

Study: **NIP Diabetes Pilot** Screening ID: **61124-3** Issue Number: **MEL**

A. GENERAL INFORMATION

1. Date of review request: 2 / JAN / 2008
DAY MONTH YEAR

2. Date response needed by: __ / __ / ____
DAY MONTH YEAR

B. GENERAL SUBJECT INFORMATION

1. NIP Diabetes Pilot Entry Pathway: Entry A Pregnant Woman Entry B Infant

2. Eligibility and Deviation Review Form for: Pregnant Woman Infant Nursing Mother

3. Age (*in days*): __ days

4. Date of birth (*if available*): 05 / DEC / 2007
DAY MONTH YEAR

5. Sex: Male Female

6. If a Pregnant Woman, gestational age (*in weeks*): __ . __ weeks

7. If a Pregnant Woman, approximate or planned date of infant delivery: __ / __ / ____
DAY MONTH YEAR

8. Last date to randomize (≤ 182 days from the date of birth) (*if applicable*): __ / __ / ____
DAY MONTH YEAR

9. Date of screening visit (*if applicable*): 05 / DEC / 2007
DAY MONTH YEAR

C. ELIGIBILITY ISSUE DETAILS

1. Provide a brief description of the eligibility issue/deviation that requires review:
Infant preterm -34 weeks/ 2days. Birth weight 6 lb, 3 oz.

2. Provide a brief justification for the subject's enrollment into the study:
The Mother was randomized to the NIP Diabetes Pilot Study on 10/26/07 and the baby is eligible to participate in the trial. The labor and delivery were uneventful with a healthy birth weight 6 lb, 3 oz. and currently the baby weighs 9 lb, 1 oz.

D. RELEVANT INFORMATION FROM STUDY DOCUMENTS

Expected due date 1-12-08. Conceived IVF. At 34 wks, subject went into spontaneous labor and delivered without complications. Baby on preterm formula in hospital; d/c Enfamil lipil. Baby having increase gas pains, spitting up. Pediatrician switched to Enfamil Lipil AR on 12/31/08. Baby also talking cymethicon with feedings. Currently feeding 6 x day (4 oz each bottle). If no improvement in 1 week, will add Zantac. Pediatrician questioning acid reflux. Has not taken study formula. Exclusively bottle fed.

TNCC USE ONLY

1. Eligibility reviewed?		Y	N
IF YES,			
a. Date of review:		__ / __ / ____ DAY MONTH YEAR	
b. Reviewer	<input type="checkbox"/> TNCC	<input type="checkbox"/> Committee Chair	<input type="checkbox"/> Full Committee
c. Eligibility decision:	<input type="checkbox"/> Eligible	<input type="checkbox"/> Not Eligible	
If NO,			
a. Reason not reviewed:			



ELIGIBILITY AND DEVIATION REVIEW FORM

Form **ELIG**

16MAY2007

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2. Comments:
