[2]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]

BILLING CODE 4160–01–S

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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screening Tool	3,300	1	3,300	.05	165
Stage 1: Part A—REALM test; Informed Consent; Read Labeling; Questionnaire	400	1	400	.45	180
Stage 1: Part B—REALM test; Informed Consent; Read Labeling; Questionnaire	400	1	400	.45	180
Stage 2—REALM test; Informed Consent; Read Labeling; Questionnaire	400	1	400	.45	180
Total	.....	.....	.....	.....	705

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

This was based on similar types of FDA studies conducted in the past. FDA has conducted both focus group studies and label comprehension studies, where similar participant activities, such as reading the labeling, taking the REALM test, signing the informed consent, and answering questions on a self-administered questionnaire took place. In order to achieve the 1,200 participants for the condom label comprehension study, FDA estimates screening 3,300 to achieve 1,200 interviews.

Dated: February 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–2716 Filed 2–15–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0355]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Exception From General Requirements for Informed Consent

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.

Medical Devices; Exception From General Requirements for Informed Consent—(OMB Control Number 0910–0586)—Extension

In the **Federal Register** of June 7, 2006 (71 FR 32827), FDA issued an interim final rule (hereinafter referred to as the June 7, 2006, interim final rule) to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The agency took this action because it is concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

FDA requested public comment on the information collection requirements in the June 7, 2006, interim final rule.

The collection of information requirements for the June 7, 2006, interim final rule were approved under the emergency processing provisions of the Paperwork Reduction Act (PRA), and assigned OMB control 0910–0586. With this approval, OMB informed the agency that the preamble and solicitation of public comment by the June 7, 2006, interim final rule would serve as a 60-day notice for the 3 year extension of this collection of information. In addition, OMB also requested that FDA, in submitting its extension request, summarize comments received in response to the 60-day notice, describe how the agency will address substantive issues raised by the commenters, and provide an update on the status of the final rule. FDA is responding to OMB's requests below:

FDA received 10 comments on the interim final rule, three of which related to the information collection requirements. The other comments on the rule will be addressed in the preamble to the final rule. FDA expects to publish the final rule in 2009.

One comment suggested that the requirement that a laboratory certify to an institutional review board (IRB) that the testing was done in a life-threatening situation and that it was not feasible to obtain consent serves no purpose, since these issues have already been pre-determined by FDA and provide the basis for exemption. FDA disagrees. The certification requirement ensures that the laboratory documents for the IRB that it is complying with the requirements of the regulation. The comment also stated that the concurrence of an independent physician, which will occur post-