Supporting Statement for:
Survey of Need for Condom Label Comprehension Study (Part A)

A. JUSTIFICATION

1. Need and Legal Basis

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) is the regulatory Agency responsible for the safety and effectiveness of a variety of health products including medical devices and radiological products. The FDA Commissioner is authorized to undertake this collection under 21 USC 393 (Attachment A). Condoms are devices that were on the market prior to the enactment of the Medical Device Amendments of 1976 and were intended for contraceptive and prophylactic (preventing transmission of sexually transmitted diseases (STDs)) uses. Condoms with spermicidal lubricant containing nonoxynol-9 (N-9) have been required to bear a contraceptive effectiveness statement. Condoms are subject to specific labeling requirements and recommendations.

FDA believes that adherence to the labeling recommendations, in addition to general already-established controls, will provide reasonable assurance of the safety and effectiveness of latex condoms. In response to a 2000 Congressional mandate, the FDA published a draft guidance document for latex condom manufacturers to propose more specific condom packaging labels and to provide more accurate information about the product's effectiveness. The FDA issued its *Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex* on November 14, 2005 (70 FR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). The mandate required the FDA to review the medical accuracy of claims that condoms can prevent STDs. The agency concluded that condoms provide less protection against certain STDs that spread through contact with infected skin outside the area covered by a condom. In this document, FDA proposed amended classifications that would provide special controls guidance for male condoms made from natural rubber latex. The draft special controls guidance recommends labeling to inform users about the extent of protection provided by condoms against unintended pregnancy and against various types of STDs, as well as information about possible risks associated with exposure to N-9 contained in the spermicidal lubricant of some condoms. The labeling recommendations provide important information for condom users to assist them in determining whether latex condoms are appropriate for their needs and, if so, to determine whether a condom with or without N-9 lubricant is most suitable. FDA believes that this draft guidance is an appropriate special control to help provide reasonable assurance of the safety and effectiveness of latex condoms and latex condoms with spermicidal lubricant containing N-9.

The labeling recommendations in the guidance reflected an extensive review on the part of FDA, in consultation with the National Institutes for Health (NIH) and the Centers for Disease Control and Prevention (CDC), of the available medical literature on the safety and effectiveness of condoms intended to prevent pregnancy and protect against STDs.

In order to evaluate the understandability of the condom labeling language currently on the market and the labeling language proposed in the draft guidance, as well as a future revised version of the labeling, FDA plans to evaluate readers' comprehension of three (3) versions of condom labeling through a label comprehension study.

The label comprehension study will follow a sequential design, first testing both the current market labeling (Part A) and the draft proposed labeling in the guidance (Part B) in Stage 1, and then a future revised version of the labeling in Stage 2. The future revised version of the labeling will be a revision of the proposed labeling.

2. Information Users

A contracted research firm will conduct this study for FDA. They will recruit participants using a screening tool, and conduct a label comprehension study via a mall intercept/central location intercept methodology. See section B.1. for screening criteria. The contractor will administer a questionnaire related to the condom labeling. FDA will use this information to revise the condom labeling that will provide condom consumers with consistent warnings and labels addressing the important risk and use issues associated with condoms in easily understood language.

3. Improved Information Technology

Automated information technology will be used in the collection of information for this study. The contractor will collect data during face-to-face interviews using a Computer Assisted Personal Interview (CAPI) program. The contractor will read questions and possible answer choices. Some questions are read without answer choices and the participants answer choices will be recorded based on the interviewer's observations. Responses to the questionnaire will be recorded by the contractor using this program. The randomization of answer choices that are read to the participant will be performed by the CAPI software.

In addition to its use in data collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time basis for each respondent, and by keeping interviews to 30 minutes. The contractor's experience suggests improvement times of 20% or greater between computer assisted interviews and paper based interviews.

4. Duplication of Similar Information

   In 2004, FDA conducted four focus groups during the development of the draft proposed condom labeling. The groups were designed to determine the understanding, perceptions, opinions, beliefs, and attitudes toward condom labeling messages.

   Many comments received for the draft guidance document stated that the proposed labeling language was overly complicated, confusing, or misleading. Although the focus group study provided a formative evaluation of the draft proposed condom labeling, the label comprehension study will allow for a more precise targeting of the specific labeling language areas that need revision in the future revised version of the labeling. Whereas a focus group is a qualitative study providing a general discussion of key areas, the one-to-one interview of each individual within the quantitative label comprehension study will give more specific feedback on comprehension.

   From this label comprehension study we hope to get a clear picture of 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. Specifically, this study will determine the clarity of labeling related to unintended pregnancy, sexually transmitted disease (STD) risk, proper condom use, and N-9 spermicidal lubricant by assessing the respondent's understanding and awareness of these issues.

5. Small Businesses

   This collection does not involve small businesses. Data collected will be a collection of consumers' responses.

