ADUFA V Summary

ANIMAL HEALTH INSTITUTE

The Food and Drug Administration (FDA) and the Animal Health Institute (AHI) have reached a new Animal Drug User Fee Agreement which must be ratified by Congress by September 20, 2023 when the current ADUFA IV expires: The agreement is designed to close the gap between capacity and performance by controlling cost increases while putting in place new mechanisms to measure and improve performance.

Funding

The ADUFA V base funding is $33.5 million per year with one-time funding from carryover to cover cost for the third-party assessment (up to $3M) and IT enhancements (up to $1M). Base funding rates will be adjusted for inflation in years 2-5 and may be increased by the workload adjuster in years 3-5 if the criteria are met.

About 32% percent of the Center for Veterinary Medicine's new animal drug review budget will be user-fee funded.

Program Enhancements

The agreement contains enhancements and improvements to increase productivity, promote consistency and create accountability to bring safe and effective products to the market.

- Annual Educational Conferences for Industry
- Early feedback for virtual presubmission conferences
- Updating internal policies and procedures for industry-Agency meetings prior to designing and beginning studies (H submissions)
- Implementation of a process for clarifying required raw data and commitment to maintain evaluation of the process
- Ongoing commitment to collaborate with industry to improve manufacturing of animal drugs
- Issue Guidance on Parallel submission of phased data submission for CMC (manufacturing)
- Commitment to work toward improvements in residue method trials, revision of ADAA combination language and exploration of new programs such as clock stops.
- Explore ways to improve feedback on sponsor's development plans

New metrics

The agreement includes new metrics to be immediately implemented in addition to commitments to investigate the process for additional metrics. Metrics for immediate implementation include:

- Submission outcomes to be displayed by technical section along with average review hours.
- Number of H Submissions by division
- Number of certain filed/submitted sentinel submissions by review division
- Use of information from Good Manufacturing Practice (GMP) in Mutual Recognition Agreements (MRAs) in regulatory decisions

Commitments to explore include:

- Metrics on time in the agency and time in industry
- Development of a report on how many cycles it takes to achieve a favorable outcome for each key section.

Financial Sustainability

Sustainability of the program is a key priority. The agreement incorporates additional areas for evaluation of the program, creation of mechanisms for regular performance reporting and better alignment of fees with the workload.

- Third Party Assessment
- Annually publish a 5-Year Financial Plan
- Set a carryover cap (16 weeks) and minimum (12 weeks) and simplify carryover provisions by:
  - Eliminating shortfall provision
  - Eliminating current final year 12-week adjustment provision
  - Eliminating provisions to offset workload adjuster or shortfall by excess collections.
- Modernize workload Adjuster by:
  - Moving to a 5-year rolling base
  - Workload Adjuster invoked only if greater than 3% twice within 5 years

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