Site Number: __ __ __ __ Screening ID: __ __ __ __ __ - __ Participant Letters: __ __ __

For this study, only events Grade 2 and above will be reported to the Coordinating Center.

The Study Coordinator should complete this form to report:

- **A new adverse event, or**
- **A change in intensity, frequency, or duration of a previously reported adverse event.**

If updating a previously reported adverse event, make the necessary changes to your site copy of the original report and send a copy of the updated pages to the Coordinating Center. Include a copy of the first page for updates so that changes can be linked to the original Adverse Event ID Number.

An ***adverse event*** is described as any unfavorable or unintended clinical event, sign, symptom, or disease, or any event that has *changed* adversely in nature, intensity, or frequency. Refer to the Manual of Operations for reportable events.

This form should be completed with as much information as is currently known regarding the adverse event. A question should be answered with a "?" if the information is currently unavailable, but will be known in future updates. Write "*" if the information is permanently unknown, and the question will be unknown in all future updates. No questions should be left blank.

A. REPORT INFORMATION

Adverse Event ID Number: #####

1. Date of report (*e.g. 05/Sep/2006*): __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
2. Report is for (*check one*): ☐ 1 Pregnant woman ☐ 2 Nursing mother ☐ 3 Infant/Child (participant)
3. Was the participant currently taking the study substance at the time of the event? Y N
4. Last attended study visit (*check one*):

☐ 91	Pregnant Woman Screening/ Enrollment	☐ 94	Infant Enroll/6 mo	☐ 15	15 Months old	☐ 36	36 Months old
☐ 1	Infant Screening	☐ 95	Entry A Screening/ Infant Enroll	☐ 18	18 Months old	☐ 40	40 Months old
☐ 2	Infant Enrollment	☐ 6	6 Months old	☐ 21	21 Months old	☐ 48	48 Months old
☐ 3	3 Months old	☐ 9	9 Months old	☐ 24	24 Months old	☐ 99	Other, a. Specify date:
☐ 93	Infant Enroll/ 3 mo	☐ 12	12 Months old	☐ 30	30 Months old		__ __/ __ __ __/ __ __ __ __ (DAY MONTH YEAR)

5. The adverse event was first reported during *(check one)*:
   ☐ 1 Interim Follow-up Visit *(unplanned)*
   ☐ 2 Routine Follow-up Visit *(planned)*
   ☐ 3 Unattended Visit (*phone-call, etc.*)
6. How many separate adverse events are being reported at this time? __ __

IF MORE THAN 1, **each** adverse event requires the completion of a separate Adverse Event Report form.

B. EVENT DESCRIPTION

1. Date of onset of adverse event: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
2. Describe the event:
   (*Include information leading up to the event, procedures or tests completed, date stopped study substance, etc.*):
   _____
   _____
   _____
   _____
3. Intensity of reported event (*check one*):
   NOTE: Refer to NCI Common Toxicity Criteria (CTC) to grade intensity
   ☐ 2 Grade 2 ☐ 3 Grade 3 ☐ 4 Grade 4 ☐ 5 Grade 5

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. EVENT DESCRIPTION (CONTINUED)

4. Has the adverse event resolved? Y N

   a. If YES, date resolved: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

5. Event Type (*check one*):

Pregnancy – Related Events

- ☐ 1 Miscarriage
- ☐ 2 Stillbirth
- ☐ 3 Pre-term delivery (< 36 weeks)
- ☐ 4 Post-partum depression

Clinically Significant Abnormality (*Mother or Infant*)

- ☐ 5 Laboratory Abnormality
  - a. If Laboratory Abnormality, specify: _____

Maternal Diabetes – Related Events During Pregnancy

- ☐ 6 Ketoacidosis w/ ER visit, but no hospital admission
- ☐ 7 Ketoacidosis requiring admission to hospital
- ☐ 8 Hypoglycemia requiring medical or non-medical assistance but not necessitating IV glucose or IV glucagon
- ☐ 9 Hypoglycemia resulting in seizure and/or coma
- ☐ 10 Hypoglycemia necessitating IV Glucagons or IV glucose

Other

- ☐ 99 Other, a. Specify: _____

If the adverse event was Grade 2, skip to section C.

6. If the adverse event was **Grade 3 or above**,

   a. Was the serious adverse experience:

   1) Congenital anomaly? Y N
   2) Cancer? Y N
   3) Life-threatening? Y N
   4) Due to overdose of study substance? Y N
   5) Condition that could have resulted in one of the previous outcomes if left untreated? Y N

   b. Did the adverse event result in any of the following?

   1) Require or prolong hospitalization Y N
   2) Permanent or severe disability Y N

   c. Was this an **unexpected adverse event**? Y N

An ***unexpected adverse event*** is defined as one for which the specificity or severity is not consistent with known events. For a list of expected adverse events for DHA or infant formula see the Manual of Operations.

C. RELATIONSHIP AND ACTIONS TAKEN

1. Relationship to study substance (*check one*):

☐ 1 Not related ☐ 2 Unlikely ☐ 3 Possible ☐ 4 Probable ☐ 5 Definite

2. Actions taken for the adverse event:

   a. Discontinued study substance? Y N
   b. Concomitant medication prescribed? *(Complete the Concomitant Medication Worksheet (NWK02))* Y N
   c. Outpatient procedure? Y N
   d. Non-drug treatment? Y N
   e. None? Y N
   f. Other? Y N
      1) Specify _____

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 __ __/__ __ __/__ __ __ __

C. RELATIONSHIP AND ACTIONS TAKEN (CONTINUED)

3. Did treatment require any of the following?

a. Visit to study site	Y	N	d. Admission to hospital	Y	N
b. Visit to emergency room	Y	N	e. Admission to skilled nursing facility	Y	N
c. Clinic visit	Y	N			

If treatment involved admission to hospital or skilled nursing facility,

1) Record length of stay: __ __ __ Days

4. Did treatment of the adverse event require unmasking of the participant's treatment group assignment? Y N

If YES, a. Describe the circumstances:

_____
_____
_____

D. EVENT OUTCOME

1. What was the outcome of the adverse event? *(check one)*

☐ 1 Recovered, no residual effect
☐ 2 Residual effect, no treatment
☐ 3 Residual effect, being treated
☐ 4 Persistent, no treatment
☐ 5 Persistent, being treated
☐ 6 Death,
a. Date of death: __ __/ __ __ __/ __ __ __ __ DAY MONTH YEAR
b. Probable cause of death: _____
☐ 99 Other,
c. Specify: _____

Reported all **Serious Adverse Events** to the TrialNet Coordinating Center **within 24 hours.**
Faxed a **TrialNet MedWatch Form** to the TrialNet Coordinating Center at **(866) 804-6058** or **(301) 468-1676** within **24 hours** of clinic notification.

E. MEDWATCH *(Complete only for serious adverse events.)*

1. Date the TrialNet MedWatch Form was faxed to the TrialNet Coordinating Center: __ __ / __ __ __ / __ __ __ __ DAY MONTH YEAR

a. Time the TrialNet MedWatch Form was faxed (*24-hour clock*): __ __: __ __ Hour Min

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

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

Signature of Principal Investigator: _____ **Signed?** Y N

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).*