# Animal Drug User Fee Act (ADUFA) Reauthorization

ANIMAL HEALTH INSTITUTE

The Animal Drug User Fee Act supplements appropriations for the review of new animal drugs with user fees paid by industry in exchange for the Food and Drug Administration meeting agreed-upon performance goals.

## Animal Drug User Fee Act

ADUFA amends the Federal Food, Drug and Cosmetic Act and authorizes the FDA to collect fees from animal health companies to enable the Center to meet performance standards. ADUFA's current five-year authorization is set to expire on September 30, 2023.

## Program Structure

ADUFA was established by Congress in 2003 and is reauthorized every five years. These resources support the FDA's responsibilities to ensure that new animal drug products are safe and effective for animals, as well as ensuring the safety of food from treated animals. ADUFA should also provide the opportunity for incentivizing innovation to improve public health outcomes and address unmet animal health needs.

Fees paid by industry are divided into four types:

- Sponsor fees: fees paid by all sponsors, or companies, that manufacture animal drugs approved by FDA
- Application fees: paid upon submission of a new animal drug application
- Product Fees: fees paid by sponsors on approved products
- Establishment fees: fees based on the number of establishments owned by a sponsor

## ADUFA Reauthorization Process

Every five years, industry and CVM negotiate an agreement on the fee level and adjustments to performance goals for the next five-year period. This process begins with the Agency holding an initial public input meeting with a 30-day comment period. Then the Agency and industry develop draft recommendations through a procedure which includes negotiations meetings with industry, publication of minutes, period meetings with stakeholders, industry clearance, Agency clearance, HHS clearance and OMB clearance. Once initial clearance is completed, there is a public review for Congress and a second public meeting for stakeholders with a 30-day comment period. Once this process is complete, the new agreement is submitted to Congress for action to reauthorize the program.

An efficient and timely review process is essential to the approval of safe and effective new animal drugs critical to animal and public health. Through the reauthorization process, industry works with the agency to explore new, creative and bold ideas for improvement to ensure additional lifesaving and innovative therapies are made available to veterinarians, food producers and animal owners.

**For more information, contact:**
Ginny Siller: gsiller@ahi.org or 202-637-2440