



CORNUCOPIA  
I N S T I T U T E

## **Official Adverse Reaction Reports Filed With the Food and Drug Administration**

Below is a sample of adverse reaction reports submitted to the FDA—these reports, filed by parents, clearly suggest that some infants cannot tolerate Martek’s DHA and ARA oils in formula.

The reports were obtained through a Freedom of Information Act request by The Cornucopia Institute.

These 15 reports are just a sample of the 98 that could confidently be linked to intolerance to the DHA/ARA oils.

Hundreds of reports of adverse reactions to DHA/ARA-supplemented formula have been filed. But in some cases it was not possible to determine that the reported problems were due to bacterial contamination of the formula, lactose intolerance or allergies, or other problems commonly experienced with infant formula. Although a clear link could not be established there is still the potential that DHA/ARA oils are implicated in some of these cases.

The adverse reaction reports filed with FDA represent only the tip of the iceberg, especially since most parents remain unaware that Martek’s DHA and ARA oils may be the cause of their infant’s problems. Many continue to feed their infants the DHA/ARA-supplemented formula—infants endure months of pain and parents months of anxiety and distress.

A warning label alerting parents to the possibility of adverse reactions caused by the DHA and ARA oils is clearly warranted, since a simple switch to non-DHA/ARA formula has been found to relieve symptoms within 24 hours in some infants.

### **Report #: 61307**

“Her baby was fed this Enfamil Lipil formula for the first 3 weeks of his life and was constantly having gas and diarrhea from it, until he was taken off this formula by his pediatrician after the child was taken to the hospital ER by the parents, while having a severe bout of gas and diarrhea. Child was given regular Enfamil with Iron and has been on it ever since without any problems.”

**Report #: 61309**

“Her child was given the Enfamil Lipil for one month. She developed diarrhea, vomiting and bowel obstruction. She was taken off this formula and put on Similac Advance for 2 weeks, was having some problems with this formula. Was given regular Similac with Iron and doing fine.”

**Report #: 61311**

“Child was given this Enfamil Lipil formula at two different times. Child developed severe diarrhea and constipation for 3 days, every time. When switched to Enfamil with Iron did fine. He is now x months old and doing OK.”

**Report #: 61670**

“Complainant fed newborn baby boy Similac Advance with DHA/ARA. Infant immediately spit formula back up. Complainant attempted to feed baby the product twice and both times infant spit it up. Baby was put on plain Similac with iron and tolerates this formula well.”

**Report #: 64191**

“Healthy term newborn receiving formula supplementation – mother with history of breast reduction surgery – in hospital. Mother reported large amounts of emesis (vomiting) with Lipil, which resolved when switched to “original” Enfamil. Subsequently she was unable to obtain more “original” Enfamil – hospital supply not repleted by formula company. Baby again vomiting today with resumption of Lipil. Hospital staff in process of searching for formula without Formulaid [DHA and ARA] at present.”

**Report #: 69559**

“The Similac Advance made my son constipated and very agitated. He would swing his head back and forth and shake his legs. When he started eating Similac with Iron, he stopped being constipated and would eat normally.”

**Report #: 69679**

“My daughter has been unable to tolerate any formula with DHA and ARA components. Particularly Lipil products by Enfamil. They have caused gastric reflux, gas, fussiness, and colic repeatedly. This includes soy and hypoallergenic formulas as well with DHA and ARA.”

**Report #: 70337**

“Ms. K states that her son has a digestive disorder. As a result, he is unable to tolerate the formulas containing DHA and ARA. He is able to tolerate the Nestle Good Start that does not contain these additives. However, Ms. K states that Nestle told her that they also were going to begin adding DHA and ARA to the formulas. Ms. K believes that formula manufacturers should offer both choices so parents can decide which formula is best for their child.”

**Report #: 73857**

“Mother normally used the Similac Alimentum powdered formula with iron and had no problems with her infant son; they could no longer find that formula in the stores and began using the Similac Alimentum with iron and added DHA and ARA. Her son had

diarrhea and was extremely fussy for 9 days. They found some of the formula without the additives DHA and ARA and he returned to normal in one day.”

**Report #: 75278**

“Anytime we put my infant son on formulas containing DHA/ARA, he has frequent and forceful spit ups and is extremely cranky. It makes his reflux a lot worse than it already is.”

**Report #: 72285**

“My son cannot tolerate the new infant formulas with DHA/ARA additives, Similac Advance, Enfamil Lipil, Goodstart with DHA/ARA – every time he has tried a DHA/ARA formula he gets extremely gassy, fussy and has terrible gas pains. He does do better on the Similac Advance, which has less DHA/ARA than the other products. I can’t find plain Similac in my local store, as they only carry the DHA/ARA formulas. Why did the FDA allow the formula companies to produce these formulas without long term testing???”

**Report #: 75951**

“Infant demonstrates marked sensitivity to infant formula containing DHA/ARA. We have tried several formulas and all containing these additives have caused severe gas and distress.”

**Report #: 76537**

“I am 100% sure my son’s reflux was exacerbated by – possibly even caused by – the DHA/ARA additives to his infant formula. They may be considered “safe” but that does not mean that all babies tolerate the ingredients and I feel there should be a warning and more research into this possibility. Other relevant history: my son has been drinking Enfamil ProsoBee Lipil formula and has had painful problems with reflux since about 2 weeks of age when he started on Enfamil Lipil formula. His GERD (acid reflux) has required multiple doctor visits and medications, formula changes, etc. I recently decided to try a non DHA/ARA formula – Enfamil ProsoBee without Lipil – and within one day his reflux completely resolved.”

**Report #: 76856**

“Ms. A believes that her daughter is unable to tolerate the DHA and ARA that is now being added to most infant formulas. Ms. A states that the 3 formulas she initially tried contained these ingredients and her child experienced discomfort with each of them. Ms. A states that her child did not improve until she began using formula without these ingredients.”

**Report #: 82072**

“My son has been having serious problems with formulas that contain DHA/ARA. From the time he was 2 weeks old he was on formula that contained DHA/ARA and from the time he went on this he became extremely gassy and fussy. He would scream at each bottle. Under the doctor’s advice we tried him on the hypoallergenic formula and he still had the problems. We were on the verge of putting him on medication for reflux when I decided to try a formula that does not contain DHA/ARA and I now have a new baby. He is content and eating without pain. I completely believe that the DHA/ARA was the cause of my son’s problem. I truly believe that the DHA/ARA should be studied more and these issues made more public as I know that I am not alone after talking with other mothers.”