United States Food and Drug Administration

Extralabel Drug Use in Animals
OMB Control No. 0910-0325

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration regulations regarding specific reporting requirements as identified below. The Animal Medicinal Drug Use Clarification Act of 1994 (P.L. 103-396) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to allow veterinarians to prescribe extralabel use of approved new animal drugs. It also permits FDA, if FDA finds 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). 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. Accordingly, we request extension of OMB approval of the information collection provisions found in 21 CFR 530.22(b), which requires the development and submission of an analytical methodology for drug residue quantification above any safe level established, as prescribed under the FD&C Act.
We therefore request OMB extension of OMB approval of 0910-0325 Extralabel Drug Use for Animals found in 21 CFR Part 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. 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

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

Without this information, FDA would not be able to assess the public health risk from certain extralabel use of drugs in animals. This is only requested or when it has been identified as a potential issue.

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 August 06, 2020 (85 FR 47794). Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted is name, work email address, and title. This information collection supports Food and Drug Administration regulations allowing veterinarians to prescribe extralabel use of approved new animal drugs. Through appropriate instruction, FDA minimized the PII collected to protect the privacy of the individuals.

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.

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

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.

Table 1. – Estimated Annual Reporting Burden[1]

21 CFR Section	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

[1]There are no capital or operating and maintenance costs associated with the information collection.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer[1]	8,320	51.57	$429,062.40

[1]May 2019 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes131041.htm)$39.67 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 Federal costs associated with the information collection will be absorbed by existing resource allocations.

15. Explanation for Program Changes or Adjustments*

There were no program changes or adjustments.

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

Display is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.