

United States Food and Drug Administration

Abbreviated New Animal Drug Applications

OMB Control No. 0910-0669

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (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 number 0910-0032. 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.

The information collection also includes 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 use the information submitted by applicants in the biowaiver request as the basis for our decision whether to grant the request. Therefore, the information collection references the guidance document GFI #171 – Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered to Be Soluble in Aqueous Media (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-171-demonstrating-bioequivalence-soluble-powder-oral-dosage-form-products-and-type-medicated>) (May 2021), which discusses statutory bioequivalence requirements as well as qualifications for requesting a waiver from the requirements. The guidance document was developed consistent with the agency’s Good Guidance Practice regulations in 21 CFR 10.115, which provide for comment at any time.

We therefore 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, as well as biowaiver requests as discussed in this supporting statement.

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.

Description of Respondents: The respondents for this collection of information are veterinary pharmaceutical manufacturers.

3. Use of Improved Information Technology and Burden Reduction

Sponsors and manufacturers of generic animal drug products must download and use eSubmitter, a secure online submission tool created by CVM, for all submissions related to the abbreviated new animal drug approval process (<https://www.fda.gov/industry/fda-esubmitter/getting-started-esubmitter>). 100% of all the ANADA submissions are submitted electronically

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 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

FDA published a 60-day notice for public comment in the *Federal Register* of March 18, 2022 (87 FR 15436).

We received and considered one comment requesting the posting of new animal drug applications for public access. While FDA posts a summary of the safety and effectiveness data and information submitted in the application, which supports the basis for FDA's approval (<https://www.fda.gov/animal-veterinary/approved-animal-drug-products-green-book/freedom-information-foi-summaries-approved-animal-drugs>), we are prohibited from disclosing commercial confidential information contained in an ANADA.

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 via Form FDA 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. FDA determined that although PII is collected it 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. Through appropriate form design, FDA limited submission fields and 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.

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 collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

In the burden hour table below, we calculate a total of 39 respondents and some line items represent a subset of those respondents.

Table 1.--Estimated Annual Reporting Burden

Activity; Guidance Document Section	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
ANADA	356v	20	1	20	159	3,180
Phased review with administrative ANADA	356v	6	5	30	31.8	954
Biowaiver request for soluble powder oral dosage form product, using same formulation/manufacturing process approach; Section IV	N/A	1	1	1	5	5
Biowaiver request for soluble powder oral dosage form product, using same API/solubility approach; Section IV	N/A	5	1	5	10	50
Biowaiver request for Type A medicated article, using same formulation/manufacturing process approach; Section V	N/A	2	1	2	5	10
Biowaiver request for Type A medicated article, using same API/solubility approach; Section V	N/A	5	1	5	20	100
Total						4,299

We base our estimates on our records of generic drug applications. We estimate that we will receive 20 ANADA submissions per year over the next 3 years and that 6 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 five 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.

While we have not made changes to the burden response itself, there has been an increase in the number of respondents, and in turn, the number of responses for ANADAs and Phased Review requests. This is due to the everchanging industry/marketplace. We also note there is a decrease in the number of biowaiver requests for Type A medicated article, using the same API/solubility method, which we also attribute to changes in the animal drug industry/marketplace.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer	4,299	\$55.16 ¹	\$237,132.84

¹May 2021 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics, 13-1041 Compliance Officer (www.bls.gov), \$42.43 plus 30% adjusted for benefits equals approximately \$55.16 per hour wage.

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 the annualized cost to the Federal government for the review and evaluation of submissions for the next three years to be \$5,102,970.85 annually. For calendar year 2021, we expended approximately 80,134.50 person hours in review and support, and approximately 12,996.50 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 2022, approximately \$52.89/hour, and the average hourly wage for supervisory personnel at the GS-14-4 level in the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA in 2022, approximately \$66.53/hour. The estimated annualized cost to the Federal government is \$5,102,970.85 [(80,134.50 hours x \$52.89/hour) + (12,996.50 hours x \$66.53/hour) = \$5,102,970.85].

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall adjustment increase of 695 hours and a corresponding increase of 12 responses. Based on a review of the information collection since our last request for OMB renewal, the increase in the burden hours estimate is attributable to an increase in the number of respondents submitting generic drug applications.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.