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

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

The Animal Medicinal Drug Use Clarification Act of 1994 (P.L. 103-396) allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the 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.

We request OMB approval for information collection required by the following citation:

21 CFR 530.22(b) – Reporting requirement for development and submission of acceptable and analytical methodology for drug residue quantification above any safe level established.

This information collection is not related to the American Recovery and Reinvestment Act of 2009.

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.

This information collection affects 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 that will best assist them in the development and submission of acceptable analytical methodology for drug residue quantification above any safe level established. Ten percent of submissions are by electronic means.

4. Efforts to Identify Duplication and Use of Similar Information

This collection requires the development and submission of an acceptable analytical methodology for drug residue quantification when such methodology is not available; therefore, no similar data/information exists.

5. Impact on Small Business or Other Small Entities

Seventy-five percent of respondents are businesses. The proposed collection of information carries the same burden for small or large firms. The law and corresponding regulations governing methodology development must be applied consistently and equally to all enterprises. While we cannot establish different standards with respect to statutory requirements, we do provide special help to small businesses. A small business coordinator has been established on the Commissioner's staff to ensure that small businesses have an adequate opportunity to express their concerns and to keep our management apprised of how its regulatory decisions may impact the small business community. Furthermore, we encourage sponsors, whether small or large businesses, to meet with the Center for Veterinary Medicine to discuss development and submission of the required residue methodology.

6. Consequences of Collecting the Information Less Frequently

If the information is not reported, we may not be able to determine the risk to public health of an extralabel use of a drug. If we find that an extralabel animal drug use presents a risk to public health, and no analytical method has been developed and submitted, the agency may prohibit such extralabel use.

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

All of the reporting requirements are consistent with 5 CFR 1320.5.

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

In accordance with 5 CFR 1320.8(d) FDA published a 60-day notice in the Federal Register of November 4, 2014 (79 FR 65408). No comments were received.

9. Explanation of any Payments or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information will be kept confidential in accordance with 18 USC 1905 and 21 USC 331(j), as well as section 301(j) of the Act.

11. Justification for Sensitive Questions

This information collection does not contain questions pertaining to sexual behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

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. We believe there will be instances when analytical methodology will be required. Thus, we will continue to estimate burden based on the possibility of requiring development and submission of methodology for up to two drugs per year.

FDA estimates the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden1

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry compliance officer	8,320	$38.00	$316,160

Total cost to respondents for an industry compliance officer is estimated at 8,320 hours x $38.00 per hour equals $316,160.

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

None.

14. Annualized Cost to the Federal Government

Estimated total hours per year per method = 160
No. of methods developed per year = 2

160 x 2 = 320 hours x $46.42 (GS-13/3, 2015 Washington Metro Area Federal Pay Scale) = $14,854 cost to Federal Government. Costs to the Federal Government reflects 2015 cost-of-living pay scale adjustment.

15. Explanation of Program Changes or Adjustments

There are no changes or adjustments to the burden estimates for respondents.

16. Plans for Tabulation and Publication and Project Time Schedule

Information is not to be published for statistical use.

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.