

## FDA Conditional Approval: What Does It Mean & What Should Veterinarians Know?

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

### What Is Conditional Approval?



Conditional FDA approval helps niche animal populations access much-needed drugs while those drugs are still being evaluated for full FDA approval. Similarly to drugs fully approved by the FDA, conditionally approved drugs must be proven safe when used according to the label; however, unlike fully approved drugs, they must show “reasonable expectation of effectiveness” rather than “substantial evidence” of effectiveness (**Table 1**).<sup>1</sup> Drug companies are given up to 5 years to provide this substantial evidence of effectiveness; during this time, they are required to submit annual requests for renewal to indicate progress toward efficacy but can sell the drug under conditional approval while gathering the necessary data.<sup>1</sup> Before—as well as after—full approval, the FDA performs active postmarketing surveillance of all adverse effects.<sup>1,2</sup>

**TABLE 1**

Full vs Conditional Approval

	Full Approval	Conditional Approval
<b>Safety</b>	Proven safe	Proven safe
<b>Evidence of effectiveness</b>	Substantial evidence	Reasonable expectation
<b>Extra-label use</b>	Legal, under certain conditions	Illegal
<b>Postmarketing monitoring</b>	Conducted by FDA	Conducted by FDA

This process allows critical drugs to be available sooner to difficult-to-study animal populations, limited to<sup>1</sup>:

- ▶ Major species with serious, life-threatening conditions or an unmet need that requires complex or difficult studies to demonstrate drug effectiveness

### What This Means in Practice

- ▶ Conditionally approved drugs carry a measure of FDA confidence and should be prescribed similarly to fully approved drugs.
- ▶ Drugs with conditional approval must be used according to the label. It is illegal to use them in an extra-label fashion.<sup>1</sup>
- ▶ Adverse events from conditionally approved drugs should be reported in a similar manner as those that are fully approved.<sup>1</sup>
- ▶ 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.<sup>1</sup>
- ▶ Drugs with conditional approval may be necessary when treating serious, life-threatening or uncommon conditions of dogs and cats.

### Conclusion

Having access to conditionally approved drugs can be an asset to the veterinary team, allowing them to treat patients and conditions that would otherwise have limited treatment options. Increasing veterinary team awareness of these drugs and feeling comfortable utilizing them is key to ensuring these drugs are used safely and appropriately and for veterinarians to help keep themselves legally protected.

### 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 January 20, 2022.
2. US Food & Drug Administration. Postmarketing surveillance programs. FDA website. <https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs>. Accessed February 3, 2022.