

UNITED STATES FOOD & DRUG ADMINISTRATION

Compounding Animal Drugs from Bulk Drug Substances

OMB Control No. 0910-0904 – EXTENSION

SUPPORTING STATEMENT – **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection helps support recommendations discussed in Food and Drug Administration (FDA) guidance. Animal drugs compounded from bulk drug substances by pharmacists and veterinarians do not meet certain important requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). To be legally marketed in accordance with animal drug approval requirements of the FD&C Act, an approval, conditional approval, or listing on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species is required, and compounded drugs do not go through any of these pre-market review processes. (Information collection associated with new animal drug applications is approved under OMB control no. 0910-0032; information collection pertaining to index of legally marketed unapproved new animal drugs for minor species is approved under OMB control no. 0910-0605.) Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (CGMP) requirements and have adequate directions for use, requirements not met by compounded drugs. Thus, drugs compounded from bulk drug substances violate the FD&C Act because they are not approved or indexed, are not made according to CGMP, and cannot satisfy the FD&C Act's adequate directions for use provision (which requires, among other things, that a prescription drug have FDA-approved labeling). However, FDA has generally refrained from taking enforcement action against animal drugs compounded from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist.

To assist respondents in understanding FDA's current thinking about animal drug compounding from bulk substances, our Center for Veterinary Medicine developed GFI #256 entitled "Compounding Animal Drugs from Bulk Drug Substances" (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-256-compounding-animal-drugs-bulk-drug-substances>). The guidance describes circumstances under which FDA generally does not intend to take enforcement action against pharmacists and veterinarians who compound animal drugs from bulk drug substances.

We therefore request OMB extension of OMB approval of the information collection discussed in GFI #256, "*Compounding Animal Drugs from Bulk Drug Substances*."

2. Purpose and Use of the Information Collection

The policies described in the guidance document are intended to protect the public health by limiting the use of animal drugs compounded from bulk drug substances to when a veterinarian,

acting within a valid veterinarian-client-patient relationship (VCPR),¹ determines there is no medically appropriate human or animal drug that is FDA-approved,² conditionally approved, or indexed to treat the animal.

Description of Respondents: Respondents include veterinarians and pharmacists compounders.

3. Use of Improved Information Technology and Burden Reduction

The information collection recommendations describe agency enforcement policy. The guidance makes no recommendation regarding the format for the information collection discussed in the guidance; however, we believe that it is standard business practice for these licensed respondents to maintain records electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection poses undue burden on small entities. Respondents to the information collection are pharmacists in either State-licensed pharmacies or Federal facilities, or veterinarians who compound animal drugs from bulk drug substances. At the same time, FDA provides small business assistance through agency staff and resources available through our website.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this information collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice inviting public comment in the *Federal Register* of May 1, 2025 (90 FR 18665). Three comments were submitted to the docket by various trade associations, however the first two were not responsive to the information collection topics solicited under 5 CFR 1320.8(d). Rather, the comments appeared to be proffered in accordance with our Good

¹ A valid VCPR is a relationship in which, among other things, the veterinarian: (1) has assumed responsibility for making medical judgments concerning the health of the animal patient and the need for medical treatment; (2) is familiar enough with the animal patient to make a general diagnosis of the medical condition; and (3) is readily available for follow-up should an adverse reaction occur or the prescribed therapy is not effective. For a complete definition of VCPR, see 21 CFR 530.3(i).

² Unless explicitly limited to “animal drugs,” the term “FDA-approved drugs” includes FDA-approved human drugs, FDA-approved animal drugs, conditionally approved animal drugs, and licensed human biologics.

Guidance Practice regulations in 21 CFR 10.115 and we therefore refer the commentors to 21 CFR 10.115(f) regarding how the public may participate in the development of FDA guidance documents. The third comment suggested improvements to increase the utility of Form FDA 1932a, *Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect Report*, approved for use in OMB control no. 0910–0291, currently pending OMB review. We appreciate this comment and continue to make technological enhancements to our collection instruments as our limited resources allow. At the same, none of the comments offered an alternative estimate, and we therefore retain the estimate of burden for the information collection as communicated in our 60- day notice.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

We have determined that no personally identifiable information (PII) or information of a personal nature is collected. We also determined that the information collection is not subject to the Privacy Act of 1974, and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not maintain information that facilities collect and does not use names or any other personal identifiers to retrieve records from the information collected.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. *Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Recordkeeping Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Documenting Rationales by licensed veterinarian/pharmacist compounders in state-licensed pharmacies or Federal Facilities	7,500	1,134	8,505,000	0.017 (1 minute)	144,585

12b. Annualized Cost Burden Estimate

Table 2 – Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pharmacist Compounder ^{1,2}	144,585	\$84.25	\$12,181,286.25

¹May 2023 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (<https://www.bls.gov/oes/current/oes291051.htm>)

²We currently do not have data regarding the number of veterinarians who compound drugs.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate the annualized cost to the Federal Government to be \$13,566. We estimate that we spend 200 hours annually reviewing rationales as part of pharmacy inspections. We estimate the average hourly wage for personnel to review rationales as part of a pharmacy inspection at the 2024 OPM wage rates for a GS-13- Step 7 employee in the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA area, to be approximately \$67.83/hour. Thus, the estimated annualized cost to the Federal government is \$13,566 (200 hours x \$67.83/hour = \$13,566).

15. Explanation for Program Changes or Adjustments

We have made no changes or adjustments to the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Consistent with established practice FDA will publish a *Federal Register* notice announcing OMB approval of the information collection associated with this guidance document and will display in that notice both the OMB control number and its current expiration date. In addition, the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.