

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0274]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Establishing and Maintaining a List of United States Dairy Product Manufacturers/Processors With Interest in Exporting to Chile

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 7, 2006 (71 FR 70972), 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 0910-0509. The approval expires on January 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 9, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-2708 Filed 2-15-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0435]

#### 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 March 19, 2007.

**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 BURDEN<sup>1</sup>

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

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

<sup>2</sup>Electronic 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: February 9, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-2710 Filed 2-15-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0050]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Label Comprehension Study

**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 a questionnaire to evaluate reader's comprehension of three versions of

condom labeling through a label comprehension study.

**DATES:** Submit written or electronic comments on the collection of information by April 17, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. 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 the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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 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.

#### Label Comprehension Study (U.S.C. 393(d)(2)(C))

FDA issued the "Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex" on November 14, 2005 (70 FR 69156). Section 21 U.S.C. 393(d)(2)(C) of the Federal Food, Drug and Cosmetic Act (the act) states that the Secretary, through the Commissioner, shall be responsible to conduct research relating to devices in carrying out this chapter. In order to evaluate the understandability of the condom labeling language currently on the market and the labeling language proposed in this draft guidance, as well as a future revised version of the labeling, FDA plans to evaluate readers' comprehension of three versions of condom labeling through a label comprehension study.

The proposed label comprehension study will measure current and potential condom consumers' understanding of the current market labeling and the proposed condom labeling in the draft guidance of the retail package, foil and package insert of condom labeling, as well as a future revised version of the labeling. The label comprehension study will follow a sequential design, first testing both the current market labeling (Part A) and the draft labeling in the guidance (Part B) in Stage 1, and then a revised version of the labeling in Stage 2.

FDA will conduct a label comprehension study via a mall intercept/central location intercept methodology with pre-screened participants. FDA will administer a screening instrument, the REALM (Rapid Estimate of Adult Literacy in Medicine) test, an informed consent, and a questionnaire with approximately 20 questions related to the condom labeling language to a total of 1,200 participants: 400 participants for Part A of Stage 1, 400 participants for Part B of Stage 1, and 400 participants for Stage 2 of the study. Results of the study will be considered in FDA's condom labeling recommendations to provide important risk/benefit and use information associated with condoms in an easily understood language.

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