APhA
American Pharmacists Association

September 26, 2025

Dockets Management
Docket: FDA-2018-D-4533
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: CVM GFI #256 – Compounding Animal Drugs from Bulk Drug Substances

The American Pharmacists Association's (APhA) Compounding Community is writing to seek clarification on the FDA's "Compounding Animal Drugs From Bulk Drug Substances" guidance and request FDA provide compounding pharmacists with additional information to ensure compliance and best practices.

The mission of APhA's Compounding Community of over 3,400 compounding pharmacists is to provide a professional network for compounding professionals. The Compounding Community focuses on education, communication, collaboration, advocacy, and the sharing of ideas in compounding pharmacy practice.

In line with Secretary Kennedy's and Commissioner Makary's goal of increasing transparency regarding communications and decision-making at FDA,[1] APhA's Compounding Community makes the following requests.

1. Guidance for 503B Outsourcing Facilities

Compounding pharmacists have sent several inquiries regarding guidance for 503B outsourcing facilities that produce compounded products from bulk drug substances for office use in products for animals. APhA members had hoped that additional guidance would be released last year. The lack of FDA guidance has created uncertainty of what constitutes a violation, especially as the information provided on 503B company websites greatly differs regarding whether they must comply with GFI #256 and if they are exempt from certain compounding

[1] Marty Makary, *A Statement from FDA Commissioner Marty Makary, M.D., M.P.H.: 100 Days of Embracing Gold-Standard Science, Transparency, and Common Sense*, U.S. Food & Drug Administration (July 10, 2025). Available at: https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-marty-makary-md-mph-100-days-embracing-gold-standard-science-transparency#:~:text=A%20Statement%20from%20FDA%20Commissioner%20Marty%20Makary%2C,Transparency%20and%20Common%20Sense.%20More%20Press%20Announcements.

standards. APhA requests that FDA provide clarity on this issue and any updates on further guidance it plans to issue.

2. Warning Letters & Untitled Letters

Currently, compounding pharmacists have access to minimal records of perceived violations of GFI #256, as indicated by warning letters and untitled letters published by FDA or the Center for Veterinary Medicine (CVM) following inspections. Pharmacists compounding veterinary products want to know more and are requesting information about the specific practices that have been identified as deficient or non-compliant. Additionally, compounding pharmacists have noted that the speed at which warning and untitled letters are shared is untimely. Pharmacists compounding these medications need access to these communications in a timely manner to ensure that regulations are being followed. As such, APhA encourages FDA or CVM to promptly post warning letters and untitled letters related to GFI #256. APhA recommends FDA send this information in a similar manner to the Weekly FDA Warning Letters, as individual or firm names could be excluded to expedite the posting process.

3. Additional Information Regarding the 8,505,000 Total Annual Records

As noted in our previous comments to FDA, APhA members have not had the opportunity to review the over 8.5 million responses that CVM has collected relevant to GFI #256. Not only does not having this information make it difficult for the public to provide FDA with meaningful feedback during its requests for comments or information, it also leaves those within the veterinary compounding community confused as to what data is being utilized to form policy at FDA and CVM. Understanding what data FDA and CVM are using will lead to both greater transparency and a better understanding of the intricacies of GFI #256. Accordingly, APhA reiterates our previous ask for an annotated sample of this information.

4. Review of Bulk Drug Substance Nominations

APhA members are concerned about the panel, committee, or decision-making body responsible for reviewing bulk drug substance nominations. Our members are concerned that the body is not representative of the veterinary compounding community. As such, members are requesting that the curriculum vitae (CV) of the members of this body be shared publicly on FDA's website. FDA shares the CVs for members of the Pharmacy Compounding Advisory Committee (PCAC), which plays a similar role in regulating compounding drugs for human use. Accordingly, APhA encourages FDA to share the CVs of those making these important decisions and requests FDA ensure that those making these decisions are representative of the entire compounding community, including veterinary compounding pharmacists.

Compounding pharmacists are also concerned about the definitive criteria for reviewing these nominated bulk substances. APhA members again point to the processes in place with PCAC and request FDA review this process publicly, as well as provide transcripts of the decision-making for each of the substances reviewed and the rationale for the body's decision of inclusion or exclusion on the list. Both of these asks align with the Secretary's and Commissioner's commitment to radical transparency and ensuring that conflicts of interest do not influence the work of FDA.[2] As such, APhA urges FDA to take swift action to make this information readily accessible to compounding pharmacists across the country.

5. Lists and Timeframe Regarding the Listing Process

APhA members are also seeking clarity on how to navigate the bulk drug substance lists. More specifically, APhA requests FDA provide a clear statement on whether pharmacists can compound items that have not yet been nominated. For example, edetate calcium disodium serves as a valuable antidote for lead poisoning in livestock and exotic birds; however, it has only been nominated for use in dogs, cats, and horses. Given the urgent nature of treating lead poisoning in livestock and exotic birds and the likelihood that multiple animals are affected simultaneously, the availability of this antidote as office stock could be instrumental in saving the lives of many animals and birds. Thus, APhA urges FDA to issue a statement concerning pharmacists' ability to compound drugs that have yet to be nominated to resolve potential issues like the one highlighted above that practitioners are likely to encounter.

Additionally, compounding pharmacists request more information regarding the timing of how long a pharmacist can continue to compound with bulk drug substances once they have been added to the "Bulk Drug Substances Reviewed and Not Listed" list. CVM representatives have provided APhA with differing answers during previous meetings and listening sessions. In one meeting with CVM, a representative provided that pharmacists could continue to use these substances for compounding for six months following their inclusion on the "Bulk Drug Substances Reviewed and Not Listed" list.[3] However, during a subsequent listening session, CVM representatives stated that the six-month answer was inaccurate, but they did not provide an exact timeline. Accordingly, APhA asks FDA to provide a definitive answer to this question and timeline.

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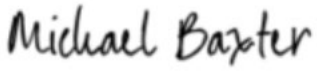
[2] *FDA Commissioner Makary Announces New Policy on Individuals Serving on FDA Advisory Committees*, U.S. Food & Drug Administration (Apr. 17, 2025). Available at: https://www.fda.gov/news-events/press-announcements/fda-commissioner-makary-announces-new-policy-individuals-serving-fda-advisory-committees.

[3] *Compounding for the Animal Kingdom* [Continuing Education Event], APhA2024 Annual Meeting & Exposition, March 23, 2024, Orlando, Florida. Available at: https://apha2024.eventscribe.net/agenda.asp?BCFO=&pfp=days&fa=&fb=&fc=&fd=&all=1.

APhA looks forward to FDA's responses to these requests and appreciates the opportunity to provide additional comments on CVM GFI #256. If you have any questions regarding these comments, would like to arrange a meeting with APhA on this topic, or require additional information, please contact Corey Whetzel, Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,



Michael Baxter
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CC: Dr. Timothy C. Schell, Acting Director, CVM, FDA