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:

On behalf of our collective members who raise, feed, and provide care and other services for the nation’s nearly 10 billion food animals, we are writing in support of timely reauthorization of an enhanced Animal Drug User Fee Act (ADUFA) that includes expansion of authority for conditional approval for the new animal drugs addressing serious and life-threatening unmet medical needs for major uses in major species.

Our members all play important roles in the food value chain that Americans rely upon for safe and nutritious food. Our ability to meet this challenge starts with healthy animals. We rely on access to a variety of animal medicines to protect the health and welfare of animals.

ADUFA has worked well to provide stability and predictability in the U.S. Food and Drug Administration’s Center for Veterinary Medicine’s (FDA CVM) process for the review of new animal medicines and we support its reauthorization. This year’s ADUFA reauthorization consideration provides Congress the opportunity to spur innovation in animal health, similar to the improvements provided in the 21st Century Cures Act for human health sector, through the expansion of conditional approvals for major uses in major species.

There are many serious and life-threatening unmet medical needs among food animals that would be ideal candidates for conditional approval solutions. Porcine Epidemic Diarrhea Virus (PEDv) in pigs, and Blackhead disease in turkeys and breeding chickens, are diseases that cause significant mortality where no fully approved treatment or prevention options currently exist. Johne’s disease in cattle, sheep and goats is a progressive, intestinal disease where clinical signs may not be evident for months or years, making it difficult to design controlled trial studies for a new drug evaluation.
The health and well-being of the animals we care for is paramount for a safe and nutritious food supply for American families. We rely on the availability of affordable medicines to address the various diseases and conditions to which our animals are susceptible. We appreciate your timely consideration of the ADUFA reauthorization 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 for major uses in major species.

Sincerely,

American Association of Avian Pathologists
American Association of Bovine Practitioners
American Association of Mycobacterial Diseases
American Dairy Goat Association
American Dairy Science Association
American Feed Industry Association
American Goat Federation
American Sheep Industry Association
FASS
Mycobacterial Diseases of Animals – Multi-state Initiative
National Association of Federal Veterinarians
National Association of State Departments of Agriculture
National Aquaculture Association
National Cattlemen’s Beef Association
National Dairy Herd Information Association
National Grain and Feed Association
National Milk Producers Federation
National Pork Producers Council
National Turkey Federation
North American Meat Institute
United Egg Producers
U.S. Dairy Forage Research Center Stakeholder Committee
U.S. Poultry and Egg Association