March 29, 2018

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, D.C. 20510

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Alexander, Ranking Member Murray, Chairman Walden, and Ranking Member Pallone:

The American Veterinary Medical Association (AVMA) and the American Association of Veterinary Medical Colleges (AAVMC) write to you in support the timely reauthorization of the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA). The AVMA is the voice for over 91,000 veterinarians, the vast majority of veterinarians in the United States, who care passionately about protecting animal health, animal welfare and human health. The AAVMC provides leadership for and promotes excellence in academic veterinary medicine to prepare the veterinary workforce with the scientific knowledge and skills required to meet societal needs through the protection of animal health, the relief of animal suffering, the conservation of animal resources, the promotion of public health, and the advancement of medical knowledge.

There simply are not enough FDA approved animal drugs to meet the needs across the variety of species and the number of diseases that veterinarians encounter on a daily basis. Improving the availability of approved animal medicines is an important factor in promoting the health and welfare of the almost 400 million pets that are in over 67% of US households, and the billions of food animals raised in this country. We understand that having both a robust pioneer animal drug industry and a robust generic animal drug industry are important for meeting the needs of veterinary patients. Both ADUFA and AGDUFA have helped to create a predictable environment for animal drug research and development, and we urge both Congress and the FDA to explore additional policies to encourage new product development.

Because of this need, we also support the expansion of the conditional approval provisions of the Minor Use and Minor Species (MUMS) section of the Food, Drug and Cosmetic Act. Expanding these provisions to allow FDA to grant conditional approvals for unmet medical needs in major species will help create incentives for drug development and innovation for the ultimate benefit of veterinary patients. Additionally, veterinarians should be able to utilize these conditionally approved products in the same

manner as other FDA approved drugs. After careful evaluation and determination that there is no appropriate drug approved to treat a given condition or species, the ability to use a conditionally approved drug in the same manner as fully approved drug while following appropriate food animal restrictions would give veterinarians the opportunity to select the most appropriate product with proven safety data for a species or disease for which no better therapy exists.

Veterinarians increasingly treat and manage chronic conditions in pets, such as renal disease, heart disease, and arthritis, as well as providing increasingly sophisticated cancer treatments. These are examples where conditional approvals of animal drugs could help. There are also serious and life threatening unmet medical needs among food animals that would be ideal candidates for conditional approval solutions, including Porcine Epidemic Diarrhea Virus (PEDv) in pigs and Blackhead disease in turkeys and breeding chickens. These are diseases that cause significant mortality where no treatment options currently exist. In minor species such as sheep and goats, veterinarians do not have safety or efficacy data on most of the drugs they must use to treat diseases in these species, as there are very few drugs for MUMS that have gone through a full approval process due to market considerations.

We appreciate your timely consideration of the ADUFA and AGDUFA reauthorizations and ask that you provide a pathway for new and innovative products to help us keep animals healthy by expanding the authority for conditional approval and making needed changes to MUMS provisions to help veterinarians provide their patients with the care they need.

Sincerely,

Janet D. Donlin, DVM, CAE
Chief Executive Officer
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Andrew T. Maccabe, DVM, MPH, JD
Chief Executive Officer
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