

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1505]

SMB

Display Date	<i>9/20/00</i>
Publication Date	<i>9/21/00</i>
Certifier	<i>SN Reese</i>

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 that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

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

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

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

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

Title: Guidance for Industry on How to Use E-Mail to Submit a Notice of Intent to Slaughter for Human Food Purposes

Description: Under § 511.1(b) (21 CFR 511.1(b)), the Center for Veterinary Medicine (CVM) issues slaughter authorizations for food animals treated with investigational new animal drugs. To assist with monitoring the slaughter of food animals treated with investigational new animal drugs, a slaughter authorization letter is sent to sponsors by CVM which states that they must submit slaughter notices each time such animals are to be slaughtered unless the authorization letter waives that notice. Currently, slaughter notices are submitted to CVM on paper (OMB Control No. 0910-0117). This guidance will give sponsors the option to submit a slaughter notice as an e-mail attachment to CVM by the Internet.

This final guidance describes the procedures for persons who are sponsors of new animal drugs and who wish to file a slaughter notice on FDA Form No. 3488 by e-mail. The information that should be filed on the form includes: Identification of the sponsor, the animals to be slaughtered, and the compound used to treat the animals.

Description of Respondents: The likely respondents for this collection of information are animal drug sponsors who have conducted clinical investigations under § 511.1(b). In the **Federal Register** of June 29, 2000 (65 FR 40106), FDA announced availability of this guidance as a draft document and requested public comment on the proposed collection of information. No comments were received on the estimated annual reporting burden. We therefore believe the annual reporting burden estimate of 27 hours should remain unchanged.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours Per Response	Total Hours
3488	190	0.35	66	0.41	27

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

Submitting a slaughter notice electronically represents a new medium for submission of information currently submitted on paper. The estimates in table of this document resulted from discussions with sponsors about the time necessary to complete this form.

Dated: September 14, 2000



William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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