March 11, 2022

Arkansas State Board of Pharmacy
Executive Director John C. Kirtley, Pharm.D.
322 S. Main St. #600
Little Rock, AR 72201

Re: Animal Compounding / Veterinary Office Stock

Dear Dr. Kirtley:

The Alliance for Pharmacy Compounding provides the comments below in response to the Arkansas State Board of Pharmacy's (Board) call for input[1] concerning the allowance for veterinary office stock.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers. Every day, APC members play a critical role in patients' lives, preparing essential, custom medications for a range of health conditions, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, animal health, and others.

1. The Issue.

The specific question before the Board is this: Is retail pharmacy compounding for veterinary office stock (also referred to as office-use) allowed in the absence of a patient-specific prescription? APC asserts that compounding for veterinary office-use is expressly allowed under state law, and neither federal law nor regulations address animal drug compounding.

2. Authorization Under State Law.

Arkansas lawmakers have provided clear and unqualified guidance on office stock. Under the germane Arkansas state law,[2] this type of activity is expressly allowed.

> (L) Compounding for a Prescriber's Office Use:
> (1) Pharmacies may prepare compounded drug products for a duly authorized prescriber's office use.
>
> (M) Compounding Veterinarian Products:
> (2) These prescriptions are to be handled and filled the same as the human prescriptions.

[1] As requested during Arkansas State Board of Pharmacy's vet compounding committee hearing on the 08.Feb.2022.
[2] See 070.00.01 Arkansas Code R. § 001-07-02-0002 (§§ L, M), Good Compounding Practices (Agency 070 – Board of Pharmacy).

Because current Arkansas state rules clearly allow veterinary office stock, with no further limitations, it seems apparent that the Board regulations may not add limitations. Short of a statutory change or a formal rulemaking measure, APC believes the Board is bound to allow veterinary office stock as prepared by both 503A and 503B operations.

3. Applicability of Federal Law.

Regarding the application of any federal law, rules or guidances on the state practice of animal compounding, APC strongly asserts that U.S. Food and Drug Administration (FDA) has no statutory authority over this practice. Federal oversight is limited to the approval and monitoring of animal drugs by the Center for Veterinary Medicine (CVM) which is housed within the FDA. The CVM does not regulate the practice of veterinary medicine or the practice of animal compounding.

Despite that, the FDA issued a draft guidance on animal drug compounding[3] (GFI 256) that has caused uncertainty among practitioners and State Boards of Pharmacy. APC filed comments in response to the GFI 256 asserting that the FDA has no legal authority to regulate animal drug compounding.[4] This draft guidance remains in draft form and has not been issued in final. Even if the guidance were finalized, guidance is the FDA's current thinking on an issue and is not meant to have the effect of law. Thus, even if finalized, GFI #256 would not be binding on Arkansas.

Veterinary medicine and animal drug compounding have been historically and traditionally regulated by state boards of veterinary medicine and pharmacy pursuant to state laws passed by state legislatures and carried out by veterinarians and pharmacists licensed by those state boards. This has been the case since at least 1938 when the Food, Drug and Cosmetic Act (FDCA) was originally passed, and Congress has not passed any amendments to the FDCA to expressly preempt those state laws and create a new federal regulatory framework over the compounding of animal drugs. It is inappropriate for FDA to attempt to do so in a non-binding guidance for industry, without formal rulemaking, and without any clear statutory authority from Congress to do so.

FDA appears in draft GFI #256 to be attempting to greatly expand the authority given to the agency in the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) to assert regulatory authority to limit bulk ingredient compounding of animal drugs. But AMDUCA doesn't speak directly to animal drug compounding either. AMDUCA simply allows veterinarians to prescribe certain FDA- approved human or animal drugs for extra-label use when certain conditions are met. (*see* USC §§ 360b(a)4 and (a)5). The implementing regulations (21 CFR § 530 *et. seq*.) neither authorize nor prohibit bulk ingredient compounding for animals, and simply establish the requirements that must be met for prescribing extra-label use of FDA approved drugs, including drugs compounded from FDA-approved drugs for extra-label use. Those regulations also point parties to non-binding FDA guidance for information on compounding

[3] In 2019, FDA Draft Guidance for Industry #256, *Compounding Animal Drugs from Bulk Drug Substances* (84 Federal Register 64085) (20.Nov.2019). In 2015, FDA Draft Guidance for Industry #230, *Compounding Animal Drugs from Bulk Drug Substances* (80 Federal Register 28624) (19.May.2015), was withdrawn by the 2019 GFI 256.

[4] See APC comments on GFI 256 (May.2020, Oct.2020, Nov.2021) See also, GFI 256 "FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance documents means that something is suggested or recommended, but not required."

(*see* 21 CFR § 530.13). Extra-label use is not bulk substance compounding. They are two completely unrelated activities that have nothing to do with each other and it is not plausible that Congress would have intended to give FDA broad regulatory authority over animal drug compounding in a section of the law related to a completely different subject.

Therefore, any constraints placed on veterinary office stock via rules or guidances (draft or otherwise) on the federal level do not apply nor limit what is permissible by state boards of pharmacy.

APC sees draft GFI 256 as a remarkable overreach by the FDA.

4. APC's Position.

The practice of compounding has traditionally been administered by state authorities, and that tradition continues even under today's federal regulatory models. The matter at hand does not provide so unique a scenario to step outside of that tradition. In sum, APC urges the Board to stand by the current Arkansas state rules that allow compounding for veterinary office stock.

Thank you for the consideration. The APC is available to further discuss these comments or explore this topic with the Board.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
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