

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

The Study Coordinator should complete this form at the Entry A Infant Screening, Entry A Infant Enrollment, 3, 6, 9, and 12 months and every 3 months thereafter. Complete this form while the mother or participant (infant) is taking study substance or until the participant reaches 36 months of age.

A. VISIT INFORMATION

1. Date of visit (e.g. 05/Sep/2006):

____/____/____
DAY MONTH YEAR

2. Visit: (check one)

<input type="checkbox"/> 91 Pregnant Woman Screening/ Enrollment	<input type="checkbox"/> 95 Entry A Infant Screening combined with Infant Enrollment	<input type="checkbox"/> 12 12 Months old	<input type="checkbox"/> 30 30 Months old
<input type="checkbox"/> 92 Delivery	<input type="checkbox"/> 3 3 Months old	<input type="checkbox"/> 15 15 Months old	<input type="checkbox"/> 36 36 Months old
<input type="checkbox"/> 1 Infant Screening	<input type="checkbox"/> 6 6 Months old	<input type="checkbox"/> 18 18 Months old	
<input type="checkbox"/> 2 Infant Enrollment	<input type="checkbox"/> 9 9 Months old	<input type="checkbox"/> 21 21 Months old	
<input type="checkbox"/> 96 Non-Qualified Debriefing Visit		<input type="checkbox"/> 24 24 Months old	

B. INFANT FORMULA COMPLIANCE INFORMATION

1. Was the study formula prescribed for the infant since the last study visit?

Y N

2. Did the infant take any study infant formula since the last study visit?

Y N

If NO, skip to B3.
If YES,

a. How often did the baby take the following study formula amounts (check one per line)?

Amount of Study Formula	Didn't take	A few days per month	1-3 days per week	4-6 days per week	Every day
	1) ≤ 16 oz. per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
2) 16 to 32 oz. per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
3) ≥ 32 oz. per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

b. Since the last study visit, did the infant discontinue taking study formula at any time?

Y N

If YES,

1) When did the infant discontinue taking study formula (e.g. Sep/2006)?

____/____
MONTH YEAR

2) Explain why the infant discontinued taking study infant formula:

3. Since the last study visit, has the infant consumed non-study infant formula?

Y N

If YES,

a. What brand of infant formula was given?

b. How much was given on average per day?

____ ounces

*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).*

Site: _____ Screening ID: _____ - _____ Letters: _____ Visit Date: ____/____/____

B. INFANT FORMULA COMPLIANCE INFORMATION (CONTINUED)

c. For how long? _____ days

d. Explain why the infant is taking non-study infant formula:

4. Has the infant re-started study formula following a period of interruption? Y N

IF YES, a. Date infant re-started study formula: _____
DAY MONTH YEAR

C. CAPSULES COMPLIANCE INFORMATION

1. Were study capsules prescribed for the infant since the last study visit? Y N

2. Did the infant take any study capsules since the last study visit? Y N

If YES,

a. How often did the baby take the following study capsule amounts (*check one per line*)?

# of Capsules	Didn't take	A few days per month	1-3 days per week	4-6 days per week	Every day
	1) 1 Capsule per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4
2) 2 Capsules per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

b. Since the last study visit, did the infant discontinue taking study capsules at any time? Y N

If YES,

1) When did the infant discontinue taking study capsules? _____
MONTH YEAR

2) Explain why the infant discontinued taking study capsules:

c. Has the infant re-started study capsules following a period of interruption? Y N

IF YES, 1) Date infant re-started study capsules: _____
DAY MONTH YEAR

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Site: _____ Screening ID: _____ - _____ Letters: _____ Visit Date: ____/____/____

C. CAPSULES COMPLIANCE INFORMATION (CONTINUED)

3. Were study capsules prescribed for the mother since the last study visit? Y N
4. Did the mother take any study capsules since the last study visit? Y N

If YES,

a. How often did the mother take the following study capsule amounts (*check one per line*)?

# of Capsules					
	Didn't take	A few days per month	1-3 days per week	4-6 days per week	Every day
1) 1 Capsule per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
2) 2 Capsules per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
3) 3 Capsules per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
4) 4 Capsules per day	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

- b. Since the last study visit, did the mother discontinue taking study capsules at any time? Y N
- If YES,

- 1) When did the mother discontinue taking study capsules? ____/____/____
MONTH YEAR
- 2) Explain why the mother discontinued taking study capsules:

- c. Has the mother re-started study capsules following a period of interruption? Y N

IF YES, 1) Date mother re-started study capsules: ____/____/____
DAY MONTH YEAR

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

Date form completed: ____/____/____
DAY MONTH YEAR

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