

GUIDANCE DOCUMENT

CVM GFI #256 - Compounding Animal Drugs from Bulk Drug Substances

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Final

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Center for Veterinary Medicine

This guidance is intended for veterinarians, State-licensed pharmacies, and Federal facilities interested in compounding animal drugs from bulk drug substances for use in nonfood-producing animals, as antidotes in food-producing animals, or as sedatives or anesthetics in free-ranging wildlife under limited circumstances when no other medically appropriate treatment options exist.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the compounding of an animal drug from bulk drug substances results in a “new animal drug” that must comply with the FD&C Act’s animal drug approval, conditional approval, or indexing requirements (sections 512, 517, and 572 of the FD&C Act). In addition, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (cGMP) requirements (section 501(a)(2)(B) of the FD&C Act) and have adequate directions for use (section 502(f)(1) of the FD&C Act).

Animal drugs that are compounded from bulk drug substances do not meet the FD&C Act’s new animal drug approval, cGMP, or adequate directions for use requirements. However, FDA has generally exercised enforcement discretion with regard to animal drug compounding from bulk drug substances under certain circumstances. This guidance is a continuation of this practice and is intended to provide additional information and clarity to veterinarians and pharmacists about FDA’s current thinking on this matter. The guidance identifies FDA’s enforcement priorities regarding animal drugs compounded from bulk drugs substances

and describes the circumstances under which FDA, at this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, does not intend to take enforcement action for violations of the FD&C Act with respect to the compounding of animal drugs from bulk drug substances.

For more information on compounding animal drugs, please visit our webpage [Animal Drug Compounding \(/animal-veterinary/unapproved-animal-drugs/animal-drug-compounding\)](https://www.fda.gov/animal-veterinary/unapproved-animal-drugs/animal-drug-compounding).

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Questions?

CVM

Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Pl, HFV-1
Rockville, MD 20855

✉ [AskCVM@fda.hhs.gov \(mailto:AskCVM@fda.hhs.gov\)](mailto:AskCVM@fda.hhs.gov)

☎ (240) 402-7002