

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

The Study Coordinator should complete this form for every dispensation and/or return of study substance.
For Entry A participants: Dispense first time at end of Pregnant Woman Enrollment Visit.
For Entry B participants: Dispense first time at end of Infant Enrollment Visit.
Complete this form at unscheduled visits if study substance is dispensed or returned.

A. REPORT INFORMATION

1. Report date (e.g. 05/Sep/2006): _____ / _____ / _____
DAY MONTH YEAR

2. Last attended scheduled 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"/> 3 3 Months old | <input type="checkbox"/> 21 21 Months old |
| <input type="checkbox"/> 92 Delivery | <input type="checkbox"/> 93 Infant Enrollment combined with 3 Months Old | <input type="checkbox"/> 6 6 Months old | <input type="checkbox"/> 24 24 Months old |
| <input type="checkbox"/> 1 Infant Screening | <input type="checkbox"/> 94 Infant Enrollment combined with 6 Months Old | <input type="checkbox"/> 9 9 Months old | <input type="checkbox"/> 30 30 Months old |
| <input type="checkbox"/> 2 Infant Enrollment | | <input type="checkbox"/> 12 12 Months old | <input type="checkbox"/> 36 36 Months old |
| <input type="checkbox"/> 96 Non-Qualified Debriefing Visit | | <input type="checkbox"/> 15 15 Months old | <input type="checkbox"/> 42 42 Months old |
| | | <input type="checkbox"/> 18 18 Months old | <input type="checkbox"/> 48 48 Months old |

B. RETURN OF STUDY SUBSTANCE

1. Was study substance returned? Y N

If NO, skip to Section C.

2. Date study substance returned: _____ / _____ / _____
DAY MONTH YEAR

3. Randomization Color returned (check one): 1 Yellow 2 Orange 3 Red 4 Gray

4. What study substance is being returned (check all that apply):

- 1 a. Capsules
- 1) Record number of capsules returned: _____ capsule(s)
- 1 b. Formula (unopened cans)
- 1) Record number of unopened cans returned: _____ can(s)

C. REMAINING STUDY SUBSTANCE FROM LAST DISPENSATION

1. Was study substance remaining with participant? Y N

If NO, skip to Section D.

2. What study substance is remaining (check all that apply):

- 1 a. Capsules
- 1) Record number of capsules remaining: _____ capsule(s)
- 1 b. Formula (unopened cans)
- 1) Record number of unopened cans remaining: _____ can(s)

*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).*

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D. DISPENSATION OF STUDY SUBSTANCE

1. Was new study substance dispensed? Y N
 If NO, skip to Section E.

2. Date study substance dispensed: _____ / _____ / _____
DAY MONTH YEAR

3. Randomization Color dispensed (*check one*): ₁ Yellow ₂ Orange ₃ Red ₄ Gray

4. Dispensed study substance based on the following current situation and/or anticipated feeding methods (*check all that apply*):

<input type="checkbox"/> ₁ a. Pregnant <input type="checkbox"/> ₁ b. Exclusively nursing <input type="checkbox"/> ₁ c. Partially nursing and baby taking study formula	<input type="checkbox"/> ₁ d. Exclusively taking study formula <input type="checkbox"/> ₁ e. Eating solid foods <input type="checkbox"/> ₁ f. Partially nursing and baby eating solid foods
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5. What study substance was dispensed (*check all that apply*)? ₁ a. Capsules ₁ b. Formula

If CAPSULES,

- 1) Record number of capsules dispensed (*Note: 100 capsules per bottle*): _____ capsule(s)
- 2) Dispensed capsules for: _____ week(s)
- 3) Record prescribed daily dose of capsules dispensed at this clinic visit (*check all that apply*):

<input type="checkbox"/> ₁ a) Mother _____ capsules/day	<input type="checkbox"/> ₁ b) Infant _____ capsules/day
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If FORMULA,

- 4) Record number of cans dispensed (*Note: 6 cans per case*): _____ can(s)
- 5) Dispensed formula for: _____ week(s)

E. ADDITIONAL INFORMATION

1. Were there any unusual circumstances? Y N
 If YES,
 - a. Reporting unusual circumstance for (*check all that apply*): ₁ 1) Dispensation ₁ 2) Return
 - b. Explain any unusual circumstances regarding dispensation/ return of study substance:

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

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

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 Write "*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*