

May 6, 2025

Uploaded to: https://www.regulations.gov

Hon. Howard W. Lutnick Secretary of Commerce U.S. Department of Commerce 1401 Constitution Avenue NW Washington, DC 20230

RE: Comments on Section 232 Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (Docket XRIN 0694-XC120)

Dear Secretary Lutnick:

Zoetis respectfully submits these comments to the Department of Commerce ("Commerce") and Bureau of Industry and Security ("BIS") in response to the request for public comments on the national security investigation of imports of Pharmaceuticals and Pharmaceutical Ingredients under Section 232 of the Trade Expansion Act of 1962, as amended ("Section 232").<sup>1</sup>

As the global industry leader, Zoetis is at the forefront of animal health. We know how essential animal health products — including medicines, devices, and diagnostics — are to public health, the food supply, our patients, and people's well-being. Importantly, our products and industry are unique and distinct from human health pharmaceutical manufacturers. As such, they do not raise the same national security concerns that the Trump administration rightly seeks to address. Therefore, we believe these notable distinctions and differences should be taken into consideration when determining tariff policy to ensure that U.S.-based animal health companies are not inadvertently negatively impacted by measures aimed at correcting issues related to the human pharmaceutical industry.

Animal health is a vital part of the U.S. economy, generating \$13.8 billion in direct output, supporting 1.5 million jobs, and delivering a broader economic impact of \$608 billion annually across multiple sectors, including animal production, meat and dairy production, and pet and veterinary services. Of the top 10 global animal health companies, only Zoetis and 4 other companies are based in the U.S.

-

<sup>&</sup>lt;sup>1</sup> Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 Fed. Reg. 15,951 (April 16, 2025) (Docket No.BIS-2025-0022; XRIN 0694–XC120).



We support fair trade policies that enhance American companies' competitiveness, protect American workers and enable continued economic growth, while also maintaining U.S. companies' global competitiveness. This is reflected in our continued investment in our U.S. manufacturing and Research and Development (R&D) sites, and advocacy for a measured and strategic approach to strengthen U.S. manufacturing and innovation. The vast majority of our manufacturing, R&D and Intellectual Property is based in the U.S. In fact, 99% of the products we sell have their Intellectual Property (IP) in the U.S. and over 90% of our R&D is conducted in the U.S.

We have 6,700 U.S.-based colleagues, 6 R&D sites in 6 states, and 9 manufacturing sites in 7 states. Every product in our broad portfolio has an element of discovery and development in the U.S., and while just over 50% of our global revenue is generated in the U.S. market, nearly 60% is manufactured in the U.S. and 75% of what we sell in America we manufacture across sites in California, Georgia, Illinois, Iowa, Michigan, Nebraska, and North Carolina.

Since our Initial Public Offering (IPO) on the New York Stock Exchange in 2013, innovation has driven our revenue growth with an 8% compound annual growth rate, outpacing the animal health industry's 5% growth rate. Our innovation has pioneered entirely new categories in animal health and established new standards of care that address unmet critical medical needs for healthier, longer-lived pets and healthier, more productive livestock.

Zoetis continues to prioritize investment in innovation in the U.S. We have invested over \$5 billion in R&D since 2013 and invested nearly \$1 billion in the past 5 years to strengthen and expand our U.S. manufacturing sites. We expect to invest an additional \$717 million in U.S. manufacturing over the next 3 years. Our new manufacturing site near Atlanta, GA, where we are investing \$556 million and adding hundreds of new jobs, is among several sites included. The Atlanta site is expected to begin operations in 2027.

## A Strong Animal Health Sector is Good Economic Policy

Who pays for our products? Zoetis provides animal health solutions for both livestock and pets, across 8 different species. The animal health industry operates in a differentiated and unique economic environment where our customers cover the full cost of the research, development, regulatory review and manufacturing that goes into these products. The sale of our products is not based on a third-party payment system, but rather a self-pay model in which farmers, ranchers, veterinarians and pet owners purchase our vaccines, medicines and diagnostics. Our pricing is therefore a fraction of human healthcare pricing.

U.S. pet owners require an affordable and reliable supply of products to keep their animals and families healthy. An estimated two-thirds of American households own



pets. Owners rely on products to prevent and treat disease and to protect their pets and families from common pests like fleas and ticks. Animal health solutions enable pet owners to live with pets in their household and enjoy the benefits of their companionship without fearing the transfer of disease or infestations of pests.

**U.S.** ranchers and farmers rely on our products to protect the health and profitability of their livestock. Our biological animal health products such as vaccines protect cattle from 15–20 diseases, which translates into protecting \$50 billion in productivity within the \$150 billion beef and dairy markets. Similarly, vaccines protect pigs from 10 major diseases to help secure over \$10 billion in market value for U.S. pork producers. Finally, broiler chickens receive approximately 5 vaccines, and egg-laying hens receive approximately 6 vaccines to protect against common diseases. The poultry sector is valued at \$67 billion, but without vaccination, production loss could be over 20%.

