United States Food and Drug Administration
New Animal Drugs for Investigational Uses

OMB Control No. 0910-0117

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. A new animal drug application (NADA) cannot be approved until, among other things, the new animal drug has been demonstrated to be safe and effective for its intended use(s). In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. Under specific circumstances, section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) permits the use of an investigational new animal drug to generate data to support an NADA approval. Section 512(j) of the FD&C Act authorizes us to issue regulations relating to the investigational use of new animal drugs.

Our regulations in Part 511 (21 CFR part 511) set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping. The information collected is necessary to protect the public health. We use the information to determine that investigational animal drugs are distributed only to qualified investigators, adequate drug accountability records are maintained, and edible food products from treated food-producing animals are safe for human consumption. We also use the information collected to monitor the validity of the studies submitted to us to support new animal drug approval.

We therefore request extension of OMB approval for the information collection provisions under 21 CFR Part 511: *New Animal Drugs for Investigational Use*, and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Reporting: Our regulations require that certain information be submitted to us in a "*Notice of Claimed Investigational Exemption for a New Animal Drug*" (NCIE) to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse. The NCIE must contain, among other things, the following specific information: (1) identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals (§ 511.1(b)(4) (21 CFR 511.1(b)(4)). If the new animal drug is to be used in food-producing animals, e.g., cattle, swine, chickens, fish, etc., certain data must be submitted to us to obtain authorization for the use of edible food products from treated food-producing animals (§ 511.1(b)(5)). We require sponsors upon request to submit information with respect to the investigation to determine whether there are grounds for terminating the exemption (§ 511.1(b)(6)). We require sponsors to report findings that may suggest significant hazards

pertinent to the safety of the new animal drug (§ 511.1(b)(8)(ii)). We also require reporting by importers of investigational new animal drugs for clinical investigational use in animals (§ 511.1(b)(9)). The information provided by the sponsor in the NCIE is needed to ensure that the proposed investigational use of the new animal drug is safe and that any edible food will not be distributed without proper authorization from FDA. Information contained in an NCIE submission is monitored under our Bioresearch Monitoring Program. This program permits us to monitor the validity of the studies and to ensure the proper use of the drugs is maintained by the investigators.

Recordkeeping: If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery (§ 511.1(a)(3) and (b)(3)). We require complete records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug (§ 511.1(b)(7)). We also require records of all reports received by a sponsor from investigators to be retained for 2 years after the termination of an investigational exemption or approval of a new animal drug application (§ 511.1(b)(8)(i)).

Description of Respondents: Respondents to the collection of information are persons who use new animal drugs for investigational purposes. Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities, as well as research firms and members of the medical professions.

Respondents may be individuals; from the private sector (for-profit businesses or not-for-profit institutions); State, Local or Tribal Governments; or the Federal Government.

3. Use of Improved Information Technology and Burden Reduction

The animal health industry may use eSubmitter, a secure online submission tool, for all submissions related to the investigation of new animal drugs for approval. Paper submissions are still accepted. FDA estimates that 60% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires this information. The required information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

There is no exemption for small businesses from the requirements under section 512(j) of the FD&C Act; however, we do not believe this imposes undue burden on small entities. Rather, we believe the requirements for new animal drugs for investigational use impose minimal information collection while still allowing us to ensure the safety of the program. We assist small businesses to meet the requirements of the FD&C Act through our Regional Small Business Representatives and through the scientific and administrative staff within the Center. We have also created guidance documents that discuss various topics relevant to new animal drugs for investigational use, including the following:

- CVM GFI #104 Content and Format of Effectiveness and Target Animal Safety Technical Sections and Final Study Reports For Submission
- CVM GFI #106 Published Literature in Support of New Animal Drug Approval
- CVM GFI #119 How CVM Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug
- CVM GFI #197 Documenting Electronic Data Files and Statistical Analysis Programs
- CVM GFI #218 - Cell-Based Products for Animal Use
- CVM GFI #226 - Target Animal Safety Data Presentation and Statistical Analysis
- CVM GFI #237 - Oncology Drugs for Companion Animals
- CVM GFI #242 In-Use Stability Studies and Associated Labeling Statements for Multiple-Dose Injectable Animal Drug Products

These guidance documents are available on our website at www.fda.gov. We estimate that approximately 90% of respondents are small businesses.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements and occurs occasionally. There are no specific regulatory time frames imposed on an applicant for submitting an investigational new animal drug notice. If the information is not collected, we would be unable to determine whether investigational animal drugs are distributed only to qualified investigators, whether adequate drug accountability records are maintained, or whether edible food products from treated food-producing animals are safe for human consumption.

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

There are no special circumstances 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 February 22, 2018 (83 FR 7735). One comment was received but did not respond to any of the four information collection topics solicited; therefore, it was not addressed by the agency.
9. Explanation of Any Payment or Gift to Respondents

   No payment or gift is provided to respondents.
10. Assurance of Confidentiality Provided to Respondents

    FDA regulations (21 CFR 514.12) prohibit the agency from disclosing the existence of an investigational new animal drug notice unless it has been previously disclosed or acknowledged. We expect that an investigational new animal drug notice 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 collection of information does not contain questions of a personally sensitive nature.
12. Estimates of Annualized Burden Hours and Costs

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

    12 a. Annualized Hour Burden Estimate

    Description of Respondents: Respondents to this collection of information are persons who use new animal drugs for investigational purposes. Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities, as well as research firms and members of the medical professions.

Table 1.--Estimated Annual Reporting Burden

21 CFR Section/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
511.1(b)(4); submission of NCIE.	104	15.38	1,600	1	1,600
511.1(b)(5); submission of data to obtain authorization for the use of edible food products.	104	0.30	31	8	248
511.1(b)(6); submission of any additional information upon request of FDA.	104	0.02	2	1	2
511.1(b)(8)(ii); reporting of findings that may suggest significant hazards pertinent to the safety of the new animal drug.	104	0.14	15	2	30
511.1(b)(9); reporting by importers of investigational new animal drugs for clinical investigational use in animals.	104	0.14	15	8	120
Total			1,663		2,000

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
511.1(a)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery.	104	2.5	260	1	260
511.1(b)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug or feed containing same is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery.	104	15.38	1,600	1	1,600
511.1(b)(7); maintain records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug.	104	15.38	1,600	3.5	5,600
511.1(b)(8)(i); maintain records of all reports received by a sponsor from investigators.	104	15.38	1,600	3.5	5,600
Total			5,060		13,060

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on our informal communication with industry. Based on the number of sponsors subject to animal drug user fees, we estimate that there are 104 respondents. We use this estimate consistently throughout the table and calculate the "*number of responses per respondent*" by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours (i.e., the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from our records. The burden for this information collection has changed since the last OMB approval. We estimate an overall increase in burden that we attribute to an increase in the number of annual responses and records.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance officer	15,060	$50	$753,000

FDA estimates the cost of the information collection request to industry to be $753,000. This figure was calculated by multiplying the hourly wage rate for an industry compliance officer ($50) by the total number of burden hours (15,060).

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

The agency allocates resources for the receipt, processing, review, and evaluation of investigational new animal drug submissions and estimate the cost to be $746,374 (rounded to the nearest dollar). This is based on an average hourly wage of a GS-13-3 level employee in the locality pay area of Washington-Baltimore-Arlington in 2018, $49.56/hour. The overall estimated cost is $201.57 (15,060 burden hours x $49.56/hour = $746,373.60).

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. While our data suggests that there are fewer respondents to the collection, we have observed an increase in the number of submissions per respondent. This results in an overall increase to the collection by 497 annual responses and 1,255 annual hours. Also, in our last submission we erroneously recorded certain costs. These costs have been removed as they previously appeared, however, they are identified and discussed at *Question 12b.* of this Supporting Statement.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish this collection of information.

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.