6. Less Frequent Collection

   This is a one-time collection.

7. Special Circumstances

   This survey does not have any special circumstances, according to 5 CFR 1320.5(d)(2).

8. *Federal Register* Notice/Outside Consultation

   In accordance with 5 CFR 1320.8(d), on Friday, February 16, 2007, in Volume 72, No. 32, page 7661, a 60-day notice for public comment (Attachment B) was published in the *Federal Register*. No comments were received from the public.

9. Payment/Gift to Respondent

   Compensation is provided to motivate users to take a few moments to complete the study. In addition, FDA recognizes that the public's time is valuable.

   Participants recruited at malls, who complete the study, will receive payment of $10. If a sufficient number of low literates are not recruited from standard mall intercept sites, recruitment from non-standard sites will be used. Specifically, the over sample of low literates will be recruited from two geographies: Philadelphia (e.g., literacy centers) and Mississippi (e.g., pharmacies), with two sites in each locality. Participants from non-standard sites, who complete the study, will receive payment of $20. The reason for the higher payment for the low-literacy population is that this population is more difficult to recruit.

10. Confidentiality

    Prior to any data collection, individuals will be asked to sign an informed consent (Attachment C) advising the following: the nature of the activity, the purpose and use of the data collection, all responses will remain anonymous and completely confidential, names will not be used in any reports, information collected is for research only, and the fact that participation is voluntary at all times. Participants' names will not be on the survey questionnaire. All records containing participants' names will not be transmitted to the FDA and will be destroyed after the final report is completed to ensure anonymity of participants.

11. Sensitive Questions

    The contractor will screen for potential participants who are able to read English, who are between the ages of 18-54, and those who have used or would consider using male latex condoms.

    The questionnaire includes questions about sexually transmitted diseases and condom use. Participants' sexual orientation and sexual practices will not be judged in this study. The questionnaire will not ask participants any personal questions (e.g., a sexual behavior or religious beliefs). Participants will be asked to base their answers on their understanding of what they read in the condom labeling. Evaluating condom users' understanding of the condom labeling will allow FDA to provide important risk/benefit and use information associated with condoms in an easily understood language. The decision to conduct a label comprehension study was in direct response to the comments we received on the labeling language proposed in the draft guidance. Because we received a significant number of comments that told us our proposed labeling language was overly complicated, confusing or misleading, we decided to conduct the label comprehension study to hone in on the areas of the labeling that may be problematic.

12. Burden Estimates (Total Hours and Wages)

The estimated total hour burden of the information collection is 709 hours. The burden includes nine 30 minute interviews to pretest the final questionnaire. The study will have five parts: a screening tool, REALM (Rapid Estimate of Adult Literacy in Medicine) test, informed consent, reading the labeling, and a questionnaire. The times estimated for participants to complete the screening and the study, respectively, are 3 and 25 minutes, based on in-house testing and similar FDA label comprehension studies. There are no direct costs to respondents other than their time to participate in the study.

Estimated Annual Reporting Burden[1]					
Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	9	1	9	.45	4.05
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					709

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

13. Capital costs and operating and maintenance costs

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

14. Cost to Federal Government

    Total data collection costs by the contractor will be $279,436.40. This figure represents a total cost for pretest, screening participants, administer the questionnaire, incentive payment, data entry, analysis, and prepare reports.

15. Program or Burden Changes

    This is a new collection.

16. Publication and Tabulation Dates

    Data collection will begin as soon as logistically possible after OMB approval is obtained.

    The data will be tabulated and analyzed to examine consumers understanding of the current, proposed, and future revised condom labeling. The issues covered in the questionnaire include: unintended pregnancy, STD risk, proper condom use, and N-9 spermicidal lubricant.

    The label comprehension study will follow a sequential design, first testing both the current market labeling (Part A) and the draft proposed labeling in the guidance (Part B) in Stage 1, and then a future revised version of the labeling in Stage 2. The future revised version of the labeling will be a revision of the proposed labeling. The Contractor will write reports for each stage of data collection (Stage 1 and Stage 2). Analysis of Part A & B questionnaires and final report writing for Stage 1 will take 17 weeks from the start of Stage 1 participation. Analysis of questionnaires and final report writing for Stage 2 will take 14 weeks from the start of Stage 2 participation.

Activity	Date
Begin Stage 1 of Study	July 2007, or as soon as logistically possible after OMB approval is obtained
Analysis and Report of Stage 1	17 weeks from the start of Stage 1 participation (November 2007)
Begin Stage 2 of Study	January 2008
Analysis and Final Report	14 weeks from the start of Stage 2 participation (April 2008)

It is anticipated that the findings from this study will be presented in FDA reports and may include publications and Internet posting.

17. Display of OMB Approval Date

The OMB number and expiration date will be listed on the questionnaires.

18. Exceptions to "Certification for Paperwork Reduction Act Submissions"

None