United States Food and Drug Administration

New Animal Drugs for Investigational Use

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, 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 a 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 OMB extension of OMB approval of the information collection provisions of the following citations:

21 CFR 511.1(a)(3) – Recordkeeping
Requires maintenance of 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.

21 CFR 511.1(b)(3) – Recordkeeping
Requires maintenance of 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.

21 CFR 511.1(b)(4) – Reporting
Specifies a general format for the filing of a "Notice of Claimed Investigational Exemption (NCIE) for a New Animal Drug" prior to introducing the new animal drug into interstate commerce for clinical investigations in animals.

21 CFR 511.1(b)(5) – Reporting
Specifies the need for data to be submitted for the authorized use of edible food products from treated food-producing animals consistent with the public health.

21 CFR 511.1(b)(6) - Reporting
Specifies requirements for transmitting information to FDA to determine if there are grounds for terminating an exemption.

21 CFR 511.1(b)(7) - Recordkeeping
Requires maintenance of complete records for two years of any investigation by a sponsor, including shipment or delivery of the new animal drug.

21 CFR 511.1(b)(8)(i) - Recordkeeping
Requires maintenance of all reports received by a sponsor from investigators for two years after the termination of an investigational exemption or approval of a New Animal Drug Application. All records established during the study of an investigational new animal drug must be available for inspection by FDA officers.

21 CFR 511.1(b)(8)(ii) - Reporting
Requires sponsors to report findings that may suggest significant hazards of the safety of the new animal drug.

21 CFR 511.1(b)(9) - Reporting
Requires reporting by importers of investigational new animal drugs for clinical investigational use in animals.

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 help 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 help 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 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.

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. CVM's eSubmitter program is an electronic, question-based tool for submitting information electronically through the FDA Electronic Submission Gateway (ESG) and CVM Electronic Submission System (ESS). 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 these submissions will be submitted electronically in the next three years.

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

There is no exemption from the section 512(j) of the FD&C Act for small businesses. We believe that our requirements for new animal drugs for investigational uses impose the minimal information collection burden necessary 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 estimate that approximately 93% of respondents are small businesses.

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 investigational new animal drug notice. If this information is not collected, FDA would not be able 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.

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

FDA published a 60-day notice for public comment in the *Federal Register* of December 21, 2020 (85 FR 83092). Although two comments were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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 is name and work address of the clinical investigator. Through appropriate guidance, 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.

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

Table 1.--Estimated Annual Reporting Burden[1]

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.	279	5.94	1,657	1	1,657
511.1(b)(5); submission of data to obtain authorization for the use of edible food products.	279	0.10	28	8	224
511.1(b)(6); submission of any additional information upon request of FDA.	279	.001	0.28	1	0.28
511.1(b)(8)(ii); reporting of findings that may suggest significant hazards pertinent to the safety of the new animal drug.	279	0.05	14	2	28
511.1(b)(9); reporting by importers of investigational new animal drugs for clinical investigational use in animals.	279	0.05	14	8	112
Total			1,713		2,021

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average 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.	279	0.99	276	1	276
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.	279	5.94	1,657	1	1,657
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.	279	5.94	1,657	3.5	5,800
511.1(b)(8)(i); maintain records of all reports received by a sponsor from investigators.	279	5.94	1,657	3.5	5,800
Total			5,247		13,533

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

12b. Annualized Cost Burden Estimate

The annual hourly burden for the information collection requirements in these regulations is estimated at 15,554 burden hours. The cost to the respondents is estimated by assuming a cost of $51.57 per hour for 15,554 burden hours for a total cost of $802,119.78.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Industry Compliance Officer[1]	15,554	$51.57	$802,119.78

[1] May 2019 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics and including 30% for benefits (https://www.bls.gov/oes/current/naics4_325400.htm).

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

The agency believes the time it expends for receipt, processing, review, and evaluation for an investigational new animal drug submission is commensurate with that for industry. We therefore estimate the cost of the information collection to the Federal government to be $824,362. 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 2021, $53.00/hour (15,554 burden hours x $53.00/hour = $824,362).

15. Explanation for Program Changes or Adjustments

The number of respondents has increased due to an error in calculating the number of sponsors subject to animal drug user fees in the 2018 renewal. When calculating the number of recordkeepers, we inadvertently used the number of sponsors that paid user fees (i.e., those that did not qualify for user fee waivers) as opposed to the total number of sponsors subject to animal drug user fees. Both fee-paying and non-fee-paying sponsors are respondents with respect to this information collection.

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. There is a small increase in the total burden hours which we attribute to an increase in the number of annual responses and records.

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.