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Alliance for Pharmacy Compounding

Compounding the Joy of Living

April 20, 2023

Dr. William Flynn, DVM
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Pl, HFV-1
Rockville, MD 20855

Re: Additional GFI #256 compliance questions and input

Dear Dr. Flynn:

In the few weeks since FDA's Center for Veterinary Medicine kindly provided us answers to the questions we submitted to the agency about GFI 256 compliance, we have undertaken to socialize those answers in a variety of briefing and training sessions for our members. One result of those sessions has been to bring to light additional input and/or questions that your answers raise. I am sharing several of those here; We ask that you consider them and provide additional responses to us. Those responses will of course allow to provide our members the most accurate information about GFI 256 compliance.

Below, I have quoted from your February letter in blue. Our question and/or comment on each statement follows in black.

1. "On the other hand, if there is a drug shortage (due to supply chain issues or backorders) compounding pharmacies should contact FDA by emailing AnimalDrugShortages@fda.hhs.gov. FDA addresses each drug shortage on a case-by-case basis. GFI 256 does not provide blanket enforcement discretion to compound copies of drugs in shortage."

We understand that the FDA lacks statutory authority to require manufacturers of animal drug product report their shortages and that the agency is urging reporting on a voluntary basis. However, when a product isn't available to treat the patient and FDA is evaluating the potential existence of a shortage along with what options are available to address that shortage if it exists, the patient still needs care. That care of the animal should be allowed to move forward, and in that instance a compounded preparation is appropriate and should be allowed. Compounders should be able to document the lack of availability of the drug product just as they can when they can't access an animal drug as noted in the guidance. We also urge CVM to create a process for investigating animal drug product shortages and posting them to the animal drug shortage website.

2. "Compounders are expected to know what ingredients may be harmful or cause side effects to the species for which the drug is being compounded."

Because they are not listed in the approved package insert, it simply is not possible for pharmacists to know the excipients in manufactured animal drug products. Likewise, it is not possible to evaluate them against the species for which the manufactured animal medication is to be used. The statement above expects of pharmacy compounders knowledge that is not available to them.

3. "The FD&C Act contains a variety of legal requirements that apply to all drugs, including active ingredients, inactive ingredients, and finished dosage forms. For the most common standards relevant to this provision, please see FD&C Act Sections 501 and 502 and their implementing regulations."

The cited portions of the FD&C Act above in part relate to CGMP. GFI 256 speaks to compliance with USP and/or state regulation. Please clarify that it is not FDA's intention that animal medications compounded from bulk drug substances comply with CGMP.

4. "As described in GFI 256, for patient-specific prescriptions, pharmacies should dispense a compounded drug directly to the prescribing veterinarian (which may include mobile veterinarians) or to the patient's owner or caretaker. Pharmacies should not dispense patient-specific prescriptions to a veterinarian who did not write the prescription because it is not clear that there is a valid veterinarian-client-patient relationship."

While we appreciate the point made here about the VCPR between the veterinarian and the client, it creates an unnecessary logistical hurdle not to be able to provide the compounded drug to another veterinarian within the same practice solely because the veterinarian who prescribed the compounded drug is not present at the time of delivery.

5. "(a) For purposes of this guidance, a drug compounded from bulk drug substance is a copy if it:
   - has the same active ingredient or active moiety[29] as a marketed FDA-approved or indexed drug, and
   - can be given by the same route of administration as the marketed FDA-approved or indexed drug."

The GFI's criteria for what is considered a copy creates an unnecessary distinction between some dosage forms. Under this criteria, a compounded oral suspension of the of a drug for which there is a manufactured tablet or capsule is considered a copy of the manufactured tablet or capsule. If the veterinarian wanted the animal treated with that manufactured tablet or capsule, they would have dispensed that manufactured medication themselves or have written a prescription for that product. If they are writing for a suspension to be compounded, it is because that is what is needed for that animal. This specific example should be excluded from the documentation requirement or the criteria for a copy should be modified to include a different dosage form.

Thank you in advance for your consideration of this input. We look forward to your responses. Please direct any questions or reply to me at scott@a4pc.org.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer