

Site Number: _____ Screening ID: _____ - ____ Participant Letters: _____

The Study Coordinator should complete this form for changes in participant’s study status. Do NOT complete this form for participants who are inactive.

A. VISIT INFORMATION

Missed Visit Identification Number: _____

1. Which visit was missed? (*check one*)

- | | | | | | | | |
|-----------------------------|--|-----------------------------|---------------|-----------------------------|---------------|-----------------------------|---------------|
| <input type="checkbox"/> 1 | Entry A: Infant Screening | <input type="checkbox"/> 3 | 3 Months old | <input type="checkbox"/> 18 | 18 Months old | <input type="checkbox"/> 42 | 42 Months old |
| <input type="checkbox"/> 2 | Infant Enrollment | <input type="checkbox"/> 6 | 6 Months old | <input type="checkbox"/> 21 | 21 Months old | <input type="checkbox"/> 48 | 48 Months old |
| <input type="checkbox"/> 93 | Infant Enrollment combined with 3 Months Old | <input type="checkbox"/> 9 | 9 Months old | <input type="checkbox"/> 24 | 24 Months old | | |
| <input type="checkbox"/> 94 | Infant Enrollment combined with 6 Months Old | <input type="checkbox"/> 12 | 12 Months old | <input type="checkbox"/> 30 | 30 Months old | | |
| <input type="checkbox"/> 95 | Entry A Infant Screening combined with Infant Enrollment | <input type="checkbox"/> 15 | 15 Months old | <input type="checkbox"/> 36 | 36 Months old | | |

B. PARTICIPANT INFORMATION

1. Has there been any contact with the participant for the missed visit? Y N

If YES,

a. What was the primary reason for the missed visit? (*check one*):

- 1 Illness, surgery, or hospitalization (*If checked, must fill out Adverse Event Report Form (NPP23)*)
- 2 Out of region
- 3 Conflicting responsibilities (*e.g. job, family*)
- 4 Subject no longer wishes to participate in the study
- 99 Other

1) If Other, specify: _____

2. Is the participant expected to continue with future follow-up visits? Y N

If YES,

a. Is the participant (mother/ baby) willing to continue taking the study substance? Y N

If NO, complete Study Substance Dispensation and Return Form (NPP15) and Participant Status Form (NPP18).

Initials (first, middle, last) of person completing this form: _____
F M L

Date form completed: _____
DAY MONTH YEAR

*On all questions write “?” if the desired information is currently unavailable, but is being checked and will be known in future updates.
Write “*” if the desired information is permanently unavailable (i.e. will not be known in any future updates).*