

SUPPORTING STATEMENT
New Animal Drugs for Investigational Uses
(OMB Control Number 0910-0117—Extension)

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Drug Amendments of 1962, authorized FDA to establish investigational new animal drug regulations. These regulations were initially established under section 505(i) and were subsequently authorized under section 512(j) of the act as amended by the Animal Drug Amendments of 1968. The regulations are codified in 21 CFR Part 511. The regulations protect the public health by, among other things, requiring that investigational animal drugs be distributed only to qualified investigators, that adequate drug accountability records be maintained, and that edible food products from treated food-producing animals be safe for human consumption.

Section 512(a)(1) and (2) state that a new animal drug or an animal feed bearing or containing a new animal drug is unsafe unless it is the subject of an approved application. Section 512(j) authorizes promulgation of regulations for exempting investigational use.

We are requesting OMB approval for the information collection requirements contained in the following specific citations within 21 CFR Part 511:

21 CFR Part 511.1

(a)(3) - Recordkeeping

Requires maintenance of records for two years on the shipment of new animal drugs into interstate commerce for laboratory research.

(b)(3) - Recordkeeping

Requires maintenance of records for two years on the shipment of new animal drugs into interstate commerce for clinical investigations.

(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.

(b)(5)(i),(ii) & (iii) – 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.

(b)(6) - Reporting

Specifies requirements for transmitting information to FDA to determine if there are grounds for terminating an exemption.

(b)(7)(ii) - Recordkeeping

Requires maintenance of complete records for two years of any investigation by a sponsor, including shipment/delivery of the new animal drug.

(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.

(b)(8)(ii) - Reporting

Requires sponsors to report findings that may suggest significant hazards of the safety of the new animal drug.

(b)(9) - Reporting

Requires reporting by importers of investigational new animal drugs for clinical investigational use in animals.

We are also requesting approval of FDA Form 3458 (attached).

2. Purpose and Use of the Information

In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. A new animal drug application (NADA) cannot be approved until the new animal drug has been demonstrated to be safe and effective for its intended use(s). Under specific circumstances, section 512(j) of the act permits the use of an investigational new animal drug to generate data to support NADA approval.

FDA regulations governing investigational use of new animal drugs can be found in 21 CFR 511.1. These regulations require certain information to be submitted under a “Notice of Claimed

Investigational Exemption” (NCIE) in order to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse.

If the new animal drug is to be used in food-producing animals, e.g., cattle, swine, chickens, fish, etc., data is needed to show that the edible food products are safe for human consumption. An authorization must be secured from FDA for the use of edible food products from treated food-producing animals.

The information provided by the sponsor in the NCIE is needed to assure 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 the agency's "Bio-Research Monitoring Program.” This program permits the agency to monitor the validity of the studies and to assure the proper use of the drugs is maintained by the investigators.

3. Use of Information Technology and Burden Reduction

We are continuously seeking ways through advances in information technology to reduce the burden on the government and sponsor/respondent. New electronic computerized equipment will permit the utilization and dissemination of information. Word processing has greatly reduced the amount of time needed to compile and arrange documents for submission to the Agency. We allow the submission of Notice of Claimed Investigational Exemption (NCIE), commonly known as drug shipment notices, and notices of intent to slaughter by electronic submission, which increases the efficiency of the review process of the NCIE.

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

Our charge is to ensure the safe use of investigational drugs applies regardless whether the studies were conducted by small or large businesses. We believe that the law and regulations apply to all persons equally. While we do not believe we can apply different standards with respect to statutory requirements, we do provide special help to small business. A small business coordinator has been established on the Commissioner's staff to ensure that small businesses have an adequate opportunity to express their concerns and to keep our management apprised of how regulatory decisions might impact the small business community. Furthermore, we encourage sponsors, whether large or small businesses, to meet with the Center for Veterinary Medicine.

6. Consequences of Collecting the Information Less Frequently

The information is only collected once.

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

There are no special circumstances for the collection of information requirements.

8. Consultations Outside FDA

In accordance with 5 CFR 1320.8(d), on April 8, 2008, in volume 73, No. 68, page 19073, a 60-day notice for public comment (Attachment 1) was published in the Federal Register. One comment was received, but it was outside the scope of paperwork renewal or paperwork issues.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided or will be 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. All information will be kept confidential in accordance with 18 USC 1905 and 21 USC 331(j).

11. Justification for Sensitive Questions

This collection of information does not contain questions of a sensitive nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

The regulations setting forth the conditions for investigational use of new animal drugs are codified at 21 CFR part 511. 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 two years after such shipment or delivery. Before shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). 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. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, and that the distribution is controlled to prevent potential abuse. The agency uses these required records under its Bio-Research Monitoring

Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Table 1. -- Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(4)	134	7.66	1027	8	8216
511.1(b)(5)	134	.19	25	140	3500
511.1(b)(6)	134	.01	2	1	2
511.1(b)(8) (ii)	134	.11	15	20	300
511.1(b)(9)	134	6.7	20	8	160
Total Burden Hours					12,178

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

Table 2—Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(a)(3)	134	2.96	400	9	3600
511.1(b)(3)	134	7.66	1027	1	1027
511.1(b)(7) (ii)	134	7.46	1000	3.5	3500
511.1(b)(8)(i)	134	7.46	1000	3.5	3500
Total Burden Hours					11,627

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

13. Estimated Annual Cost to Respondents

12,178 plus 11,627 equals 23,805 total burden hours. The hourly wage of a compliance officer employed by an animal drug sponsor is estimated to be approximately \$38 per hour.¹ \$38 times 23,805 equals \$904,590.

14. Estimated Annual Cost to Government

The estimated time for processing, receipt, review, and evaluation conducted by FDA personnel for an investigational new animal drug submission is estimated to be approximately the same as that for industry to report, or a total of 12,178 hours.

The cost to the Federal government is therefore estimated to be \$494,183.
(12,178 hours X \$40.58/hour - GS-13, step 3).

15. Changes in Burden

The burden is considerably less due to fewer submissions.

16. Publication of Results

There are no plans to publish this collection of information.

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

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions.

¹ 2006 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (www.bls.gov/oes/current/naics4_325400.htm) \$29.27 hourly wage plus 30% adjusted for benefits.