New Animal Drugs for Investigational Uses

SUPPORTING STATEMENT A

(OMB Control Number 0910-0117)

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.

The Food and Drug Administration (FDA) is requesting approval of this *reinstatement* from the Office of Management and Budget (OMB) for the collection of information 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.

FDA is also requesting approval of FDA Form 3458.

2. <u>Purpose and Use of the Information Collection</u>

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 Improved Information Technology and Burden Reduction

As a part of the reauthorization of the Animal Drug User Fee Act (ADUFA) in 2008, CVM committed to developing an electronic submission tool for industry submissions within 24 months of appropriated ADUFA funds for FY 2009. The tool was made available by CVM's Office of New Animal Drug Evaluation (ONADE), for voluntary use by sponsors and manufacturers in the animal health industry, on March 11, 2011. The animal health industry may now use the eSubmitter, a secure online submission tool, for all submissions related to the investigation of new animal drugs for approval.

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. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the Federal Register of June 28, 2011 (76 FR 37814), a 60-day notice was published for public comment on this information collection. No comments were received that pertained to the information collection.

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 Annualized Burden Hours and 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 Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
511.1(b)(4)	206	6.01	1,238	1	1,238
511.1(b)(5)	206	.34	70	8	560
511.1(b)(6)	206	.01	2	1	2
511.1(b)(8) (ii)	206	.07	15	2	30
511.1(b)(9)	206	.07	15	8	120
Total Burden Hours					1,950

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

Table 2—Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
511.1(a)(3)	206	2.30	474	1	474
511.1(b)(3)	206	6.01	1238	1	1,238
511.1(b)(7)(ii)	206	6.01	1238	3.5	4,333
511.1(b)(8)(i)	206	6.01	1238	3.5	4,333
Total Burden Hours					10,378

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

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance officer	12327	$44[1]	$542,388

13. Estimates of Other Total Annual Costs and/or Recordkeepers/Capital Costs

None.

14. Annualized Cost to the Federal 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 10,377 hours.

The cost to the Federal government is therefore estimated to be $472,257.
(10,377 hours X $45.51/hour - GS-13, step 3).

15. Explanation of Program Changes or Adjustments

FDA decreased the average number of hours based on improved administrative processes and the increased use of electronic submissions. The number of sponsors of animal drugs has increased over the last 3 years due to more businesses developing new animal drugs.

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 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] Bureau of Labor Statistics, Department of Labor, May 2010 National Occupational and Employment Wage Estimates.