



Katrina Emmel
GRAS Associates, LLC
27499 Riverview Center Blvd.
Suite 212
Bonita Springs, FL 34134

Re: GRAS Notice No. GRN 000826

Dear Dr. Emmel,

The Food and Drug Administration (FDA, we) is granting the request on behalf of Blue California to cease our evaluation of GRN 000826, which we filed on December 18, 2018. We received this request on August 28, 2019.

The subject of the notice is dihydroquercetin for use as an ingredient in non-alcoholic beverages (up to 0.02 g/L), flavored fermented milk and dairy products (up to 0.02 g/kg), and chocolate products (up to 0.07 g/kg). The notice informs FDA of Blue California's view that dihydroquercetin is GRAS through scientific procedures.

On August 22, 2019, in a telephone conversation with you, we discussed the issues we identified during our evaluation of GRN 000826. In general, our comments related to the characterization of the substance as an ingredient as defined in [21 CFR 170.3\(o\)\(20\)](#), and the discussion of its purported benefits in the clinical studies, as well as its biological activity. We discussed that we consider the safety of the intended use of a substance in our evaluation of GRAS notices, not the beneficial effects claimed. We noted that while it is appropriate to discuss the biological activity of the ingredient, it is important that this discussion be done in the context of supporting its safe use in food. Additionally, we discussed that Blue California has the opportunity to request that we cease our evaluation of the notice. In a follow-up email on August 26, 2019, we provided a detailed list of issues and also suggested that Blue California request a pre-submission meeting with us to discuss safety studies of dihydroquercetin with respect to the toxicological endpoints measured, prior to re-submitting the revised notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000826 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan
J. Carlson -S
Date: 2019.09.25 15:36:47
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Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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