

TO: Brenda Aguilar, FDA—OMB Desk Officer

Through: Denver Presley, FDA – PRA Team

FROM: Paula Silberberg, FDA, CDRH

DATE: August 15, 2007

SUBJECT: Condom Label Comprehension Study: Response for OMB

This memo addresses comments and revisions we received from OMB. The attached documents incorporated most of the suggested revisions. We would be glad to discuss any response further by a conference call, if there is need for further clarification.

We made revisions on the revised questionnaires, rather than the older ones that were submitted originally, before the pre-testing was conducted. This should make it easier for the review of the updated questionnaires, rather than the older ones that were reviewed. The revised questionnaires had some of the questions re-ordered, and I have provided the new numbering scheme in the discussion below. If there was a revision that we did not think appropriate to change, we addressed it in this memorandum.

1. **Informed Consent:** “You will be paid \$20 for participating in the survey. The payment will be given at the end of the survey.”

“Participating” rather than “completing” is accurate. If the participant withdraws from the survey, we will still provide the payment.

2. **Current Labeling Questionnaire:**

**Screener: Question #3** Have you ever used or would you consider using male latex condoms with a past, current or future partner?

This screening question is critical to the survey, as we need to recruit people who would consider condom use, as this is the target audience for the labeling. It is not specifically asking about their sexual behavior, as the tense allows for the consideration of future use. If we were not to ask this screening question, we could potentially recruit people who would never consider using condoms.

**Questionnaire #1** - This question is now #6 and was revised after the pre-testing.

**Questionnaire #5 and #6** – These are now questions #2 and #3. We prefer to leave in the phrase “transmission of” because this is the language in the current labeling. Just as the proposed labeling uses the phrase “catching or spreading,” we would like to keep a parallel verb construction between the 2 questionnaires.

In label comprehension studies, matching the wording in the questions to the wording in the labeling is advised.

**Questionnaire #9** – This question was deleted after the pre-testing. During pre-testing, participants did not offer suggestions for making the package information easier to understand. The preceding question that asks participants if they found any words or phrases they did not fully understand or thought were a little confusing gave us the most valuable information.

### **3. Proposed Labeling Questionnaire:**

**Screener: Question #3 – same as screener response above.**

**Questionnaire #2** - This question is now #13 and was revised after the pre-testing.

**Questionnaire #5** – This question is now #2. We prefer to use the term “catching” rather than “contracting,” because this is the exact language from the proposed labeling. In label comprehension studies, matching the wording in the question to the wording in the labeling is advised.

**Questionnaire #8** – This question is now #3. (See response above.)

**Questionnaire #9** – This question is now #8 and was revised after the pre-testing. We incorporated the “in each pair” change, but still prefer to use “catching” from the labeling language.

**Questionnaire #16** – This question was deleted after the pre-testing. During pre-testing, participants did not offer suggestions for making the package information easier to understand. The preceding question that asks participants if they found any words or phrases they did not fully understand or thought were a little confusing gave us the most valuable information.

### **4. Proposed Labeling (XYZ Package Insert):**

We cannot change the draft proposed labeling from the draft guidance document for the study because this is exactly what we want to test. After we complete Stage I of the study and analyze the results, we will revise the labeling for Stage II. At that time, we can make revisions to the labeling based on study results and comments received about the labeling.