ADUFA V: Closing the Gap Between Capacity and Performances

ANIMAL HEALTH INSTITUTE

Introduction

The animal health industry and the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) will begin negotiations in the Fall of 2021 on the fifth authorization of the Animal Drug User Fee Act (ADUFA), which must be reauthorized by Congress by September 30, 2023. While ADUFA has successfully built robust capacity at CVM over its nearly 20-year history, innovation has declined, and the U.S. has become less competitive. Industry and FDA must now find ways to employ this capacity to stimulate and keep pace with innovation and ensure veterinarians, pet owners and livestock producers have timely access to a growing number of new therapies to keep animals healthy and productive.

The Opportunity

Innovative animal drugs products are needed to address many serious animal diseases, including epilepsy, asthma, arthritis, cardiac disease, tick borne illnesses like Lyme Disease, feline infectious anemia, Johne's disease in cattle, sheep, and goats, and blackhead disease in turkeys. There are only 1600 animal drug products approved by FDA to treat diseases and conditions in several animal species, as compared to 20,000 prescription drug products for people.[1] Reforms at CVM are needed to incentivize innovation to address unmet medical needs in veterinary medicine.

The changing climate will require greater and faster innovation to meet the needs of animals and help protect people from zoonotic diseases. Current scientific forecasts predict disease carrying vectors (like flies, fleas, and ticks) will affect wider geographic areas meaning more animals will potentially be exposed to new infectious diseases and existing infectious diseases will affect more animals.

Currently many diseases can only be prevented, controlled, and treated by using medically important antibiotics. There is a need to find new ways to take care of animal patients to decrease the amount of antibiotic use in veterinary medicine. As industry seeks to develop alternatives to medically important antibiotics, regulators need to adapt processes to new and emerging categories of products.

Close the Gap

Over the 18-year existence of ADUFA, a gap has developed between the fees paid to CVM and performance:

- From the 2004 baseline, fees paid to CVM by industry have increased nearly 600 percent while the overall workload has decreased by 12.5 percent over the same period.
- Over the past decade, ADUFA full time equivalents (FTE's) at CVM have increased 30 percent while the workload metrics for the program have decreased 25 percent.
- The level of submission reviews has remained relatively consistent in the past 10 years, despite the increase in fees and FTEs.

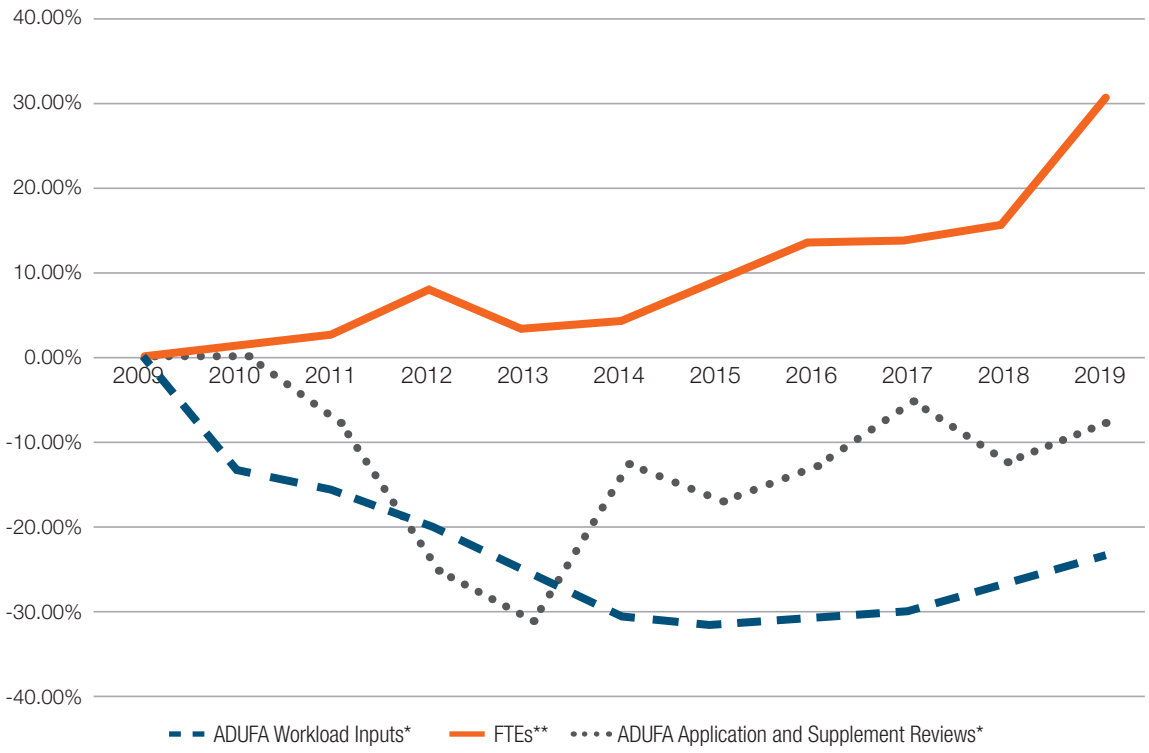
This gap between capacity and performance has reduced US competitiveness. Since 2004, 39 veterinary drugs have been approved for the same indication by FDA/CVM and the EMA. Sixty-six percent of those received EMA approval prior to FDA approval and the average time difference for these was 27 months. That gap has widened to 32 months in the past 5 years.

The gap between escalating fees and performance has stifled innovation. Most animal health products have annual sales of $1 million or less. Increasing fees and time to approval means it is not economically feasible to invest resources in pursuit of potential therapies that could meet animal health needs.

ADUFA V should optimize the capacity and capabilities of the CVM staff and ensure that performance is aligned with the resources provided by the program. FDA and industry should prioritize workload requirements and allocate resources to effectively meet the goals of timely review and approval of new products and new indications for existing products.

[1] FDA at a Glance. Available at https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance

FTEs v Workload v Submission Reviews



* FDA. Annual Fee Setting for ADUFA (https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa)
** FDA. ADUFA Financial Reports (https://www.fda.gov/about-fda/user-fee-financial-reports/adufa-financial-reports)
*** FDA. ADUFA Performance Reports (https://www.fda.gov/about-fda/user-fee-performance-reports/adufa-performance-reports)

Realize the Vision of the ADUFA

Timely approval of safe and effective new animal drugs is critical to animal health and industry and FDA should work to ensure efficiencies and enhancements that will improve the public health ecosystem. Congress established the vision for ADUFA when the program was first authorized in 2003:

> *"The fees authorized by this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions…"*

The animal health industry is eager to work with FDA and Congress to ensure this goal is fully realized. ADUFA V should incentivize innovation to ensure that additional lifesaving and life-enhancing therapies are made available to veterinarians, food producers and animal owners.

ABOUT AHI

The Animal Health Institute (AHI) represents the companies that develop and produce animal medicines. Our industry is a global leader whose products improve the health of nearly 10 billion companion and food-producing animals in the U.S., which results in significant economic and social benefits for Americans.

For more information on innovation in animal health, see: https://ahi.org/animal-health-innovation/

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