Preventing animal disease benefits the U.S. general population's health. Animal health products help prevent and control diseases that could otherwise spread through livestock and food products. By keeping animals healthy, farmers reduce the need for emergency treatments and minimize the risk of harmful bacteria entering the food chain while producing a safe and affordable food supply. This leads to safer, higher-quality products reaching our tables in a more efficient, profitable, and cost-effective manner.

# <u>How Sectoral Tariffs on Animal Health Products Could Negatively Impact our Company & Customers</u>

Given Zoetis is a net exporter of products, we are not only vulnerable to the effects of U.S. tariffs, but more acutely impacted by the negative effects of reciprocal tariffs that would hinder our ability to export to international markets.

Sectoral tariffs on pharmaceuticals would significantly impact our Cost of Goods (CoGs) needed to manufacture our medicines. For example, if a 25% sectoral tariff on all pharmaceuticals is imposed, we would experience an increase in the CoGs for finished products which are supplied to self-paying customers.

Moreover, tariffs will increase the spend by farmers, ranchers, veterinarians and pet owners to keep animals safe and healthy. Lower availability or higher cost of products can lead to increased disease, lower production and increased food prices in the U.S. Meanwhile, small U.S. animal veterinarians and pet owners worry that fewer vet visits and increased price sensitivity may shift demand toward lower-cost products, affecting premium and innovative offerings.



# Policies to Incentivize U.S. Domestic Manufacturing

As evidenced by our continued U.S. investment outlined above, Zoetis supports financial incentives to advance the re-shoring and expansion of U.S. manufacturing. Relocating or expanding manufacturing production in the U.S. time-consuming, costly, and complex. Building a new manufacturing facility is costly and can take 5 to 10 years to operationalize. Such incentives would aim to address the high costs associated with building new facilities and transferring operations to existing sites, ensuring robust supply capabilities, and strengthening domestic production. This proposal aligns with the Trump administration's goal of increasing U.S.-based manufacturing and would further reinforce the administration's broader commitment to advancing economic growth and innovation.

We commend President Trump for issuing his May 5, 2025 Executive Order to "Reduce Regulatory Barriers to Domestic Pharmaceutical Manufacturing" and look forward to reviewing the FDA's forthcoming report on existing regulations/guidance and proposed next steps.

#### **Promoting Regulatory Efficiency**

Zoetis has long supported implementing more efficient processes that will expedite the approval and market entry of new, innovative products aimed to address unmet needs in the U.S. Regulatory inefficiencies, however, are a barrier to domestic R&D and manufacturing, and our industry faces unique challenges to bring innovation to market. The approval process for novel products and uses takes significantly longer at the Food & Drug Administration's (FDA) Center for Veterinary Medicine (CVM) than in other major markets around the world. For instance, the FDA generally takes 12-18 months longer than the European Medicines Agency (EMA) to review and approve new animal drug applications. To keep the U.S. competitive, efficient drug application reviews and timely approvals are essential. For businesses, time is a valuable resource and unpredictability is expensive.

In addition, the U.S. Department of Agriculture's (USDA) Center for Veterinary Biologics (CVB) plays a critical role in overseeing the quality, efficacy, and safety of veterinary biologics. Despite its vital function, the CVB faces several regulatory inefficiencies and inconsistencies that hinder its operational excellence. Zoetis has long supported implementing more efficient processes that will expedite the licensure and market entry of new, innovative veterinary biological products, which are foundational to healthy animals and offer an effective way to prevent deadly diseases from harming animals. With over 20% of animal production losses linked to animal disease, biological products protect billions in productivity while costing a fraction of the market value they safeguard.



### **Conclusion**

Zoetis continues to prioritize and advance investment and innovation in the U.S. and stands ready to work with Commerce, the Trump administration and Congress to achieve sustained economic growth and job creation in the U.S.

We strongly believe that the longstanding exemptions from tariffs and/or duties for animal health veterinary products and inputs should remain. Simply put, our products and industry are distinct and unique from the human health pharmaceutical industry and do not raise the same national security concerns that the Trump administration aims to address. Therefore, inadvertently impacting the animal health industry by including essential animal health veterinary products among human pharmaceutical products that may be subject to sectoral tariffs will not address the administration's concerns, but would instead have implications for food security and access to affordable animal protein while imposing a significant financial burden on the U.S. farmers, ranchers, veterinarians and pet owners we serve.

Therefore, should broad sectoral tariffs on pharmaceutical products be imposed, we advocate for the utilization of existing specific Harmonized Tariff System (HTS) codes (8 or 10 digit) to exempt animal health products, including drugs, vaccines and diagnostics, from any potential pharmaceutical tariffs. If helpful, Zoetis can provide a list of animal health or veterinary-specific HTS codes.

Thank you in advance for your consideration and we look forward to working with you.