

Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

**OMB Comment:** OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: [Karen.T.\\_Matsuoka@omb.eop.gov](mailto:Karen.T._Matsuoka@omb.eop.gov).

Dated: November 3, 2006.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 06-9111 Filed 11-7-06; 8:45am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0435]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on extending OMB approval on the existing

reporting requirements for the information collection activity entitled "How to Use E-mail to Submit a Notice of Intent to Slaughter For Human Food Purposes."

**DATES:** Submit written or electronic comments on the collection of information by January 8, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed

collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Guidance for Industry on "How to Use E-mail to Submit a Notice of Intent to Slaughter for Human Food Purposes," Section 512j, Federal Food, Drug, and Cosmetic Act; (OMB Control Number 0910-0450)—Extension

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)). 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. (OMB No. 0910-0450). CVM's guidance on "How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes" provides sponsors with the option to submit a slaughter notice as an e-mail attachment to CVM and USDA by the internet.

The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submissions.

The likely respondents are new animal drug sponsors.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses <sup>2</sup>	Hours per Response	Total Hours
FDA Form #3488	25	.08	2	0.41	.82

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup>Electronic submissions received between July 1, 2005 and June 30, 2006.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (25). The number of total annual responses are based on a review of the actual number of submissions made between July 1, 2005, and June 30, 2006.  $2 \times \text{hours per response} (.41) = .82$  total hours.

Submitting a slaughter notice electronically represents an alternative to submitting a notice of intent to slaughter 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. 0910-0450). The estimates in Table 1 of this document reflect the burden associated with putting the same information on FDA Form #3488 and resulted from previous discussions with sponsors about the time necessary to complete this form.

Dated: November 2, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0432]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the

PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on extending Office of Management and Budget (OMB) approval on the existing reporting requirements relating to how one may submit information electronically to the Center for Veterinary Medicine (CVM), using e-mail.

**DATES:** Submit written or electronic comments on the collection of information by January 8, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine—21 CFR 11.2 (OMB Control Number 0910-0454—Extension)

CVM accepts certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. CVM's guidance entitled "Guidance for Industry #108: "How to Submit Information in Electronic Format by E-Mail" outlines general standards to be used for the submission of any information by e-mail.

The likely respondents are sponsors for new animal drug applications.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses <sup>2</sup>	Hours per Respondent	Total Hours
11.2	25	5.62	140	.08	11.2

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Electronic submissions received between July 1, 2005, and June 30, 2006.