

SUPPORTING STATEMENT

EXTRA-LABEL DRUG USE IN ANIMALS - 0910- 0325

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary.

21 CFR 530.22(b) permits FDA to establish a safe level for extralabel use of an approved new drug or new animal drug when we find that there is a reasonable probability that an extralabel use may present a risk to the public health. When establishing a safe level, we may require the development of an acceptable analytical method for the quantification of residues. The sponsor may develop the methodology, while in other cases, FDA and/or a third party (eg., State agency or a professional association) may be involved in method development.

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 analytical methodology for drug residue quantification above any safe level established.

2. Purpose and Use of the Information

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.

3. Use of 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

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

5. Impact on Small Business or Other Small Entities

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. Efforts to Obtain Comments on the Information Collection Before Submission to OMB.

In the **Federal Register** of January 28, 2002, (67 FR 3903), the Agency requested comments

on the collection of information. In response, FDA received one comment. The comment is listed below with the agency's response:

The comment asked whether the proposed collection of information was necessary for the proper performance of FDA functions including whether the information would have practical utility. As detailed, the Food and Drug Administration under this regulation, is permitted to request development of an acceptable residue detection method for human or animal drugs used in an extralabel manner which could result in unsafe residues in edible products of the treated animal. If no acceptable analytical method is developed, FDA is permitted to prohibit extralabel use of the drug. Thus, this collection of information is necessary to permit licensed veterinarians to prescribe extralabel use of certain drugs.

9. Explanation of Any Payment or Gift to Respondent

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

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

12. Estimates of Hour Burden Including Annualized Hourly Costs

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. In the three years since the regulation requiring this information collection was finalized, we have not found circumstance to require the establishment of a safe level and subsequent development of analytical methodology.

However, as we stated when the regulation was proposed on May 17, 1996, we believe that 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. Estimated burden remains as in the 1996 proposal and is as follows:

Estimated Annual Reporting Burden ¹					
21 CFR	No. of Respondents	No. Of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320
TOTAL HOURS					8,320

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

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

Total annual cost burden is included in the preceding paragraph. There are no additional costs to respondents.

14. Annualized Cost to the Federal Government

For the same reasons expressed in paragraph 12 above, estimates will be the same as those in the proposal of May 17, 1996, as follows:

The estimate incorporates the review of the method and does not include costs involved should FDA participate in method development. Burden from any FDA participation would be captured in paragraph 12.

Estimated total number of hours per year per method. - 160

Estimated number of analytical methods developed each year. - 2

Estimated number of hours for record review. – 320

Estimated total cost for review of methodology - \$9,600*

- (320 hours x \$30/hour for review by mid-grade GS-13)

15. Explanation of Program Changes or Adjustments

There are no changes or adjustments to previous burden estimates.

16. Plans for Tabulation and Publication and Project Time Schedule.

Information is not to be published for statistical use.