American Pharmacists Association

June 16, 2025

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Compounding Animal Drugs from Bulk Drug Substances [Docket No. FDA-2025-N-0082]

The American Pharmacists Association's (APhA) Compounding Community is pleased to respond to FDA's "Comment Request: Compounding Animal Drugs from Bulk Drug Substances," and the recordkeeping provisions outlined in Guidance for Industry, GFI #256 -- Compounding Animal Drugs from Bulk Substances.

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 sharing of ideas in compounding pharmacy practice.

FDA invites comments on the following topics: "(1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology."

It is challenging to provide comments on collected data that APhA members have not had the opportunity to review. Accordingly, APhA requests an annotated sample of the 8.5 million responses that the Center for Veterinary Medicine (CVM) has thus far collected relevant to GFI #256. The guidance has been finalized and enforced for over 2 years, and APhA has not seen any of the collected data, only the number of responses in the burden estimate.

APhA provides the following comments regarding the itemized topics in FDA's comment request:

(1) Is the collected data necessary for FDA's proper performance?

Since APhA has not seen an example of what data has been collected, it is difficult to comment. However, GFI #256's recommendation to report adverse events and product defects associated with compounded drugs is consistent with FDA's mission to ensure the safety and effectiveness of animal drugs as well as to protect animal and human health. The practical utility of this collected information lies in its public dissemination, which could alert veterinarians and pharmacists to problematic compounds and product defects, offering insights into how to continuously improve the quality of compounded therapies for animals (through compounding consultants, USP monographs, and ongoing animal clinical investigations using compounds). Careful analysis of data collected by subject matter expert (SME) panels could reveal deficiencies in formulas, packaging materials, prescribing and dispensing practices, and animal owners' understanding of proper use of compounds (e.g., following labeled dosing, handling, and storage instructions, and discarding compounds by the labeled Beyond Use Date (BUD)).

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

APhA has not received many complaints about the time it takes to collect information. Still, we do not know how many veterinarians and pharmacists are complying with this requirement and reporting data, as APhA has not seen any data collected. The provided chart offers no units for the value of "0.017" per response, only parenthetically "1 minute", which appears low without seeing more detail. APhA recommends that FDA divide the collected data into specific demographics for those who reported, as well as categories of what was reported (e.g., adverse event, product defect). APhA is unaware of the methods used to calculate the effort required; the FDA's rationale, "We base our estimates on our experience with the regulation of compounded animal drugs," does not provide statistically valid information.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected.

Until APhA can view the information that has been collected (actual responses and demographics), we cannot comment.

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adverse Drug Events (ADEs) and product problems: The electronic submission of Form 1932a is primitive at best, and the information required on the form is not intuitive. The instructions (pasted below from the CVM website) are also not user-friendly. Most veterinarians and pharmacists attempt this once and give up.

"Note: You must download (as described below) and save the blank form to your computer BEFORE filling out the form. DO NOT OPEN THE FORM IN YOUR BROWSER.
1. Right-click the 1932a electronic form link above.
2. Click your browser's Save option. On most browsers, this is the Save Link As option, but on other browsers this may be Save Target As or Download Linked File and save the file to your computer.
3. Open the file.
4. Complete the fillable form.
5. Save the completed version to your computer.
6. Email the completed form to CVM1932a@fda.hhs.gov.
CVM should assemble a multidisciplinary team of veterinarians and pharmacists to redesign 1932a into a genuine data collection system that will upload to a centralized database. The 1932a form has never been a useful survey instrument in my opinion."

Rationale: This is not currently reported (nor should it be mandated); however, the FDA should be aware of medical rationales in real-time and not be driven by inspection-driven data. APhA again recommends a centralized, non-mandatory reporting system that could be made available and simplified by using drop-down menus (bulk drug substance, rationale, and "other" with a text response). Collecting this data would better inform what the CVM panel is reviewing in the lists of nominated bulk drug substances. In addition, FDA should make deliberations available to the public, including the composition of that panel and the criteria for acceptance or rejection. APhA also notes that this panel lacks subject matter experts (SMEs) on the clinical use of bulk drug substances for veterinary compounding.

If you have any questions regarding these comments and would like to meet with members of APhA's Compounding Community, please contact us at mbaxter@aphanet.org.

Sincerely,

Michael Baxter
Vice President, Government Affairs