OMB Control Number 0910-0453

SUPPORTING STATEMENT

GUIDANCE FOR INDUSTRY ON HOW TO USE E-MAIL TO SUBMIT A NOTICE OF FINAL DISPOSITION OF ANIMALS NOT INTENDED FOR IMMEDIATE SLAUGHTER

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

CVM monitors the final disposition of food animals treated with investigational drugs in situations where the treated animals do not enter the human food chain immediately at the completion of the investigational study. CVM's monitoring of the final disposition of such food animals is part of the acceptable standard of study conduct for Investigational New Animal Drugs (21 CFR 514.117(b)(2)). CVM issues a slaughter authorization letter to INAD sponsors which sets the terms under which animals treated with INADs may be slaughtered (21 CFR 511.1(b)(5)). Also in this letter, CVM requests that sponsors submit notice of final disposition of animals not intended for immediate slaughter (NFDA) for animals that are treated with investigational new animal drugs and are not intended for immediate slaughter. NFDAs have historically been submitted to CVM on paper. This guidance gives the sponsors the option to submit an NFDA as an e-mail attachment to CVM by the Internet.

The specific citations within 21 CFR 500 regarding information collection requirements for which we request OMB approval are:

21 CFR 514.117(b)(2) Adequate and well-controlled studies.

The study is conducted in accordance with an appropriate standard of conduct that addresses, among other issues, study conduct, study personnel, study facilities, and study documentation. CVM's monitoring of the final disposition of such food animals is part of the acceptable standard of study conduct for Investigational New Animal Drugs.

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.

2. Purpose and Use of the Information

CVM requests this information because some animals are held for 30 days after the investigational withdrawal period ends and thus are waived from having to submit a notification of intent to slaughter. Animals held for this period may still be sent for slaughter.

3. Use of Information Technology and Burden Reduction

In the Federal Register of March 20, 1997 (62 FR 13430), the FDA published the Electronic Records, Electronic Signatures final regulation. This regulation (21 CFR 11) provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. This rule also established public docket number 97S-0251 to provide a permanent location for a list of the documents or parts of the document that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. CVM will identify the NFDA in this public docket as a submission type which may be made in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

This information is not collected by any other Agency in the Government. The information collection required as a result of 21 CFR 514.117(b)(2) does not duplicate any other information collection.

5. Impact on Small Business or Other Small Entities

This information collection does not impact on small businesses.

6. Consequences of Collecting the Information Less Frequently

The information required under these regulations must be developed for each notice of final disposition of animals not intended for immediate slaughter. There is no time schedule for information collection. The frequency is set by the manufacturer production schedule.

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

The reporting requirements are consistent with 5 CFR 1320.5.

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

In the Federal Register of November 9, 2006 (71 FR 65827), FDA published a notice providing a 60 day comment period on this information collection. In response to that notice, no comments were received.

9. Explanation of Any Payment or Gifts to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondent

During working hours, only FDA employees have access to the computer files and database on a need to know basis. During duty and non-duty hours building security is provided through a contract with a private protection agency. None of these provisions bar the release of the confidential information if subpoenaed by a court of law. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act. Further, under the terms of the Freedom of Information Act, the sponsor's name, address, and phone number reported on FDA Form 3487 cannot be made available to a public request.

11. Justification for Sensitive Questions

This information does not contain questions pertaining to sex behavior, attitude, religious beliefs, or any other matter commonly considered private or of a sensitive nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

ESTIMATED ANNUAL REPORTING BURDEN[a]

21 CFR Section No./ FDA Form No.	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(5)/ Form FDA 3487	25	1.44	36	.08	2.88

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]A middle manger salary at $35/hour.

13. Estimate of Other Total Cost Burden to Respondents

CVM used a wage rate of $35.00 per hour, and multiplied times the total hour burden estimated above (2.88 hours), the total cost burden to respondents is $100.8 (2.88 hours X $35/hour).

14. Annualized Cost to the Federal Government

The cost to the federal government to receive and file notices (paper copy or e-mail) would be the essentially the same cost of burden to industry. A wage rate of $35.00 per hour is used and multiplied times the total hour burden estimated above (2.88 hours), the total cost to the Federal government is $100.8 (2.88 hours X $35/hour).

15. Explanation of Program Changes or Adjustments

There was a decrease (adjustment), in the number of burden hours based on FDA's review of submissions submitted from July 1, 2005 to June 20, 2006 and from previous discussions with sponsors regarding the time necessary to fill out this form.

16. Plans for Tabulation and Publication and Project Time Schedule
Information is not to be published for statistical use.