Re: GRAS Notice No. GRN 000690

Dear Mr. Hahn:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of GRN 000690, which we filed on February 27, 2017. We received your request on June 20, 2017.

The subject of the notice is a blend of vitamins extracted from fruits and vegetables (vitamin extract blend). The notice informs FDA of Hogan Lovells US LLP (Hogan Lovells)’s view that vitamin extract blend is GRAS, through scientific procedures, for use as a source of vitamins in foods intended for infants from 6 months to 1 year of age, toddlers and young children from 1 to 4 years of age, and the general population 4 years of age and over at a level less than or equal to 100 percent of the recommended daily intake of vitamins for the population 4 years and older per 450 mg ingredient.

In telephone conversations on April 27, 2017, and May 8, 2017, we discussed issues identified during our evaluation of the notice. We noted that the subject of the notice is a mixture of ingredients and we recommended submission of an individual notice for each vitamin from its defined fruit and vegetable sources, with the exception of vitamin D which may not be addressed in a GRAS notice. We advised that each notice include a discussion of maximum use levels for the ingredient and exposure resulting from the intended uses, as well as a discussion of any other components from the fruit and vegetable sources that would be in the ingredient.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000690 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson

Susan Carlson, Ph.D.
Director
Division of Biotechnology and GRAS Notice Review
Office of Food Additive Safety and Applied Nutrition

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1 Hogan Lovells is identified as the notifier of this notice in section 1.2 (Name and Address of the Notifier) and on FDA Form 3667. As such, we consider Hogan Lovells to be the notifier even though other pages refer to this notice as submitted by Hogan Lovells on behalf of NutriFusion LLC.