OMB Control Number 0910-0450

SUPPORTING STATEMENT

GUIDANCE FOR INDUSTRY ON HOW TO USE E-MAIL TO SUBMIT A NOTICE OF INTENT TO SLAUGHTER FOR HUMAN FOOD PURPOSES

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

Section 512(j) of the Federal Food, Drug, and Cosmetic Act, gives FDA the authority to set conditions under which animals treated with investigational new animal drugs may be marketed for food use. Under this authority, CVM issues a slaughter authorization letter to new animal drug sponsors (sponsors) which sets the terms under which animals treated with investigational new animal drugs may be slaughtered. USDA also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act, 21 USC 601-95. To assist CVM and USDA with monitoring, sponsors must submit slaughter notices each time such animals are to be slaughtered unless this requirement is waived in the Authorization letter. Submission of a slaughter notice to CVM and USDA is one of the sponsor's obligations to monitor investigational new animal drugs used in food animals. 21 CFR 511.1(b)(5), (9 CFR 309.17). Slaughter notices were previously submitted to CVM and USDA on paper. (OMB No. 0910-0117). This guidance gives sponsors the option to submit a slaughter notice as an e-mail attachment to CVM and USDA by the Internet.

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

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

Sponsors are requested to submit their slaughter notification to FDA and USDA at least 10 days prior to shipment for slaughter unless conditions outlined in the authorization letter waived this requirement.

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 slaughter notices 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

Information is collected from the sponsor as an e-mail attachment to CVM. The sponsor copies USDA the same information to avoid duplication.

5. Impact on Small Business or Other Small Entities

There is no impact on small business or other small entities.

6. Consequences of Collecting the Information Less Frequently

The information required under these regulations must be developed for notice of intent to slaughter for human food purposes. 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 8, 2006 (71 FR 65532) the 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 3488 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 3488	25	.08	2	.41	.82

[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.

Submitting a slaughter notice electronically represents a new medium for submission of information submitted on paper. The reporting burden for compilation and submission of this information on paper is included in OMB clearance of the information collection provisions of 21 CFR 511.1 (OMB No. 0910-0117). The estimates in the table above reflect the burden associated with putting the same information on FDA Form #3488 and resulted from discussions with sponsors about the time necessary to complete this form.

13. Estimate of Other Total Cost Burden to Respondents and Recordkeepers

CVM used a wage rate of $35.00 per hour, and multiplied times the total hour burden estimated above (.82 hours), the total cost burden to respondents is $28.7 (.82 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 (.82 hours), the total cost to the Federal government is $28.7 (.82 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 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.