Exit Form Instructions EXT Version A: 01/09/09

QxQ Date: 01/26/09

I. GENERAL INSTRUCTIONS

The purpose of the Exit form (EXT) is to obtain information on how well vitamin treatment assignment was masked to the participant, investigator and study coordinator.

This form should be completed at the participant's last visit after all FAVORIT forms and procedures have been completed. A clinic visit is preferred for the last visit however, a telephone contact is acceptable. For participants who did not agree to extend follow-up past the original five years and the participant has already completed the fifth year contact then you will need to telephone the participant and complete the EXT.

Prior to completing the EXT form, interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures. The form header information (ID, Contact Occasion, Sequence Number, Last Name and Initials) is completed as described in that document.

II. SPECIFIC INSTRUCTIONS

A. Study Coordinator's Guess

- 1. Record what vitamin dose you think the participant was taking. Even if you do not know, guess the dose they were on.
- 2. Record how certain you are that the participant was on that dose. If you are uncertain then record "U" and skip to item 4.
- 3. Record the reasons why you think the participant was on that dose.

IMPORTANT: These results regarding the success or failure of blinding will be published. Interviewers must be careful not to bias the participant's response with their opinions, and record their own response <u>before</u> asking the participants for their response.

B. Participant's Guess

- 4. Record what vitamin dose the participant thinks they were taking. Even if they do not know, ask that they guess the dose they were on.
- 5. Record how certain they are that they were on that dose. If they are uncertain record "U" and skip to item 7

6. Record the reasons why the participant thinks they were on that dose.

C. Administrative Information

- 7. Record date of data collection.
- 8. Record the method of data collection, either paper or computer direct entry.
- 9. Record the data collector's initials.