



Nga Tran, DrPH, MPH  
Exponent  
1150 Connecticut Ave, NW  
Suite 1100  
Washington, D.C. 20036

Re: GRAS Notice No. GRN 001023

Dear Dr. Tran:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Merck and Cie to cease our evaluation of GRN 001023, which we filed on September 23, 2021. We received this request on December 20, 2021.

The subject of the notice is monosodium L-5-methyltetrahydrofolate (L-5-MTHF-Na) for use as a replacement for folic acid as a source of the vitamin folate in the same food categories as listed under 21 CFR 172.345, except for corn masa flour, at a level equivalent on a molar basis to that of folic acid. The notice informs us of Merck and Cie's view that these uses of L-5-MTHF-Na are GRAS through scientific procedures.

In an email dated November 19, 2021, and teleconference on December 2, 2021, we informed you that we had concerns regarding the following: 1. use of hydroxyethylmorpholine (HEM) in the manufacturing process, 2. lack of dietary exposure data to sodium L-5-MTHF in infants, and 3. the insufficient safety discussion related to use by infants. In an email dated December 10, 2021, Merck and Cie asked to remove the use in infant formula from the notice. However, concerns regarding the use of HEM were not adequately addressed. In an email dated December 17, 2021, we recommended that Merck and Cie request that we cease our evaluation of GRN 001023, which they did on December 20, 2021.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001023 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: 2022.01.25 14:14:00  
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