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COMMERCIAL FEED REGULATORY PROGRAM

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SAFE

SAFE ANIMAL FEED EDUCATION

Livestock Drug Program

STATE OF THE SCIENCE SUMMIT

Regulatory Approval Process

OUTLINE

Product Approval

- Regulatory authority
- Pre-market pathways
- Common misconceptions

Investigational Use

- Study design
- Investigational food use authorizations

CDFA Program Regulatory Authority

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Commercial Feed

Food And Agricultural Code Division 7, Chapter 6.

California Code Of Regulations Title 3, Division 4, Chapter 2, Subchapter 2.

https://www.cdfa.ca.gov/is/docs/FeedLaw_Regs.pdf

Livestock Drug

Food And Agricultural Code Division 7, Chapter 4. Livestock Drugs
And Division 7, Chapter 4.5. Livestock: Use Of Antimicrobial Drugs

California Code Of Regulations Title 3, Division 5, Chapter 1. Livestock Drugs
And Title 3, Division 5, Chapter 2. Sales Of California Prescription Drugs

https://www.cdfa.ca.gov/is/docs/LivestockDrugLaws_andRegs.pdf

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COMMERCIAL FEED REGULATORY PROGRAM

Mission Statement

Food and Agricultural Code Section 14901

(a) Enable the feed and feeding industry, with the aid of the state, to ensure in every way possible a clean and wholesome supply of meat, milk, and eggs for the benefit of the consumer.

(b) Provide assurance to the consumer-buyer of commercial feed that the product he or she purchases is properly identified and of the quality and quantity represented by the manufacturer of the commercial feed.

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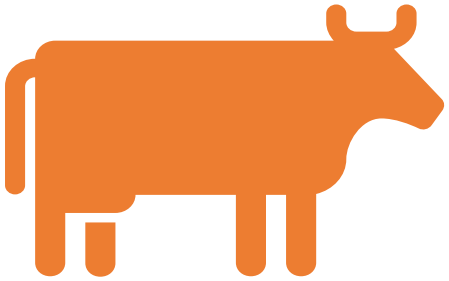
Center for Veterinary Medicine

Federal Food, Drug and Cosmetic Act (FD&C)

- States must adhere to federal laws and regulations for interstate commerce.
- Under the FD&C Act to be legally marketed and used, a substance must be approved.
- Otherwise, it is considered unsafe and any product that bears or contains it is adulterated.

Center for Veterinary Medicine

Federal Food, Drug and Cosmetic Act



“Animal Food” is any article that is intended to be used as an animal food ingredient, to become part of an ingredient or food, or added to an animal's drinking water.

Dietary Supplement and Health Education Act DOES NOT APPLY TO FOOD FOR ANIMALS.

Everything administered to an animal is considered either "foods" or "new animal drugs" depending on the intended use.

Center for
Veterinary Medicine

Federal Food, Drug and Cosmetic Act

- The term “drug” means articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

Center for
Veterinary Medicine

Federal Pathways for Market Access

FOOD

- Food Additive Petition (FAP)
- Generally Recognized as Safe (GRAS) Notification Program

DRUG

- New Animal Drug Application Process

Intended affect on the structure or any function of the body

Innovative Feed Enhancement and Economic Development Act of 2025

A **Zootechnical Animal Food Substance** is added to food or drinking water of animals; is intended to:

- affect the byproducts of the digestive process of an animal;
- reduce the presence of foodborne pathogens of human health significance in an animal intended to be used for food; or
- affect the structure or function of the body of the animal, other than by providing nutritive value, by altering the animal's gastrointestinal microbiome; and
- achieves its intended effect by acting solely within the gastrointestinal tract of the animal

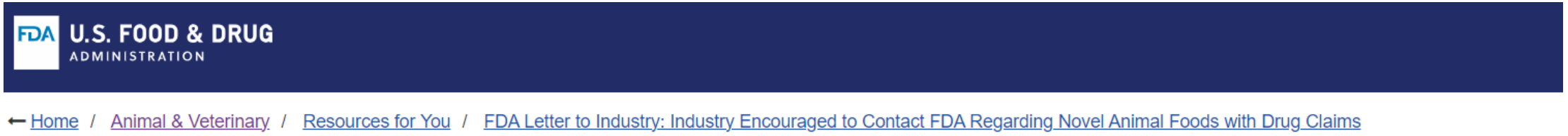
A zootechnical animal food substance shall be deemed to be a food additive

Center for Veterinary Medicine

Animal Food Ingredient Consultation (AFIC)

- Announced on August 8, 2024, the FDA is evaluating its FAP and GRAS programs to determine if changes are needed to better serve public health and improve the path to market for new animal food ingredients.
- During this evaluation period, the FDA intends to conduct voluntary consultations with firms developing animal food ingredients through AFIC.
- Guidance for Industry #294 Animal Food Ingredient Consultation

What is the Pathway Today?



