American Academy of Veterinary Pharmacology and Therapeutics

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The American Academy of Veterinary Pharmacology and Therapeutics (AAVPT) welcomes the opportunity to provide comments on the FDA CVM Draft Guidance for Industry #256. The mission of the AAVPT is the promotion of veterinary pharmacology and therapeutics, and our more than 300 members participate in academia, industry, and regulatory agencies. We have been involved with the issue of compounding in Veterinary Medicine for many years. For example, we co-sponsored Stakeholder Forums with the United States Pharmacopeia and the FDA Center for Veterinary Medicine (CVM) in 2012 and 2014 to assist with addressing this complex issue.

The current draft GFI addresses many of the issues that CVM has stated in various public forums, however it still lacks clarity for some situations in veterinary medicine, putting veterinarians, pharmacists, and their clients in a difficult position when it comes to compounding. We agree with and support the CVM's position and policy regarding who can and should be compounding in a veterinary practice. We support the statement that all animal drugs are required to be made in accordance with cGMP requirements and that in most cases veterinary compounding should be done using the approved veterinary product, not bulk API.

We are disappointed and frustrated that CVM is making the public statement that they do not intend to take enforcement action for violations of the FD&C Act with regards to bulk compounding in veterinary medicine. The AAVPT does not endorse or support this position. This could be interpreted as a lack of support for the veterinary pharmaceutical industry as they are encouraged to bring new, innovative products to CVM for approval.

While the lack of enforcement renders most of this GFI irrelevant, we also do believe that there are issues that have not been addressed or considered. First, we suggest that instead of issuing this as a GFI, the CVM/FDA consider that this document would be better issued as a Compliance Policy Guide (CPG). We understand and respect that not every scenario can be addressed in this document, but we believe that enforcement discretion should also include when there is a need for compounded APIs without a patient-specific prescription in zoological/nondomestic animal facilities that need immobilization agents readily available should animals escape from their enclosures. It is not possible, in real time, to write a prescription, have an appropriate volume of product compounded, dispensed and then used before injuries occur either to the escaped animal or attending personnel.

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This draft GFI acknowledges that patient-specific compounding from bulk is appropriate in very specific circumstances. The "List" appears to apply only to Office Use Compounding. “Office use” is not a standard or well-defined term across the veterinary industry and needs to be better defined in this document (i.e. ambulatory vehicles, housing outside of the veterinary office, etc.). However, with regulations on compounding, such as sterility testing requirements by most State Boards of Pharmacy, and the lag time between compounding and receipt of compounded products, it is equally appropriate for Office Use products because, just like with exotic animals, horses and other animals require medication when they require it and weeks are too long to wait for products to be ordered, compounded and then dispensed. Further, the concept of the "List" is like a "mini-approval" taking the FDA an undetermined amount of time between submission of a pharmaceutical ingredient and their decision to add it. This period is likely to be quite long since veterinary compounding is “of low regulatory concern”. It would be helpful if a defined time period for review and response be defined in this document, such as 60 days.

The AAVPT is supportive of the restrictions and concerns expressed in this draft GFI regarding the use of compounded products in food animals and the potential for violative residues in edible tissues. Regarding this, CVM should consider a prohibited list, much like that regarding product prohibited from extra-label use in food animals under AMDUCA. While that list is appropriate here too, there are likely additional products that should not be compounded from bulk for use in food animals.

The AAVPT supports CVM’s effort to formalize its policy on veterinary compounding from bulk.

Sincerely,

The AAVPT Executive Council & the Committee on Veterinary Compounding

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