For Pharmacists: Compounding Animal Drugs

FDA regulates animal drugs, including compounded drugs, under the Federal Food, Drug and Cosmetic Act (FD&C Act). Here is what you need to know about the FD&C Act and FDA policies when you compound drugs for animals.

Compounding animal drugs using finished FDA-approved animal or human drug products as the source of the active ingredients is an extralabel use of an approved drug, which is legal under the FD&C Act if the conditions in FDA's extralabel use regulations are met. See 21 CFR Part 530. Compounding animal drugs using bulk drug substances (BDS), however, produces animal drugs that violate the FD&C Act. Animal drugs compounded from BDS do not meet the requirements for FDA-approval, manufacturing under current good manufacturing practices (CGMPs), and adequate directions for use. Nothing in the FD&C Act exempts these compounded animal drugs from these requirements.

FDA's *Guidance for Industry # 256, Compounding Animal Drugs from Bulk Drug Substances* (GFI #256 or "the guidance"), describes the circumstances under which, at this time, FDA does not generally intend to take action against drugs compounded from BDS for violations of the FD&C Act's requirements for approval, adequate directions for use, and CGMPs. FDA recognizes that veterinarians prescribe drugs to be compounded from BDS by pharmacists when the patient cannot be treated with an approved or indexed drug. The checklist is intended to summarize the circumstances described in GFI #256.

General Recommendations When Compounding Animal Drugs

- ☐ **Confirm whether patient(s) is a nonfood-producing animal or a food-producing animal**
  - Determine whether the prescription or order is for a food-producing animal, free-ranging wildlife, or a nonfood- producing animal.
- ☐ **Follow all your state's laws and regulations that apply to compounding animal drugs**.
- ☐ **Meet USP standards and FD&C Act requirements**
  - Compound with BDS and other components that meet the standards set in any USP-NF monographs for the ingredient, if such monographs exist, and FD&C Act requirements for drug components.
- ☐ **Include all labeling information**
  - Include the following on the labeling of the compounded drug: name and strength or concentration of drug; species and name or identifier of patient(s); name, address, and contact information for the compounding pharmacy and name of the prescribing veterinarian; a beyond use date; the withdrawal time as determined by the prescribing veterinarian; and the following statements[1]:
    - "Report suspected adverse reactions to the pharmacist who compounded the drug and to FDA using online Form FDA 1932a";
    - "This is a compounded drug. Not an FDA approved or indexed drug."; and
    - "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

[1] Certain recommendations constitute collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). These recommendations are under OMB review and are not for current implementation. See PRA statement in section IV. *Paperwork Reduction Act of 1995* of this guidance for more information.

- ☐ **Dispense the compounded drug(s) to the patient's owner or caretaker or the veterinarian who prescribed or ordered it.**
- ☐ **Report adverse events and product defects associated with the compounded drug to the FDA on Form FDA 1932a**

Drugs compounded from BDS for food-producing animals are a high priority for Agency action because of the potential for harmful residues in food from treated animals. However, because of their critical role in veterinary medicine, FDA generally does not intend to take action when animal drugs are compounded from certain BDS as antidotes for food-producing animals or sedatives or anesthetics for wildlife as long as additional measures are taken to protect the human and animal food supply.

When compounding animal drugs from BDS for *food-producing animal*s or *free-ranging wildlife species*, you should also:

- ☐ **Confirm that you are using a BDS that is on the List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species or the list of Bulk Drug Substances Currently Under Review**

When compounding animal drugs from BDS for *nonfood-producing animals* with a prescription, you should also:

- ☐ **Confirm that the prescription identifies a specific patient or group of patients at same location**
- ☐ **Consider other FDA-approved options first.**
  - If there is an FDA-approved or indexed product with the same active ingredient as the prescribed drug, determine whether it can be used to compound the prescribed drug.
    - If it can be used, it should be. Compounding from FDA-approved products is legal under the FD&C Act when extralabel use conditions are met.
    - If it cannot be used to compound the drug, you should record your reason why in the pharmacy records. The statement of why it cannot be compounded from approved or indexed products can be brief; see GFI #256 for examples.
- ☐ **Determine if you are compounding a copy of an FDA-approved product**
  - Determine if there is an approved product with the same active ingredient that can be administered via the same route of administration. If so, under the guidance it is considered a copy of an approved product, and the prescribing veterinarian should provide you with a medical rationale why the compounded copy will make a clinical difference for the patient.
- ☐ **Obtain a medical rationale and retain it in your records if a copy is needed.[2]**
  - If the prescribing veterinarian did not write the medical rationale on the prescription, you should contact them to obtain it. The statement of medical rationale can be brief; see GFI #256 for examples. Note: If the compounded drug is not a copy of an approved product, the guidance does not ask for the veterinarian's rationale. The rationale should be retained in your records.

When compounding animal drugs from BDS for *nonfood-producing animals* as office stock (i.e., drugs ordered without a prescription to be kept on-hand in the veterinarian's inventory), you should also:

- ☐ Confirm that the BDS is on the List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals **or the list of Bulk Drug Substances Currently Under Review**