Commerce and Secretary of Treasury, to “identify countries with which the United States can negotiate agreements on a bilateral or sector-specific basis...[and to] make recommendations regarding such potential agreements.”



AHI urges the President and his negotiating team to pursue a sectoral agreement focused on U.S. veterinary products that encompasses improved U.S. market access as well as foreign cooperation on U.S. standards and sanitary and phyto-sanitary measures. Through pursuing greater market access and supporting innovative domestic research and capital investments, the Administration can ensure affordable and reliable access to essential veterinary medications and continued American leadership in innovative veterinary drug development. This strategic approach not only benefits public health and animal welfare but also supports national security by ensuring a stable and robust U.S. supply chain. The implementation of science-based standards by key trading partners, such as the EU, also would boost U.S. exports of meat, chicken, and dairy products.

Additionally, the Administration could implement targeted measures to bolster the U.S. domestic industry. Additional support in the form of (i) subsidies or investment tax credits for new investments in the United States; (ii) streamlining permitting and other licenses and approval processes to facilitate further investment; and (iii) improving regulatory efficiency to bring new production facilities online faster and speed new product approvals would all support domestic industry without risking inadvertent harms to industry and its customers.

## **V. U.S. Animal Health Supply Chains Have Proven Their Resilience**

The animal health sector demonstrated extraordinary supply chain resilience during the COVID-19 pandemic, ensuring continuity of critical care. U.S. manufacturers maintained stable product inventories, with minimal disruptions for veterinarians, livestock producers, and pet owners. A survey of more than 3,000 U.S. participants, conducted in the Fall of 2020 showed that 72% of pet owners said the pandemic did not make it harder to access medicines nor did they need to provide a different medicine than their pet was used to.<sup>9</sup> The global supply chain is resilient, strong, and beneficial to U.S. interests.

Rather than imposing trade restrictions like tariffs and quotas that will only harm the animal health industry, we support policies that encourage greater domestic investments, improved regulatory agility, and enhanced domestic capacity through targeted incentives and partnerships.

## **VI. Conclusion**

To protect U.S. national security and economic strength, AHI urges the Administration to:

1. **Explicitly exempt veterinary medicines and animal health inputs** (including APIs, diagnostics, biologics, and delivery devices) from any import restrictions imposed under this Section 232 investigation. Product-specific HTS codes should be used to ensure clear exclusions. AHI offers an initial list of priority HTS codes we propose for exemption.


---

<sup>9</sup> HealthforAnimals. "Veterinary Care Experiences during COVID-19: Survey of Pet Owners." Last modified May 27, 2021. <https://healthforanimals.org/resources/publications/publications/veterinary-care-experiences-during-covid-19-survey-of-pet-owners/>

2. **Coordinate with animal health and veterinary industry stakeholders, including U.S. agricultural producers**, to identify critical components and prioritize them for incentive-based reshoring, not penalty-based trade actions.
3. **Partner with FDA and USDA regulators** to modernize and expedite the approval of new domestic manufacturing facilities and suppliers, enabling long-term investment in American capacity.
4. **Prioritize market-opening trade sectoral negotiations and domestic investment programs** to support U.S. industry and maintain cost-competitiveness.
5. **Exemption for U.S. Content.** If the Administration nevertheless turns to a tariff remedy, it should provide an exemption for U.S. content, including U.S. research and development cost. Such an exemption for U.S. content was part of the Administration's Section 232 tariffs on autos and auto parts, and in the context of veterinary drugs would maintain U.S. global leadership in innovative drug development.

Thank you for your consideration and for your continued leadership in defending America's economic and food security.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'AS Mathews', with a large circular flourish on the left side.

Alexander S. Mathews  
President & CEO  
Animal Health Institute