Contact: animalfood-premarket@fda.hhs.gov

Common Misconceptions

TRUE or FALSE?

A substance that is generally recognized as safe for human food is automatically generally recognized as safe for animal food.

FALSE: There is a separate GRAS notification listing for animal food and for human food.

Additionally, GRAS is only applicable to the intended use stated in the GRAS notice including certain species of animals. For example, a substance that is GRAS as a flavor for use in poultry feed would not automatically be considered GRAS as an enteric methane reducing feed additive for cattle.

TRUE OR FALSE?

GRAS is much faster than other pathways, and easier to obtain.

FALSE: The average GRAS review time is still 180 days. It requires the same quality and quantity of scientific data as a food additive petition; however, <u>all the data must be publicly available.</u>

We hear…

“The federal review process takes too long; therefore, we want a California-only approval”.

The truth…

- **Many packets are submitted to FDA with insufficient data to support required safety and efficacy evaluation.**

- **The average FDA review process is 180 days. Each time a packet must be re-submitted due to insufficient data, that time period starts over.**

We hear…

“I can self-attest my product as GRAS and begin selling it.”

“I have data to prove the product is safe; therefore, it should be accepted and allowed by CDFA”.

The truth…

Some states may accept self-determination of GRAS; however, many do not, including California.

CDFA does not have the resources to evaluate safety and efficacy data to the extent required to evaluate a GRAS determination.

TRUE OR FALSE?

GRAS is an appropriate pathway for substances which reduce enteric methane.

FALSE: Substances which have an intended effect on the structure or function of the body cannot be considered GRAS.

March 2025: Secretary Kennedy Announced directing the acting FDA commissioner to take steps to explore potential rulemaking to revise its GRAS Final Rule and related guidance to eliminate the self-affirmed GRAS pathway.

"For far too long, ingredient manufacturers and sponsors have exploited a loophole that has allowed new ingredients and chemicals, often with unknown safety data, to be introduced into the U.S. food supply without notification to the FDA or the public."

- Secretary Robert F. Kennedy, Jr.,
U.S. Department of Health and Human Services

Example: Elanco Inc. Bovaer®10

May 24, 2024

CVM File: G-150438

Elanco US, Inc.
PO Box 708, 2500 Innovation Way
Greenfield, IN, 46140
FEI: 3012761605

- Navigated FDA's current pathway

CVM reviewed the information you submitted on June 8, 2023, and subsequent correspondence on January 31, 2024, that addressed the safety, intended effect and the quantity of the article required to produce the intended effect, manufacturing, labeling for the article, and other relevant information. Based on a review of your data and the characteristics of your product, FDA has no questions at this time regarding whether Bovaer® 10 will achieve its intended effect and is expected to pose low risk to humans

- Then sought registration/market access within each state

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Expectations and Process for Market Access

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Karen Ross, Secretary

December 20, 2023

NOTICE TO COMMERCIAL FEED AND LIVESTOCK DRUG INDUSTRIES

Administration (U.S. FDA) authority. **Products with methane reduction claims to be offered for sale within or into California and used in commercial feed or livestock drugs must first be approved by U.S. FDA. As of December 20, 2023, there is no state or federal approval for a methane reduction claim for any livestock feed or drug products, and there is no California established process for verifying efficacy and approving methane reduction**

https://www.cdfa.ca.gov/is/ffldrs/pdfs/nti_novel_products.pdf

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 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.

https://www.cdfa.ca.gov/is/ffldrs/pdfs/20240730_NTI_Commercial_Feed_Additives_with_Claims.pdf

CDFA Process to Evaluate Products Under FDA Enforcement Discretion

- **Step 1: FDA Evaluation**
  - Safety and efficacy review and issue of public letter/notice
- **Step 2: CDFA Evaluation**
  - Labeling and use in California- NO technical safety review
- **Step 3: FIAB Technical Advisory Subcommittee (TASC)**
  - Evaluate and advise FIAB regarding labeling and use
- **Step 4: FIAB**
  - Evaluate TASC recommendations and make recommendations to Secretary
- **Step 5: CDFA issues a letter with California requirements**

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916-900-5022 • feed_lvstk@cdfa.ca.gov • https://www.cdfa.ca.gov/is/ffldrs/CommercialFeedReg.html

