Alliance for Pharmacy Compounding
Formerly IACP

APC BRIEF: FDA Guidance for Industry on Animal Compounding

On November 19, 2019, FDA issued a draft guidance for industry (GFI #256) on animal drug compounding. APC and other stakeholders are concerned that the GFI is not based on any federal statute and that it greatly exceeds the agency's regulatory authority. If finalized in its current form, this guidance would severely limit animal drug compounding from bulk ingredients and would interfere with the state-regulated practice of veterinary medicine.

GFI #256 is very similar to a previous guidance (GFI #230) issued by FDA in 2015. That controversial guidance was withdrawn in 2017 after complaints from veterinarians, pharmacy organizations, pet owners and Congress that it exceeded FDA's statutory authority, interfered with the state regulated practice of veterinary medicine and pharmacy, and endangered the health of companion and exotic animals.

Without statutory authority, GFI #256 borrows extensively from Sections 503A (traditional human compounding) and 503B (outsourcing facility compounding for humans) of the Food, Drug and Cosmetic Act, both of which are expressly limited to human health. FDA has ignored appropriations directives from Congress to propose statutory changes if the agency feels they are necessary.

APC's concerns with GFI #256 include:

- The GFI would jeopardize the ability of veterinarians to use their medical judgment to determine what medication is best to treat animals. If the vet wants to prescribe a compounded medication for a specific patient, this practitioner may be forced to document that the compounded drug produces a clinical difference in their animal patient ***and*** that there is medical rationale for the prescription.

- The GFI would restrict the compounded medication veterinarians can have on hand, in their office, for immediate treatment. Compounding pharmacies will only be able to use bulk ingredients from a positive list created by FDA to make the medications veterinarians need for office use. This positive list restricts the veterinarians' ability to treat, because FDA decides what medication is best to treat, and only allows bulk drugs onto its positive list if FDA decides they are necessary for treatment. FDA has no statutory authority to practice medicine or to develop such a list.

- FDA's decision to implement a positive list for bulk ingredients severely restricts veterinarians' ability to obtain compounded medications for office use from a compounding pharmacy even if state law allows it, compromising animal health and patient treatment. This provision is particularly dangerous for animal health, as veterinary clinics serve as hospitals and emergency rooms, and veterinarians must have commonly used compounded medications available to meet the immediate needs of animals in their care.

Congress specifically chose not to include provisions regarding animal health in the Drug Quality and Security Act of 2013, and FDA should not be allowed to act as if it has statutory authority that clearly does not exist. APC and other stakeholders will be submitting comments into the FDA docket on the GFI and urging Congress to exercise their oversight authority in a way that maintains your ability to compound medications for the vets and animals you serve. The full GFI and open public docket for comments, including nominations of substances for the office-use list can be found at: https://www.regulations.gov/docket?D=FDA-2018-D-4533

Comments or questions? Contact APC at info@a4pc.org.