DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0035]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 June 1, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0450. Also include the FDA 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: 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 Submit a Notice of Intent to Slaughter for Human Food Purposes in Electronic Format to The Center for Veterinary Medicine—(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, FDA's Center for Veterinary Medicine (CVM) issues to a new animal drug sponsor (sponsor) a slaughter authorization letter that sets the terms under which animals treated with investigational new animal drugs 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. 601–95). Sponsors must submit slaughter notices each time animals treated with investigational new animal drugs 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 of submitting a slaughter notice to CVM and USDA via the Internet as an e-mail attachment. The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submission. The likely respondents are new animal drug sponsors.

In the **Federal Register** of February 5, 2010 (75 FR 6034), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the act/ FDA Form Number	Number of Respondents	Annual Frequency of Responses	Total Annual Responses[2]	Hours per Response	Total Hours
512j/3488	40	0.4	16	.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 on paper of intent to slaughter. The reporting burden for compilation and submission on paper of this information is included in OMB clearance of the information collection provisions of 21 CFR 511.1 (OMB number 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: April 27, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10084 Filed 4–29–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0600]

Guidance for Industry on Tobacco Health Document Submission; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 20, 2010 (75 FR 20606). The notice announced the availability of a guidance entitled "Tobacco Health Document