TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
3487	12	27	324	0.81	262

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

Dated: December 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–347 Filed 1–7–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0509]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Study of Health Claim Disclaimers on Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Experimental Study of Health Claim Disclaimers on Foods'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 10, 2003 (68 FR 63802), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0531. The approval expires on June 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: December 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D–1314]

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 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.

DATES: Fax written comments on the collection of information by February 9, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (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—(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 issue regulations setting out the conditions for marketing animals treated with investigational new animal drugs for food use. Under this authority, FDA's regulations at § 511.1(b)(4) (21 CFR 511.1(b)(4)), provide that sponsors must obtain authorization to slaughter these animals for food. The Center for Veterinary Medicine (CVM) may grant such authorization to a sponsor under § 511.1(b)(5). If CVM authorizes the slaughter of investigational animals for food use, CVM issues a slaughter authorization letter to new animal drug sponsors which sets the terms under which such animals treated with investigational new animal drugs may be slaughtered. The authorization letter states that sponsors must submit slaughter notices each time such animals are to be slaughtered unless CVM waives this notice in the authorization letter. Currently, slaughter notices are submitted to CVM on paper. This guidance will give sponsors the option to submit a slaughter notice electronically as an e-mail attachment. The electronic submission of slaughter notices is part of CVM's ongoing initiative to provide a method for paperless submissions. The likely respondents to this collection of information are new animal drug sponsors who have conducted clinical studies under § 511.1(b).

In the **Federal Register** of August 7, 2003 (68 FR 47076), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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