Abbreviated New Animal Drug Applications

0910-0669

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)(21 U.S.C. 360b(b)(2)), any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an ANADA is described in section 512(n)(1) of the FD&C Act (21 U.S.C. 360b(n)(1)). Among other things, an ANADA is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved new animal drug. We allow applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review. Applicants may submit Form FDA 356v with a complete ANADA or a phased review submission to ensure efficient and accurate processing of information.

2. Purpose and Use of the Information Collection

   We use the information submitted, among other things, to assess bioequivalence to the originally approved drug and thus, the safety and effectiveness of the generic new animal drug.

3. Use of Improved Information Technology and Burden Reduction

   Sponsors and manufacturers of generic animal drug products may use the eSubmitter, a secure online submission tool created by CVM, for all submissions related to the abbreviated new animal drug approval process. FDA estimates that 50% of the respondents will use electronic means to fulfill the agency's requirement.

4. Efforts to Identify Duplication and Use of Similar Information

   The information provided in an ANADA is unique to the particular product covered by the application. There are no other regulations that require the submission of this same information. The information is generally not available from any recognized scientific sources, unless the information has been made public by the ANADA applicant.

5. Impact on Small Businesses or Other Small Entities

   We estimate that most of the veterinary pharmaceutical manufacturers that would be sponsors of new animal drug applications would have revenues greater than $1.0 million.

Consequently, we estimate that one or fewer respondents would qualify as a small business. We assist small businesses to meet the requirements of sections 512(b)(2) and (n)(1) of the FD&C Act through our Regional Small Business Representatives and through the scientific and administrative staff within the Center.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. There are no specific regulatory time frames imposed on an applicant for submitting an application or supplement. After the initial submission of an application, the applicant can submit any required information as he/she sees fit or as may be imposed by the regulations under 21 CFR parts 514, 211, 225, or 226.

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

There are no special circumstances associated for this collection of information.

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 for public comment in the FEDERAL REGISTER of May 11, 2016 (81 FR 29273). FDA received no comments.

9. Explanation of Any Payment or Gift to Respondents

We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

We expect that an ANADA will contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden

FD&C Act sections 512 (b)(2) and (n)(1)	FDA Form	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
ANADA	356v	18	1	18	159	2,862
Phased Review with Administrative ANADA	356v	3	5	15	31.8	477
Total						3,339

We base our estimates on our experience with ANADA submissions and requests for phased review. We estimate that we will receive 21 ANADA submissions per year over the next three years and that three of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately five phased reviews per application. We estimate that an applicant will take approximately 159 hours to prepare either an ANADA or the estimated 5 ANADA phased review submissions and the administrative ANADA.

As noted in section 1 of this document, applicants may submit Form FDA 356v with a complete ANADA or a phased review submission to ensure efficient and accurate processing of information. Form FDA 356v is approved under OMB Control No. 0910-0032.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer	3,339	$43.24	$144,378.36

We estimate the average hourly wage for respondents based on the May 2015 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics, 13-1041, $33.26 per hour. Increasing this wage by 30% to account for overhead costs, we estimate the average hourly cost to respondents to be $43.24 per hour. The overall estimated cost incurred by the respondents is $216,473.60 (3,339 burden hours x $43.24 per hour = $144,378.36).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/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 for the review and evaluation of submissions to be $2,248,206.15. We estimate that we expend approximately 37,419 person hours annually in review and support, and approximately 9,996 person hours annually in

supervisory support of the review of submissions. We estimate the average hourly wage for personnel to review and evaluate a submission to be at the GS-13-2 level in the locality pay area of Washington-Baltimore in 2016, approximately $44.97/hour and the average hourly wage for supervisory personnel at the GS-14-4 level in the locality pay area of Washington-Baltimore in 2016, approximately $56.57/hour. The estimated annualized cost to the Federal government is $2,248,206.15 (37,419 hours x $44.97/hour + 9,996 hours x $56.57 = $2,248,206.15).

15. Explanation for Program Changes or Adjustments

    The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

    We have no plans to tabulate and publish information from this information collection.

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

    We are not seeking an exemption from displaying the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.