Martin J. Hahn
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004

Re: GRAS Notice No. GRN 000935

Dear Mr. Hahn:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Ausnutria B.V. ("Ausnutria") to cease our evaluation of GRN 000935, which we filed on July 31, 2020. We received this request on November 19, 2020.

The subject of the notice is L-carnitine-L-tartrate (LCLT) intended for use as an ingredient in non-exempt formulas for term infants at a level of 11 mg/L of the infant formula as consumed. The notice informs FDA of Ausnutria's view that LCLT is GRAS through scientific procedures.

In a teleconference on October 15, 2020, and in a follow-up email dated October 16, 2020, we informed you that we could not continue our evaluation due to the deficiencies we identified in the notice. In the teleconference with you and Ausnutria on October 15, 2020, we discussed the following points that require clarification and additional information: insufficient information about the specifications for LCLT; insufficient analytical data demonstrating that the manufacturing process results in an ingredient that meets the stated specifications; uncertainty about the sources of the data used to estimate exposure to LCLT and L-carnitine; uncertainty about how the concentration of L-carnitine resulting from the intended use of LCLT compares to the amount of L-carnitine in human milk and to the recommended amount of L-carnitine in supplemented infant formula; insufficient or erroneous discussion of several toxicological studies cited to support the safety of the intended use of LCLT; the omission of reproductive, developmental, and/or teratogenicity toxicological studies in the safety narrative; and inappropriately cited sections of the safety narrative. In a follow-up email dated October 16, 2020, we provided you with a list of these deficiencies. Given the substantive nature of these deficiencies, we recommended that you request that we cease our evaluation of the notice. We also suggested that you request a pre-submission meeting with us to discuss the deficiencies before resubmitting the notice for evaluation without prejudice. In a letter dated November 19, 2020, you requested on behalf of Ausnutria that we cease our evaluation of GRN 000935.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000935 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2020.11.30 11:38:29 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition