# New Animal Drugs for Investigational Uses

OMB Control Number 0910-0117
Supporting Statement Part A

## 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) of the act 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 the collection of information requirements found in the regulations at 21 CFR Part 511 and cited below.

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 the electronic form entitled "Notice of Claimed Investigational Exemption."

**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 an NADA approval. Regulations governing the investigational use of new animal drugs can be found in 21 CFR 511.1. These regulations require that certain information 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, FDA's Center for Veterinary Medicine (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. At the same time, paper submissions are still accepted.

**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**

FDA believes that its 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. While the regulations do not provide exceptions for small businesses, all sponsors of new animal drugs for investigational uses are encouraged to meet with CVM staff.

**6. Consequences of Collecting the Information Less Frequently**

The information is 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 April 2, 2015 (80 FR 37269), FDA published a 60-day notice seeking public comment on this information collection. Two comments were received but did not respond to any of the four information collection topics solicited and therefore were 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. 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**

FDA estimates the burden of this information collection as follows:

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) | 263 | 5.30 | 1,395 | 1 | 1,395 |
| 511.1(b)(5) | 263 | .26 | 69 | 8 | 552 |
| 511.1(b)(6) | 263 | .01 | 2 | 1 | 2 |
| 511.1(b)(8)(ii) | 263 | .06 | 15 | 2 | 30 |
| 511.1(b)(9) | 263 | .06 | 15 | 8 | 120 |
| Total | | | | | 2,099 |

[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 | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| 511.1(a)(3) | 263 | 2.07 | 545 | 1 | 545 |
| 511.1(b)(3) | 263 | 5.30 | 1,395 | 1 | 1,395 |
| 511.1(b)(7)(ii) | 263 | 5.30 | 1,395 | 3.5 | 4,882.5 |
| 511.1(b)(8)(i) | 263 | 5.30 | 1,395 | 3.5 | 4,882.5 |
| Total | | | | | 11,705 |

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

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on informal Agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 263 respondents. We use this estimate consistently throughout the table and calculate the "annual frequency 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 Agency records.

**12b. Annualized Cost Burden Estimate**

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|---|---|
| Compliance officer | 13,804 | $44 | $607,376 |

FDA estimates the cost of the information collection request to industry to be $607,376. This figure was calculated by multiplying the hourly wage rate for an industry compliance officer ($44) by the total number of burden hours (13,804).

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

There are no start-up or other costs associated with this collection of information.

**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

$640,782 (rounded to the nearest dollar), as calculated by multiplying the hourly wage rate of GS-13, step 3, employee ($46.42) by the total number of burden hours (640,782.68).

**15. Explanation of Program Changes or Adjustments**

This request for approval reflects an overall increase that FDA attributes to an increase in the number of new animal drugs and thus a corresponding increase in the number of respondents to this collection. Specifically the number of respondents increased by **57** and results in an hourly burden increase of **1,477** and an increase in the total number of responses by **698**. The agency also notes that the cost to industry for the information collection was not previously included in our submission. We have included that information in this instant request at Question 12b. above.

**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.