SS – LABEL COMPREHENSION STUDY – PART B

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1. Respondent Universe and Sampling Methods

In this experimental study, a total of 1,200 participants: 400 participants for Part A of Stage 1, 400 participants for Part B, Stage 1 and 400 participants for Stage 2 of the study, utilizing 6 sites for the mall intercept label comprehension study per study stage (i.e. a total of 12 sites). In order to achieve the 1,200 participants for the condom label comprehension study, 3,300 individuals need to be screened to potentially achieve 2,400 to be eligible. Of the 2,400 eligible individuals, we predict 1,200 would be willing to participate. A 50% willingness to participate is typical, particularly in relation to the low-literacy population. The ultimate population should reflect diversity in rural/urban/suburban geographies, socioeconomic status, race/ethnicity and education levels as normally present in the targeted populations.

Each population of 400 subjects should have a breakdown into two literacy groups (as defined in the Rapid Estimate of Adult Literacy in Medicine (REALM) administration procedures). The REALM test considers those who get 6 or more wrong at the $7^{th}/8^{th}$ grade level or lower (low literates). There are 66 words in the REALM test, so the participant will have to get 60 or more correct to be at the 9^{th} grade and above (normal literates).

(1) **General Population** cohort, made up of "normal literates" (those with reading levels at or above the 9^{th} grade level) – **200** of the 400 subjects will be in the general population of “normal literates”

(2) **Low Literacy cohort** (those with reading levels at, or below, the 7^{th} to 8^{th} grade level), which is made up of the low literate subjects – **200** of the 400 subjects will be in the low literacy cohort

These figures reflect a 50% - 50% split between normal literates and low literates, based on the National Assessment of Adult Literacy.

Mall intercepts will take place in at least 3 different geographic areas in the country with 2 sites per area, totaling 6 sites per study stage. The Stage I mall intercepts will be from sites in New York, New Jersey, Michigan and Texas, and Stage II mall intercepts will be from sites in Maryland, New Jersey, Ohio and Tennessee. Given that 200 of the respondents need to be low literate subjects and higher levels of low literacy are present among lower income households, mall intercept sites should include sites located in low-income areas. If a sufficient number of low literates are not recruited from standard

mall intercept sites, the Contractor will recruit from non-standard sites (Philadelphia and Mississippi).

The participants for all groups must meet the criteria listed in the screener. Participants will be excluded if:

- they are under 18 years of age or over 54 years of age
- they cannot read printed materials in English
- they have never used or considered using male latex condoms
- they or a household member worked for the FDA, NIH or CDC
- they or a household member trained or work in a professional health care field,
- they or a household member work for a drug or medical device manufacturer
- they or a household member work for a market research company.
- they participated in any other research study within the past two (2) months.

B.2. Procedures for the Collection of Information

Our contractor will use a screening tool to select 400 participants for Part A of Stage 1, 400 participants for Part B of Stage 1 and 400 participants for Stage 2. The screening tool will be administered for each potential respondent. Those qualified will be provided informed consent and administered the REALM assessment and categorized as "normal" or "low" literate.

The Contractor will randomize by rotating between the current and proposed label in Stage 1 (i.e., label 1 – label 2 – label 1 – label 2, etc.). (Stage 2 will only be testing 1 version – the future revised version of the labeling.) The participant will then read the condom labeling. Participants are told they may refer back to the condom package information at any time to answer questions.

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. In addition, the participant will receive a card with each question but not the answer choices. Some questions are read without answer choices and the participants answer choices will be recorded based on the interviewer's observations. The randomization of answer choices that are read to the participant will be performed by the CAPI software. Responses to the questionnaire will be recorded by the contractor using this program.

The total time for screening, administering the REALM, informed consent, reading the labeling, and completing the questionnaire is estimated to be approximately 30 minutes.

B.3. Methods to Maximize Response Rates

If a sufficient number of low literates are not recruited from standard mall intercept sites, the Contractor will recruit from non-standard sites (Philadelphia and Mississippi). At least two sites in each area will be utilized to develop an oversample of low literates to achieve the objective of recruiting and interviewing 200 low literates per each stage of the study (i.e., Part A of Stage 1, Part B of Stage 1 and Stage 2).

The contractor will provide an incentive payment of $10 to participants recruited at malls, and $20 to the low-literate over-sample recruited from non-standard sites who complete the questionnaire. The reason for the higher payment for the low-literacy population is that this population is more difficult to recruit.

B.4. Tests of Procedures or Methods

The contractor will pretest the questionnaire with 9 participants. The pretest will replicate the main experimental study. Respondents participating in the pretest will be intercepted in a mall, screened, provided informed consent, administered the REALM, read the condom labeling, and administered the questionnaire. Furthermore, the interviewer will ask cognitive interview type questions after the participant finishes the questionnaire. The questions asked after the interview are typically based on what the participant answered in the interview, e.g., "On question 2 you answered "…" (wrong answer), could you explain why you thought that?" The objective will be to gain enough feedback from the pretest on the questionnaire and protocol procedures. The pretest will help to determine if any questions on the questionnaire need to be modified and, if so, what the nature of those modifications would be.

B.5. Individuals Consulted on Statistical Aspects and Information Collection

The following individuals were consulted on the statistical aspects of the condom label comprehension study:

Richard Kotz, CDRH, 240-276-3152
Hesha Jani Duggirala, Ph.D., CDRH, 240-276-2341
Susanna Weiss, Ph.D., CDER, 301-796-1020
Kathryn Aikin, Ph.D., CDER, 301-796-1200
Chung-Tung (Jordan) Lin, CFSAN, 301-436-1831

The contacts for the contractor, M. Davis and Company, Inc. are Morris Davis and Ron Campbell (917) 783-1501.