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. Form FDA 356v is approved under OMB Control No. 0910-0032.

We believe the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) for soluble powder oral dosage form products and certain Type A medicated articles. We are adding to this information collection applicant requests to waive the requirement to establish bioequivalence through in vivo studies (biowaiver requests) for soluble powder oral dosage form products or certain Type A medicated articles based upon either of two methods. We will consider granting a biowaiver request if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, we will consider granting a biowaiver request without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects.

Additionally, we have found that various uses of veterinary master files have increased the efficiency of the drug development and drug review processes for both us and the animal pharmaceutical industry. A veterinary master file is a repository for submission to FDA's Center for Veterinary Medicine of confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more veterinary drugs. Veterinary master files are used by the animal

pharmaceutical industry in support of information being submitted for new animal drug applications (NADAs), ANADAs, investigational new animal drug (INAD) files, and generic investigational new animal drug (JINAD) files. In previous information collection requests, we included the time necessary to compile and submit such information to veterinary master files within the burden estimates provided for applications and amended applications (for NADAs and INAD files) and abbreviated applications and amended abbreviated applications (for ANADAs and JINAD files), respectively. We recently combined the time necessary to compile and submit such information to veterinary master files within the burden estimates provided in the collection of information supporting new animal drug applications (OMB control number 0910-0032).

We request extension of OMB approval of the information collection requirements in 21 U.S.C. 360b(b)(2) and (n)(1) and this use of Form FDA 356V, New Animal Drug Application. We also request OMB approval of biowaiver requests and the proposed increased use of veterinary master files to submit information to us.

2. Purpose and Use of the Information Collection

The reporting associated with ANADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(2) of the FD&C Act. 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. We use the information submitted by applicants in the biowaiver request as the basis for our decision whether to grant the request.

3. Use of Improved Information Technology and Burden Reduction

Sponsors and manufacturers of generic animal drug products may use eSubmitter, a secure online submission tool created by CVM, for all submissions related to the abbreviated new animal drug approval process. CVM is moving to 100% electronic submission as required by the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, signed into law on August 14, 2018. We estimate that 100% of the ANADA submissions will be submitted electronically in the next three years.

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 ANADAs 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 with 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 April 18, 2019 (84 FR 16270). FDA received one comment letter, which contained multiple comments that were outside the scope of the four collection of information topics on which the notice requested comments and will not be discussed in this document.

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

This information collection request (ICR) is collecting personally identifiable information (PII). PII is collected in the context of the individuals' professional capacity. The PII submitted for FDA Form 356V (Application for Approval of a New Animal Drug or submission to support new animal drug approval) is name, address, telephone number, fax number, and email address. This ICR involves the submission to FDA of an ANADA (an application for approval to legally market a generic new animal drug). The FD&C Act and FDA's regulations specify the information that must be submitted to FDA by persons seeking to manufacture generic new animal drugs.

FDA further 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 Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

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

The 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

Activity	FDA Form No.	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
Biowaiver request for soluble powder oral dosage form product, using same formulation/manufacturing process approach	N/A	1	1	1	5	5
Biowaiver request for soluble powder oral dosage form product, using same API/solubility approach	N/A	5	1	5	10	50

Table 1.--Estimated Annual Reporting Burden						
Activity	FDA Form No.	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Biowaiver request for Type A medicated article, using same formulation/manufacturing process approach	N/A	2	1	2	5	10
Biowaiver request for Type A medicated article, using same API/solubility approach	N/A	10	1	10	20	200
Total				51		3,604

We base our estimates on our records of generic drug applications. We estimate that we will receive 21 ANADA submissions per year over the next 3 years and that 3 of those submissions will request phased review. We estimate that each applicant that uses the phased review process will have approximately 5 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. Our estimates of the burden of biowaiver requests for generic soluble powder oral dosage form products and Type A medicated articles differ based on the type of product and the basis for the request, as shown in table 1. We estimate that an applicant will take between 5 and 20 hours to prepare a biowaiver request.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer	3,604	$51.82[1]	$186,759.28

[1]May 2018 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics, 13-1041 Compliance Officer (www.bls.gov), $39.86 plus 30% adjusted for benefits equals approximately $51.82 per hour wage.

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 for the next three years to be $4,995,680 annually. For calendar year 2018, we expended approximately 80,392 person hours in review and support, and approximately 15,560 person hours of 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-Arlington, DC-MD-VA-WV-PA in 2019, approximately $49.10/hour, and the average hourly wage for supervisory personnel at the GS-14-7 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2019, approximately $67.38/hour. The estimated annualized cost to the Federal government is $4,995,680 [(80,392 hours x $49.10/hour) + (15,560 hours x $67.38/hour) = $4,995,680].

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 previous estimate of the number of respondents submitting generic drug applications. However, as discussed, the burden for this information collection (a program change) was increased by 265 hours and 18 responses since the last OMB approval. This is due to adding to this collection burden hours and responses for biowaiver requests. We have also added to this collection a discussion of the use of veterinary master files by the animal pharmaceutical industry in support of information being submitted for NADAs, ANADAs, INAD files, and JINAD files.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Cert1ification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.