



Monique Mellema  
FrieslandCampina Ingredients B.V.  
P.O. Box 1551  
3800 BN Amersfoort  
THE NETHERLANDS

Re: GRAS Notice No. GRN 001176

Dear Ms. Mellema:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001176, which we filed on April 10, 2024. We received this request on September 20, 2024.

The subject of the notice is lacto-N-tetraose (LNT) for use as an ingredient in milk- and soy-based, non-exempt infant formula for term infants at a maximum level of 0.8 g/L. LNT will also be used as an ingredient in non-milk-based and milk-based meal-replacement and protein drinks; sports, isotonic, and “energy” drinks; soft drinks; enhanced or fortified waters; meal-replacement bars; cereal and granola bars; unflavored milk; buttermilk; flavored milk; yogurt; meal replacement drinks for young children; fruit drinks and ades; formulas and other drinks intended for children >12 months of age; cereals and other foods for infants and young children; and formula for enteral tube feeding at levels up to 2.0 g/100 g. The notice informs us of FrieslandCampina’s view that this use of LNT is GRAS through scientific procedures.

In emails dated September 6, 2024, and September 16, 2024, we informed you that we had concerns regarding deficiencies identified in the notice, including but not limited to, the composition of LNT, the lack of data and information provided on impurities in the final product, and additional questions raised by the use of cobalt in the fermentation medium.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001176 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J.  
Carlson -S  
Date: 2024.09.24 17:25:25 -04'00'

Susan J. Carlson, Ph.D.  
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