



HPTA Update: FDA Withdraws Policy on Ingredients with Drug Claims

Dear HPTA Members,

We are excited to share a pivotal development in the regulation of animal food ingredients that promises opportunities for our industry. The FDA's Center for Veterinary Medicine (CVM) recently announced its intent to withdraw its longstanding Program Policy and Procedures Manual Guide 1240.3605, a move poised to modernize the regulatory landscape for animal food ingredients. The announcement can be found [here](#).

This strategic withdrawal marks the end of the old regulatory framework that restricted many product claims as drug claims, such as production-related animal weight gain. Manufacturers will have a more straightforward pathway to market animal food substances with proven benefits in animal production, well-being, food safety, and environmental impact. This policy change will present opportunities for HPTA members to leverage their expertise in humic products, known for their beneficial effects on animal health.

The CVM encourages manufacturers to engage with the agency early in the development process to ensure products meet the necessary review standards, a step crucial for bringing novel products to market. The CVM's efforts are complemented by the proposed Innovative Feed Enhancement and Economic Development (Innovative FEED) Act, which aims to codify the regulatory pathway for ingredients that impact the animal microbiome, food safety, or digestive byproducts.

What This Means for HPTA Members:

Change is coming! This regulatory shift offers a fertile ground for innovation, especially for our members who are at the forefront of developing humic and fulvic acid-based products

for animal nutrition. It's a favorable time to explore new formulations and claims that can meet the unmet needs of the animal food industry, reinforcing the value of humic products in enhancing animal health, production efficiency, and environmental sustainability.

We encourage all members to consider how their products can contribute to this evolving regulatory and market landscape. The HPTA is committed to supporting our members through this transition, including facilitating discussions with regulatory bodies and providing guidance on navigating the new requirements.

Stay tuned for further updates and resources on this topic. Together, let's seize this opportunity to advance the role of humic products in animal nutrition and beyond.

Best regards,

HPTA Board

The ***Humic Products Trade Association*** (HPTA) is a not-for-profit membership organization that was founded in 2010 with the purpose of advancing the commercial uses of humic products through scientific and regulatory cooperation. Information regarding the ***Humic Products Trade Association***, including Membership can be found at [HumicTrade.org](http://www.HumicTrade.org). Join us and help shape an industry.

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