

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0435]

DDM

Display Date 2-15-07
Publication Date 2-16-07
Certifier A. Corbin

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

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 (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, 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 USC 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 via the Internet. The electronic submission of slaughter notices is part of CVM’s ongoing initiative to provide a method for paperless submissions.

In the **Federal Register** of November 8, 2006 (71 FR 65532), FDA published a 60-day notice soliciting comments on the information collection provisions of this collection. In response to this notice, no comments were received.

The likely respondents for this collection of information are new animal drug sponsors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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

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

²Electronic 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 is based on a review of the actual number of submissions made between July 1, 2005, and June 30, 2006 (2 x 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: 2/9/07

February 9, 2007.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

[Signature]