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, including each proposed extension of an existing 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.

Animal Drug User Fee Cover Sheet; FDA Form 3546; 21 U.S.C. 379j–12 (OMB Control Number 0910–0539)—Extension

Under Section 740 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12), as amended by the Animal Drug User Fee Act of 2003 (ADUFA), FDA has the authority to assess and collect for certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet, FDA Form 3546, is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made, is appropriately linked to that payment. The form, when completed electronically, will result in the generation of a unique payment identification number used for tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

Respondents to this collection of information are new animal drug sponsors, applicants, or manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 U.S.C. 379j–12	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
740(a)(1) FDA Form 3546 (Cover Sheet)	69	1 time for each application	69	1	69

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

Based on FDA's database system, there are an estimated 140 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 2003. The Center for Veterinary Medicine estimates 69 annual responses that include the following: 28 new animal drug premarket approval applications and 41 supplements. The estimated hours per response are based on past FDA experience with the various submissions, and range from 30 minutes to 1 hour. The hours per response are based on the average of these estimates.

Dated: June 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11527 Filed 6–14–07; 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; Submission for Office of Management and Budget Review; Comment Request; Label Comprehension Study

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 July 16, 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. All comments should be identified with the OMB control number 0910–NEW and title ''Label Comprehension Study.'' Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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. The FDA will administer a screening instrument, the Rapid Estimate of Adult Literacy in Medicine (REALM) 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.

In the **Federal Register** of February 16, 2007 (72 FR 7661), 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:

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: June 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11528 Filed 6–14–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub.