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Alliance for Pharmacy Compounding

Submitted via Regulations.gov Docket No. FDA-2025-N-0082

June 30, 2025

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comment on Proposed Information Collection—Compounding Animal Drugs from Bulk Drug Substances (GFI #256)

To Whom It May Concern:

The Alliance for Pharmacy Compounding, the national voice for pharmacy compounding, appreciates the opportunity to comment on the proposed collection of information associated with Guidance for Industry (GFI) #256: *Compounding Animal Drugs from Bulk Drug Substances*.

As outlined in our recently published *Blueprint for Eliminating Redundant, Unauthorized, or Ineffective Regulation*, APC strongly opposes the continued implementation of GFI #256 in its current form. While technically nonbinding, the guidance imposes a rigid and burdensome framework that lacks clear statutory grounding and restricts the clinical care options that veterinarians and compounding pharmacists provide for animals. Furthermore, GFI #256 increases the risk of harm to the very animal patients it aims to protect by requiring the use of suboptimal starting materials (i.e., finished products instead of pure active pharmaceutical ingredients) or driving veterinarians to seek products from less regulated or noncompliant sources.

The current docket requests comments addressing four specific questions regarding the collection of information under GFI #256:

1. **Is the proposed collection of information necessary for the proper performance of FDA's functions, and does it have practical utility?**

FDA's authority to regulate compounded animal drugs derives from the Federal Food, Drug, and Cosmetic Act (FDCA). However, the Animal Medicinal Drug Use Clarification Act (AMDUCA) authorizes certain extra-label uses of FDA-approved animal and human drugs but does not authorize the use of bulk drug substances for compounding. Despite the lack of specific statutory authorization, FDA has implemented GFI #256 in a way that effectively imposes a regulatory framework on veterinary compounding from bulk substances without sufficient statutory foundation or rulemaking.

While FDA does have the authority to regulate drug products, it is not authorized to regulate the *practice* of veterinary medicine or the practice of pharmacy. GFI #256 blurs these lines by requiring

veterinarians to provide clinical justifications for compounded medications and by deputizing pharmacists to evaluate and document medical rationales outside their scope of practice. This places pharmacists in an inappropriate position of policing veterinary medical decisions, which undermines both professions.

Moreover, the required collection of information serves no clear benefit for FDA, veterinarians, or pharmacists. The information is not reviewed in real time, is not shared with stakeholders, and is used primarily for potential enforcement actions. Unless FDA develops a system for aggregating and analyzing this data to guide policy or enhance safety, the collection offers little practical utility and imposes a chilling effect on legal and clinically necessary compounding.

2. **Is the FDA's estimate of the burden of the proposed collection accurate, and are the assumptions valid?**

FDA relied on data from respected professional organizations such as AVMA and APhA, but these data are likely outdated, potentially by as much as a decade. The veterinary compounding landscape has evolved significantly in recent years due to factors such as increased pet ownership, consolidation of veterinary practices, greater reliance on compounded medications, and evolving regulatory requirements under USP chapters 795, 797, and 800.

FDA's estimate that documenting a medical rationale takes one minute per prescription is unrealistic. The majority of veterinary clinics now use paperless systems where data entry must follow rigid protocols. Adding custom justifications freehand, especially without dropdown menus (as FDA has prohibited), requires considerably more time and disrupts clinical workflow. This burden is multiplied across thousands of prescriptions per year in high-volume practices.

3. **What are ways to enhance the quality, utility, and clarity of the information collected?**

The clearest path to improving data utility would be to streamline and improve the transparency of the bulk drug substance nomination process. Nearly 93% of nominations have been rejected to date, many without sufficient explanation, making it difficult for veterinarians and pharmacists to plan for patient care.

FDA should use any collected information to identify trends in compounding needs and evaluate whether certain categories of preparations can be exempted from documentation requirements. If used constructively, this data could inform targeted enforcement and help avoid unnecessary restrictions on access to care.

4. **What are ways to minimize the burden of information collection through automation or information technology?**

If FDA insists on retaining the current framework of GFI #256, it should accept a veterinarian's prescription itself as sufficient documentation of medical need, eliminating the need for redundant justifications. Currently, there is no viable automated technology for reporting to FDA in this context. If such tools are developed, they must be designed to support clinical practice rather than to further restrict or penalize it.

Conclusion

APC urges the agency to withdraw GFI #256 and recommend working on animal drug compounding policy in true collaboration with veterinarians, compounding pharmacists, and animal health experts. We further urge FDA to pause enforcement and data collection related to this guidance until it can be substantially revised to reflect clinical realities, legal limits of FDA authority, and the shared goal of protecting animal health.

Thank you for the opportunity to provide comments.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer