United States Food and Drug Administration

Extralabel Drug Use in Animals

OMB Control No. 0910-0325 -- Extension

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support Food and Drug Administration (FDA, us or we) implementation of section 512 of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 360b), which governs new animal drugs. Agency regulations in 21 CFR part 530, permit FDA, if we find that there is a reasonable probability that the extralabel use of an animal drug may present a risk to public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. This requirement is codified at 21 CFR 530.22(b). Although to date, we have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development.

We therefore request OMB extension of OMB approval for the information collection requirements contained in 21 CFR 530, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The analytical method developed would be used by FDA and other State and Federal agencies to assure the safety of the food supply when drugs are used in an extralabel manner.

Description of Respondents: Respondents to the information collection are private sector drug sponsors or veterinary associations, or veterinarians, state, local, and tribal governments, and Federal agencies.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques. Firms are free to use whatever forms of information technology may best assist them in development and submission of acceptable analytical methodology for drug residue quantification above any safe level established.

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

   The information collection poses no undue burden on small entities. We estimate 75% of respondents are small businesses. FDA assists small businesses in complying with its regulatory requirements through Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide guidance on our website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

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 for 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 for public comment in the *Federal Register* of June 18, 2026 (91 FR 36868). No comments were received.

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

    The Privacy Act of 1974 (5 U.S.C. 552a)

    In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted is point of contact name, business email address, and business mailing address. We have determined that although PII is collected, the 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, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.
Data will be kept private to the extent allowed by law.

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 Reporting Burden

21 CFR Part; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
530.22(b); Submission(s) of analytical method.	2	1	2	4,160	8,320

The total burden for this information collection is 8,320 hours.

This information collection requires reporting of an analytical method for residue detection of an extralabel use in animals of an approved animal or human drug. Although no submissions have been received under the information collection, we believe there will be instances when analytical methodology will be required. Thus, we continue to estimate burden based on the possibility of requiring development and submission of methodology for up to two drugs per year.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer[1]	8,320	$55.25	$459,680

[1]May 2025 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (https://data.bls.gov/oes/#/area/0000000/2025) $42.50 hourly wage plus 30% adjusted for benefits.

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 annual cost to the Federal Government to be $20,847.33. We estimate a reviewer, at the GS 13 Step 5 level, in the pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA ($66.14/hour), will spend 157.6 hours reviewing each submission (157.6 hours x 2 submissions = 315.20 hours x $66.14/hour = $20,847.33).

15. Explanation for Program Changes or Adjustments*

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.8.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.