CALIFORNIA DEPARTMENT OF
FOOD & AGRICULTURE
Karen Ross, Secretary

July 30, 2024

NOTICE TO COMMERCIAL FEED AND LIVESTOCK DRUG INDUSTRIES
Commercial Feed Additives with Drug Claims

The California Department of Food and Agriculture (CDFA) Commercial Feed Regulatory Program (CFRP) is aligned with the United States Food and Drug Administration (US FDA) position regarding the pathways to market access for animal food substances with drug claims. The December 20, 2023 Notice to Industry clearly stated CFRP and CDFA's Livestock Drug Program's (LDP) position regarding products with methane reduction claims. This notice is intended to educate industry, researchers, and stakeholders and further clarify the currently available pathways for market access.

The CFRP and LDP do not determine Generally Recognized as Safe (GRAS) or accept self-determination of GRAS for feed additives with claims intended to affect the structure or function of the body of any livestock producing products for human consumption. Any commercial feed additives or livestock drugs that have methane reduction claims cannot be recognized as GRAS or acknowledge self-determination of GRAS, because these types of products must undergo safety and efficacy review and receive technical assistance from US FDA. In addition, a product which is currently approved or considered GRAS for other purposes cannot be considered GRAS with a new intended use or with a claim intended to affect the structure or function of the body of any livestock producing products for human consumption, including methane reduction claims. To learn more about GRAS and other pathways to approval, please view the Safe Animal Feed Education (SAFE) Program's Feed and Feed Ingredients Webpage.

Our US FDA partners are working diligently to modernize their approach to animal food additive regulation, as outlined in their recent letter to industry. Additionally, FDA is awaiting new legislative authority from Congress for a clear pathway for substances added to animal food or drinking water that function in the gut of an animal in one of three ways. These substances may affect the microbiome of the animal, affect the byproducts of the digestive process (such as methane reduction), or reduce pathogens in food products made from the animal.

Currently, the only pathway for market access for any feed or drug with methane reduction claims is through US FDA. The CFRP, LDP and US FDA encourage firms to contact the US FDA Center for Veterinary Medicine (CVM) **early** in the product development process. To contact FDA-CVM about an animal food substance intended to have the effects described above, please email animalfood-premarket@fda.hhs.gov. If a demonstration feeding trial using a novel or not currently approved product intends to have egg, milk, or meat products enter the human food chain, a US FDA Food Use Authorization is needed. FDA Guidance for Industry # 262 is intended to help you submit information for effective and efficient pre-submission consultations and preparation of a Food Use Authorization (FUA) request.

Sincerely,

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Environmental Program Manager I