ISSUE BRIEF:

FDA Guidance for Industry (GFI) #256 – Compounding Animal Drugs from Bulk Drug Substances

Alliance for Pharmacy Compounding
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On April 22, 2022, FDA's Center for Veterinary Medicine finalized a guidance for industry document on animal drug compounding, (*Compounding Animal Drugs from Bulk Drug Substances* GFI #256), with plans to begin enforcement at the start of Fiscal Year 2023 (October 2022).

The ability of many pharmacists to serve animal patients will be affected by this GFI, and we believe there remain too many unanswered questions for pharmacy compounders to have clarity about what constitutes compliance – much less achieve that compliance – especially in such a short time.

We believe that the FDA should allow at least one year for compounders and veterinarians to align with the requirements of GFI #256. Immediate implementation will be disruptive to veterinarians' practice and a determent to their patients' health. There is a general lack of clarity in the new requirements that GFI #256 imposes on veterinarians and pharmacists that must be elucidated. Several points of concern include:

- Clinical difference: GFI #256 imposes new burdens on how veterinarians write prescriptions and communicate with compounders requiring clinical difference statements. Sufficient time to create new systems to comply with these requirements is necessary.

- Compounding from bulk: GFI #256 will require new record keeping practices for compounders and the necessity to put new systems in place to ensure documentation of rationales when bulk drug substances are being used.

- Adverse event reporting: The threshold for "adverse event" is only described generally and needs to be clarified by the agency prior to enforcement.

- FDA's list for office stock drugs: Until veterinarians and compounders have clarity on the process and have an adequate opportunity to nominate products for the list – and CVM has had time to review the nominations – this requirement will likely result in many drugs being immediately unavailable.

- Labeling: Compounded products are not FDA-approved drugs so there is no FDA-approved indication for use; therefore, compounders cannot identify an indication on the label, though this is required by GFI #256.

THE ASK: As a Member of Congress, please contact FDA CVM to express concerns about the general ambiguity and difficulty in determining compliance standards of GFI #256 and to request an extension on the enforcement of GFI #256 until Fiscal Year 2024 (October 2023). Also, please ask that FDA CVM continue working with pharmacy compounding and veterinarian stakeholders to provide clarification as to the process CVM will use to implement and enforce the GFI and to address concerns about its impact on animal patient health.

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