

Docket No. 98N-0363  
OMB No. 0910-0117

SUPPORTING STATEMENT  
INVESTIGATIONAL USE OF NEW ANIMAL DRUGS

A. JUSTIFICATION

1. Circumstance Making the Information Collection Necessary

The Federal Food, Drug and Cosmetic Act (the Act) under the Drug Amendments of 1962 was authorized to establish investigational animal drug regulations. These regulations were initially established under section 505(I) and subsequently following enactment of the Animal Drug Amendments of 1968 became subject to section 512(j) of the Act, ( see attachment A). The regulations are codified in 21 CFR Part 511, ( see attachment B). The regulations protect the public health by requiring that investigational animal drugs be distributed only to qualified investigators, that adequate drug accountability 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 or be the subject of an exemption for 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 2 years on the shipment of new animal drugs into interstate commerce for laboratory research.

21 CFR 511.1(b)(3) - Recordkeeping

Requires maintenance of records for 2 years on the shipment of new animal drugs into interstate commerce for clinical investigations.

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 drug into interstate commerce.

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)(ii) - Recordkeeping

Requires maintenance for 2 years of complete records of any investigation by a sponsor; includes shipment/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 after the termination of an investigation exemption or approval of a New Animal Drug Application for 2 years. 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

Specifies requirements for monitoring of investigation and reporting to FDA and investigators any findings associated with the new animal drug that may suggest significant hazards pertinent to the safety and effectiveness 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

Final approval for use of the drug under a New Animal Drug application (NADA) cannot be given until the investigational requirements are satisfactorily completed. Section 512(j) of the Act exempts the use of an Investigational New Animal Drug (INAD) from the requirements of the NADA approval process.

If the drug is to be used in food-producing animals, i.e, cattle, swine, chickens, fish, etc., data is needed to show that consumption of edible food products will not be unsafe to the public health. 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 of the INAD is needed to assure that the proposed investigational use of the drug is safe and that any edible food will not be distributed for food

without proper authorization from the FDA.

Information contained in an INAD 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 recently announced a pilot project for submission of Notice of Claimed Investigational Exemption (NCIE), commonly known as drug shipment notices, by electronic submission, which should increase the efficiency of the review process of the INAD.

### 4. Efforts to Identify Duplication and Use of Similar Information

There are no other regulations or Federal Agencies that require the submission of the same type information. There are no similar data/information that could be substituted for that required by these regulations.

### 5. Impact on Small Businesses or Other Small Entities

Our charge to insure the safe use of investigational drugs applies to small and large businesses involved in sponsoring drug studies. We believe that it requires the equal distribution of the law and corresponding regulations to all enterprises. While we do not believe we can supply 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 to discuss

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

There are no specific regulatory time frames imposed on a sponsor for the collection or recording of information. The sponsor submits information anytime they see fit.

### 7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5

Collection requirements are consistent with 5 CFR 1320.5.

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

No comments were received in response to the **Federal Register** notice of July 8, 1998, (FR/ Vol. 63/ pp 36921). In the course of inspections and reviews conducted by the FDA, there is a continual communication with the regulated industry regarding these regulations and their use. They constitute a basis of compliance with the Act. In addition, there is continual communication with various animal industry associations that permits constant dialogue concerning INADs. A number of guidelines have been issued to provide guidance on the proper conduct

of investigations. Provisions are made under the Administrative Act to secure public comment on any proposed guideline or related document at the time of publication. No major problem areas have been encountered that could not be resolved.

The following firms were contacted in September, 1997 and asked to provide estimates of burden associated with these regulations: Fort Dodge Animal Health, Princeton, NJ; Pharmacia and Upjohn Animal Health, Kalamazoo, MI; Elanco, Greenfield, IN; Merial, Iselin, NJ and Hoechst Roussel Vet, Warren, NJ.

#### 9. Explanation of Any Payment or Gift to Respondent

There are no payments or gifts to respondents.

#### 10. Assurance of Confidentiality Provided to Respondent

The existence of an exemption for investigational use of a new animal drug is a provision to insure the information under investigation remains confidential. All information will be kept confidential in accordance with 18 U.S.C. 1905 and 21 U.S.C. 331(j), as well as Section 301(j) of the Act.

#### 11. Justification for Sensitive Questions

The FDA Investigational New Animal Drug regulations do not contain questions or references pertaining to sex behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

#### 12. Estimates of Hour Burden

From consultation with several of the largest research and development (R&D), firms listed above in paragraph eight, and review of our data bases, we estimate that the 10 largest R&D firms account for 90% of all investigational studies. Data from these R&D firms projects 956 studies undertaken with 1,147 NCIEs issued to allow shipment of investigational drugs in interstate commerce. The burden on industry is estimated at approximately 8 hours per occurrence, resulting in 9,176 hours. Approximately 30% of the studies (287), will require a slaughter authorization allowing for use of edible products from treated animals. Burden estimate is 140 hours per occurrence, or 40,180 hours. Reports required by the FDA to determine whether a NCIE should be terminated or whether significant safety hazards may be associated with a drug under study, 21 CFR 511.1(b)(6) and (8)(ii) respectively, are rare. We estimate one of each per year with a burden of 250 and 20 hours respectively. We estimate the burden on import drugs for investigations use to be similar to that for NCIEs (8 hours), with an estimate of 30 occurrences per year, or 240 hours. The above estimated reporting burdens total 49,866 hours.

Required 2 year recordkeeping requirements are estimated to be 21,510 hours for the amount of investigational studies referenced above.

Respondents, while not all submit studies in any given year, total 190, the number of sponsors of approved applications listed in 21 CFR 510.600.

#### 13. Estimate of Total Annual Cost Burden Other Than Hour Burden to Respondents

We believe that the collection of information would not result in a cost burden beyond the hours burden to respondents cited above.

14. Annualized Cost to the Federal Government

The estimated time for processing, receipt, review, and evaluation conducted by Center 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 49,866 hours.

The cost to the Federal government is therefore estimated to be \$1,645,578 (49,866 hours X \$33.00/hour - mid grade GS-13).

15. Explanation for Program Changes or Adjustments

The annual burden has been adjusted from the previous 190,197 burden hours to 71,376 hours due to a decrease in the number of respondents, from 261 to 190 which has resulted in a decrease in the number of submissions.

16. Plans for Tabulation and Publication and Project Time schedules

There are no plans to publish the results of the report relative to the new animal drug approval process.