

Dated: February 2, 2010.

Jamison Citron,

Special Assistant, Office of Faith-Based and Neighborhood Partnerships.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0035]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format 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 the reporting requirements for the information collection on how to submit a notice of intent to slaughter for human food purposes in electronic format to the Center for Veterinary Medicine (CVM).

DATES: Submit written or electronic comments on the collection of information by April 6, 2010.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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 Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

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 Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to the Center for Veterinary Medicine—Section 512(j) of the 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) (21 U.S.C. 360b(j)) 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 to a new animal drug sponsor (sponsors) a slaughter authorization letter that sets the terms under which investigational animals may be slaughtered. The U.S. 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. 601-695). 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) and 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 in paper format. CVM's guidance on "How to Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to the Center for Veterinary Medicine" provides sponsors with the option for submitting 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 BURDEN¹

Section of the act/FDA Form #	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	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.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total

annual responses are based on a review of the actual number of submissions made between January 1, 2008, and December 31, 2008. Sixteen total annual

responses times .08 hours per response = 1.3 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 Control 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: January 29, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0043]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference in Electronic Format 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 the reporting requirements regarding how to use e-mail to submit a request for a meeting or teleconference in electronic format to the Center for Veterinary Medicine (CVM).

DATES: Submit written or electronic comments on the collection of information by April 6, 2010.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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 Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

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 Submit a Request for a Meeting or Teleconference in Electronic Format to The Center for Veterinary Medicine—21 CFR 10.65 (OMB Control Number—0910-0452)—Extension

CVM holds meetings and/or teleconferences when a sponsor requests a presubmission conference under 21 CFR 514.5, or requests a meeting to discuss general questions. Generally, meeting requests are submitted to CVM on paper. However, CVM now allows registered sponsors to submit information electronically, and to request meetings electronically, if they determine this is more efficient and time saving for them. CVM's guidance on "How to Submit a Request for a Meeting or Teleconference in Electronic Format to CVM" provides sponsors with the option to submit a request for a meeting or teleconference as an e-mail attachment by the internet.

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 BURDEN¹

21 CFR Section/FDA Form 3489	No. of Respondents	Annual Frequency per Response	Total Annual Responses ²	Hours per Response	Total Hours
10.64	40	2.4	96	.08	7.7

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.

The number of respondents in table 1 of this document is the number of sponsors registered to make electronic submissions (40). The number of total annual responses is based on a review of the actual number of such submissions made between January 1,

2008, and December 31, 2008, (96 x hours per response (.08) = 7.7 total hours).

Dated: January 28, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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