Guidance for Industry #87 on How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to CVM

OMB No. 0910-0450

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary--Abstract

Section 512(j) of the Federal Food, Drug, and Cosmetic Act (the 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, the Center for Veterinary Medicine (CVM), issues to a new animal drug sponsor (sponsors) a slaughter authorization letter that sets the terms under which investigational animals may be slaughtered. The United States Department of Agriculture (USDA), also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act (21 U.S.C. 601-95). Sponsors must submit slaughter notices each time investigational animals are presented for slaughter, unless this requirement is waived by an authorization letter ((21 CFR 511.1(b)(5)), (9 CFR 309.17)). 21 CFR 511.1 governs investigational use of animals. FDA Form 3488 is the form to report the slaughter of investigational animals for human food use.

2. Purpose and Use of the Information Collection

These notifications assist CVM and USDA in monitoring the safety of the food supply. Slaughter notices were previously submitted to CVM and USDA on paper. CVM's guidance # 87 ``How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to CVM", (OMB No. 0910-0450) provides sponsors with the option to submit a slaughter notice as an e-mail attachment to CVM and USDA by the Internet. The likely respondents of this information collection are new animal drug sponsors (Private Sector).

3. Use of Improved Information Technology and Burden Reduction

The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submissions. This is in accordance with 21 CFR part 11, which provides for the voluntary submission of parts or all of regulatory records in electronic format without an accompanying paper copy. Approximately 93% of the slaughter notices from March 1, 2009 through April 1, 2010 were submitted electronically.

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 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 required under these regulations must be developed for notice of intent to slaughter for human food purposes. There is no time schedule for the information collection. The frequency is set by the manufacturer’s 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 the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the **Federal Register** on February 5, 2010. No comments were received.

9. Explanation of any Payment or Gift to Respondents

There were no payments or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

During working hours, only FDA employees have access to the computer files 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 Federal, Food, Drug and Cosmetic 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 commonly considered private or of a sensitive nature.

12.a. Estimates of Annualized Burden and Costs

Table 1.—Estimated Annual Reporting Burden1

Section of the act/FDA Form #	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
512(j)/3488	40	0.4	16[2]	.08	1.3

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Electronic submissions received between January 1, 2008, and December 31, 2008.

12.b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Costs
Industry compliance officer	1.3	$38	$49

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

There are no other costs to respondents.

14. Annualized Cost to the Federal Government

[1] 2006 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (www.bls.gov/oes/current/naics4_325400.htm) $29.27 hourly wage plus 30% adjusted for benefits

The cost to the Federal government to receive and file notices would be a wage rate for an average level reviewer (GS-13) $43 times 1.3 hours (the hourly burden to review is essentially the same hours as for industry) equals $60.

15. Explanation of Program Changes or Adjustments

There were no program changes or adjustments.

16. Plans for Tabulation and Publication of Project Time Schedule

Information is not to be published for statistical use.

17. Reasons Display of OMB Expiration Date is Inappropriate

Display is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.