Hywel Griffiths, Ph.D.
Fermentalg
4 Rue Rivière
33500 Libourne
FRANCE

Re: GRAS Notice No. GRN 001000

Dear Dr. Griffiths:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001000, which we filed on June 29, 2021. We received this request on February 24, 2022.

The subject of the notice is phycocyanin-rich extract of *Galdieria sulphuraria* (*G. sulphuraria* strain "FCC3424") for use as an ingredient at levels up to 250 mg/serving in foods and beverages[1]. The notice informs us of Fermentalg's view that this use of phycocyanin-rich extract of *G. sulphuraria* strain "FCC3424" is GRAS through scientific procedures.

In a teleconference on February 17, 2022, we informed you that we could not continue our evaluation due to issues identified during our review of the GRAS notice that require clarification and additional information. In reference to the Bacterial Reverse Mutation (Ames) and the *in vitro* micronucleus assays, the notifier used the unmetabolized form of the C-phycocyanin protein. We recommended that the actual metabolite(s) of C-phycocyanin be identified and evaluated for genotoxicity in these assays. Given the substantive nature of these issues, we recommended that Fermentalg request that we cease our evaluation of the notice.

In an email dated February 24, 2022, you requested that we cease our evaluation of GRN 001000.

[1] Fermentalg states that phycocyanin-rich extract of *G. sulphuraria* strain "FCC3424" is not intended for use in infant formula or in products under the jurisdiction of the United States Department of Agriculture.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001000 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2022.03.08 15:45:06 -05'00'

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