Ingredient Review and Approval Process

IFEEDER®

Institute for Feed Education & Research

About

The American Feed Industry Association is working to modernize and improve the animal food ingredient review and approval process at the Food and Drug Administration's Center for Veterinary Medicine (CVM). For years, companies struggled to move ingredients through the review process and into the marketplace – a struggle that has placed the U.S. feed industry at a competitive disadvantage globally. This long overdue update to the process would remove this disadvantage and barrier to developing innovative solutions to improve animal nutrition and production and reduce the industry's environmental footprint. The Institute for Feed Education and Research commissioned a study to better understand the economic impact the industry is facing from the lengthy and cumbersome federal regulatory approval process.

Results

In 2016, the IFEEDER hired Informa Economics to conduct an independent, in-depth review of how the FDA's lack of a cohesive, functioning process for approving new technologies is affecting the feed industry. The results were staggering. On average, the firm found that it takes three-to-five years for a new feed ingredient to move through the FDA's review and approval process, causing companies to lose $1.75 million annually.

This data is assisting the AFIA as it works with Congress and the administration to address many of the barriers and resource issues impacting new product review timelines. This data has been instrumental in detailing the impact and getting attention to find solutions.

Impact

Using this data, the AFIA developed a two-pronged approach to address the logjam of approvals and improve the overall regulatory approval process by 1) seeking provisions in key legislation and 2) providing recommendations to the FDA. In 2018, the AFIA applauded Congress for its leadership in passing bipartisan legislation – the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (H.R. 5554), which provided changes regarding the use of foreign data in ingredient submissions and removed legislative language creating a barrier for recognition of ingredients defined by the Association of American Feed Control Officials. Additional resources were also sought for the FDA's CVM approval office and was received as part of the fiscal year 2020 congressional appropriations process. These dedicated funds allowed the CVM to hire 14 new ingredient review staff to speed up its review process. These incremental changes will improve the time companies must wait for their ingredient reviews to be completed and products to ultimately reach the marketplace.