

FDA CONDITIONAL APPROVAL:

What Does It Mean & What Should Veterinarians Know?



Certain veterinary drugs have the abbreviation CA after their name; it stands for “conditional approval.” Here’s what veterinarians should know about it.

What Is Conditional Approval?

Conditional FDA approval helps niche animal populations—either minor species (eg, reptiles, ferrets) or those with uncommon disease indications in major species (eg, dogs, cats)—access much-needed drugs while those drugs are still being evaluated for full FDA approval. Like fully approved drugs, conditionally approved drugs have been proven safe when used according to the label and carry explicit FDA confidence regarding safety; however, unlike fully approved drugs, which must show “substantial evidence” of effectiveness, conditionally approved drugs must show a “reasonable expectation of effectiveness” (**Table 1**).¹ Conditionally approved drugs are given ≤5 years to provide this substantial evidence of effectiveness; during this time, they are required to submit annual renewal requests to maintain conditional approval while demonstrating progress toward meeting full efficacy requirements.¹ In line with responsible pharmacovigilance practices, the FDA conducts routine postmarketing surveillance for adverse events both during the conditional approval period and after full approval.^{1,2}

TABLE 1: Full Versus Conditional Approval

	Full Approval	Conditional Approval
Safety	Proven safe	Proven safe
Evidence of effectiveness	Substantial evidence	Reasonable expectation
Off-label use	Legal under certain conditions	Illegal
Postmarketing monitoring	Conducted by the FDA	Conducted by the FDA

Conditional Approval = Critical Access

Conditional approval allows critical drugs to be available sooner when an animal population is facing a serious, life-threatening condition or for an unmet need that requires complex studies to demonstrate drug effectiveness.¹ It provides much-needed options without compromising safety in these complicated, high-risk scenarios, helping to avoid delays in care while additional efficacy data are gathered.¹

What This Means in Practice

- Conditionally approved drugs are not experimental drugs. They carry explicit FDA confidence regarding safety and can be prescribed similarly to fully approved drugs.¹
- Drugs with conditional approval must be used according to the label. It is illegal to use them in an off-label fashion.¹
- Adverse events from conditionally approved drugs should be reported in a manner similar to those that are fully approved to support responsible pharmacovigilance efforts.¹
- Once a drug is fully approved, the CA abbreviation will no longer be included as part of the drug name; however, the drug formulation will remain the same.¹
- Full approval should not hinder access to critical care. Conditional approval provides early, safe access to care for animals with serious, life-threatening or uncommon conditions when waiting for full FDA approval would delay critical treatment.

Why Critical Access Matters

Having access to conditionally approved drugs can be an asset to the veterinary team, allowing them to treat patients with conditions that would otherwise have limited treatment options. Conditional approval was designed as a safe, accelerated pathway to bring critical therapies to the animals that need them most while additional research continues to support full approval. Increasing veterinary team awareness and familiarity with these drugs is key to ensuring they are used safely and appropriately, keeping veterinarians legally protected while offering hope to patients that would otherwise face delayed treatment options.

References

1. US Food & Drug Administration. Conditional approval explained: a resource for veterinarians. FDA website. <https://www.fda.gov/animal-veterinary/resources-you/conditional-approval-explained-resource-veterinarians>. Accessed March 5, 2026.
2. US Food & Drug Administration. Postmarketing surveillance programs. FDA website. <https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs>. Accessed March 5, 2026.

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