

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*):  <sub>1</sub> Yellow  <sub>2</sub> Orange  <sub>3</sub> Red  <sub>4</sub> Gray
  
4. Dispensed study substance based on the following current situation and/or anticipated feeding methods (*check all that apply*):
 

<input type="checkbox"/> <sub>1</sub> a. Pregnant <input type="checkbox"/> <sub>1</sub> b. Exclusively nursing <input type="checkbox"/> <sub>1</sub> c. Partially nursing and baby taking study formula	<input type="checkbox"/> <sub>1</sub> d. Exclusively taking study formula <input type="checkbox"/> <sub>1</sub> e. Eating solid foods <input type="checkbox"/> <sub>1</sub> f. Partially nursing and baby eating solid foods
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5. What study substance was dispensed (*check all that apply*)?  <sub>1</sub> a. Capsules  <sub>1</sub> 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"/> <sub>1</sub> a) Mother _____ capsules/day	<input type="checkbox"/> <sub>1</sub> 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*):  <sub>1</sub> 1) Dispensation  <sub>1</sub> 2) Return
  - b. Explain any unusual circumstances regarding dispensation/ return of study substance:

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

**Date form completed:** \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
DAY MONTH YEAR

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