CDFA's Process w/ Bovaer®10

- Reviewed summary of feed and food safety data provided and the letter issued by FDA CVM
- CDFA Milk and Dairy Food Safety Program requested notification from FDA Center for Food Safety and Applied Nutrition (CFSAN) regarding the use of Bovaer®10 and the Pasteurized Milk Ordinance
- August 15, 2024 - FDA CFSAN issues a letter citing enforcement discretion for Bovaer® 10 under the PMO
- October 3, 2024 – Evaluated by TASC and FIAB for labeling and use in California
  - Q/A regarding applicability and use on-farm included:
    - Stability
    - Diet
    - PPE
    - Mixability
    - Pelleting
  - Discussed standards for labeling feeds containing Bovaer®10

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CDFA Process Outcomes

- Feed Inspection Advisory Board (FIAB) recommended to the Secretary that Bovaer®10 falls under Feed Program authority as prescribed in Food and Agricultural Code Sections 14902.1 and 15011.

- FIAB recommended to the Secretary requirements for labeling of commercial feeds containing Bovaer®10.

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Labeling Commercial Feeds Containing Bovaer®10

- Adequate directions for use (Food and Agricultural Code Section 14992(f))
- Capable of being followed and likely to be followed in usual feeding practices (California Code of Regulations, Title 3, Section 2690)
- Statement of the concentration in milligrams per pound (mg/lb) of 3-nitrooxypropanol (3-NOP) in the commercial feed
- Directions to further manufacture the feed to achieve a rate of 27.2-36.3 mg 3-NOP per pound of dry matter in the total mixed ration (TMR)
- All guarantees, limitations, warnings, and caution statements which appear on the Bovaer®10 label

CALIFORNIA DEPARTMENT OF FOOD & AGRICULTURE

Karen Ross, Secretary

November 4, 2024

NOTICE TO COMMERCIAL FEED INDUSTRY

Labeling and Use of Elanco's Bovaer®10

CDFA has released a letter to Elanco Inc. regarding the labeling and use of Bovaer® 10 in commercial feed in California.

Research & Investigational Use

Safety and Efficacy of New/Novel Feed Additives

CDFA defers to federal evaluation by the experts with U.S FDA.

- Human Food Safety
  - Meat, milk and eggs
- Feed Safety
  - Animal health
  - Target species and non-target species
- Efficacy
  - Truth in labeling
  - Consumer protection

Designing Studies to Support a Regulatory Decision

- Highly recommend FDA pre-submission consultation meetings
- GFI # 262: Pre-submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe Notices
- GFI #221 Recommendations for Preparation and Submission of Animal Food Additive Petitions

FDA Guidance for Research

- GFI #56: Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials
- GFI #3 General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food
- GFI #149 Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food.

Human Food Safety – Carcinogenicity

- Delaney clause - FDA cannot approve an article identified as a probable or known carcinogen to humans or animals, unless when given to animals, it does not result in residues in the human food.

- Must use a validated method that can reliably measure and confirm the presence of any residue of carcinogenic concern.

- Residue detection should be equal to or below the "no residue" level for the compound.

FDA Investigational Food Use Authorizations (FUA)

- Permits entry of edible products (e.g., meat, milk, eggs) from a specified number of animals to enter human food, and/or rendered material into animal food, during the investigational phase (prior to approval)

- FUAs are intended for research that will support a future regulatory submission

When is a FUA not required?

- Investigational studies may be performed without a FUA if the animals or animal products are not going to enter the food supply
  - Destruction of animals

How to request a FUA

- If not previously established, submit request to establish an investigational food additive (IFA) file to:

  animalfood-premarket@fda.hhs.gov

- Provide information to support FUA request

Informational Webinar on FDA Pathways to Market Use of New Animal Feed Ingredients- Sept 2024

Summary

- CDFA requires FDA evaluation of new/novel feed additives prior to market access

- Consultation with FDA's AFIC Program early in the research/product development phase will expedite the regulatory review process:

  animalfood-premarket@fda.hhs.gov

- Investigational Food Use Authorizations from FDA are required if products from the experiment animals using an unapproved feed ingredient will enter the human food or animal food chain

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Questions?

CALIFORNIA DEPARTMENT OF FOOD & AGRICULTURE
Karen Ross, Secretary

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https://www.cdfa.ca.gov/is/ffldrs/CommercialFeedReg.html

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feed_lvstk@cdfa.ca.gov

SAFE ANIMAL FEED EDUCATION

https://www.cdfa.ca.gov/is/ffldrs/safe.html

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