APhA
American Pharmacists Association

August 28, 2025

[Submitted electronically to www.regulations.gov]

Grace R. Graham
Deputy Commissioner for Policy, Legislation, and International Affairs
Food and Drug Administration
10903 New Hampshire Avenue, Building 1
Silver Spring, MD 20993

RE: [Docket No. FDA-2025-N-0082-0005] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Compounding Animal Drugs From Bulk Drug Substances

Dear Deputy Commissioner Graham,

The American Pharmacists Association's (APhA) Compounding Community is pleased to respond to FDA's "Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Compounding Animal Drugs From Bulk Drug 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.

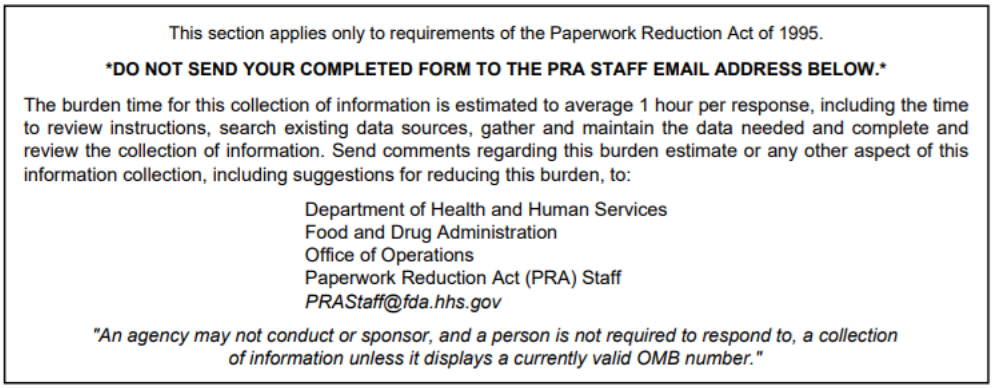
Earlier this year, FDA solicited comments on "Agency Information Collection Activities; Proposed Collection; Comment Request; Compounding Animal Drugs From Bulk Drug Substances" [Docket No. FDA-2025-N-0082]. FDA received three comments in total to this collection of information, and APhA's comments were the only ones to address 5 CFR 1320.8(d).[1] APhA comments stated that the 1-minute time burden value appeared low, without seeing more detail, and recommended "that FDA divide the collected data into specific demographics for those who reported, as well as categories of what was reported (e.g., adverse

[1] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Compounding Animal Drugs From Bulk Drug Substances, 90 Fed. Reg. 35693, 35694 (July 29, 2025). Available at: https://www.federalregister.gov/d/2025-14226/p-12.

event, product defect)."[2] FDA responded by indicating that the form is currently pending Office of Management and Budget review and stating that they "continue to make technological enhancements to our collection instruments as our limited resources allow."[3]

Within this request for information, FDA noted that "none of the comments offered an alternative estimate, and [they] therefore retain the estimate of burden for the information collection as communicated in [their] 60-day notice," which included the 0.017 (1 minute) average burden per response.[4] APhA's Compounding Community draws FDA's attention to the FDA's own "Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect Report (For VOLUNTARY Reporting," form 1932a, which states, "The burden time for this collection of information is ***estimated to average 1 hour per response [emphasis added],*** including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information."[5] See Image #1 from the FDA's Form 1932a below.

Image #1:



This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

APhA's Compounding Community believes this is a more accurate representation of the time burden associated with completing FDA's form 1932a without having greater access to the data already collected by FDA. As such, APhA's Compounding Community requests that FDA adjust the burden estimate to be set at a minimum of 1 hour, as the FDA has used this time

[2] American Pharmacists Association, Agency Information Collection Activities; Proposed Collection; Comment Request; Compounding Animal Drugs from Bulk Drug Substances [Docket No. FDA-2025-N-0082] (June 16, 2025). Available at: https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=kp8YmehQ9LQ%3d.

[3] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Compounding Animal Drugs From Bulk Drug Substances, 90 Fed. Reg. 35693, 35694 (July 29, 2025). Available at: https://www.federalregister.gov/d/2025-14226/p-12.

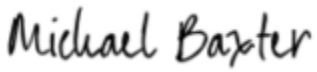
[4] *Id.* Available at: https://www.federalregister.gov/d/2025-14226/p-12.

[5] Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect Report, Form FDA 1932a (9/23), OMB No. 0910-0284, Food and Drug Administration (Expiration Date Aug. 31, 2026).

burden with the current 1932a form—which only requires a portion of the reporting requirements.

Thank you for the opportunity to submit additional comments. If you have any questions or would like to meet with APhA's Compounding Community to discuss our comments or meet with a veterinary compounding pharmacist, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,



Michael Baxter
Vice President, Government Affairs