Regulatory Pathways for US Product Use

*Veterinary extra-label drug use (ELDU) is a legally permitted practice where veterinarians use FDA-approved drugs in ways not listed on the label (different species, dose, indication, etc.) under strict conditions set by the Animal Medicinal Drug Use Clarification Act (AMDUCA).

FDA Regulated

NADA

- This is the standard pathway for drug products in the US.
- It can take decades to develop the data and move through review depending on the drug's properties and proposed use.
- ELDU applies.*

Conditional Approval – FDA

- This pathway allows "conditional" approval of a product while efficacy data are still being generated, allowing earlier entry of the product into the market.
- ELDU is not permitted.*

Emergency Use Authorization (EUA)

- EUAs are used in cases of emergency and are similar to Section 18 registrations.
- Supportive data are required for efficacy, safety, and withhold requirements.
- ELDU is not permitted.*

EPA Regulated

Section 3 registration

- This is the standard pathway for pesticide products in the US.
- It can take decades to develop the data and move through review depending on the pesticide's properties and proposed use.

Section 18 registration

- This type of registration is used for emergency purposes such as entry of a new pest into the US creating a significant threat to agricultural crops or, animals where appropriate management products have not been established (such as NWS).
- Supportive data are required for efficacy, safety, and withholding requirements.

Section 2(ee)

- This is an option available to the states which allows addition of only a new pest vs. use, site, application, dose, etc. States work directly with product registrants to request desired bulletins.
- Evidence of efficacy is required on the part of the manufacturer.

> EPA products must only be used according to label.

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