



James Heimbach, Ph.D., F.A.C.N.  
JHeimbach LLC  
923 Water Street #66  
Port Royal, VA 22535

Re: GRAS Notice No. GRN 000909

Dear Dr. Heimbach,

The Food and Drug Administration (FDA, we) is granting the request on behalf of Arla Foods Ingredients Group P/S (Arla) to cease our evaluation of GRN 000909, which we filed on May 29, 2020. We received this request on August 10, 2021.

The subject of the notice is fractionated whey protein concentrate containing 41% *alpha*-lactalbumin for use as an ingredient at levels ranging from 4-30% (by weight) in baked goods, snack bars, ready-to-drink milk-based drinks and meal replacements, flavored milks, sport drinks, enhanced waters, fruit juice drinks, yogurt, fermented milk drinks, and beverage powders. The notice informs us of Arla's view that these uses of fractionated whey protein concentrate containing 41% *alpha*-lactalbumin are GRAS through scientific procedures.

On January 29, 2021, in a telephone conversation with you, we discussed the issues we identified during our evaluation of GRN 000909. In general, we commented on the insufficient detail about the identity and method of manufacture of the ingredient, the cumulative estimate of dietary exposure, and the reliance on the incorporation by reference of safety information from previous GRAS notices without an accompanying narrative explaining how the incorporated information supports the GRAS status of the intended use of the ingredient in GRN000909. At that time, we suggested that Arla consider requesting that we cease our evaluation of the notice. On March 1, 2021, we received an amendment to the notice responding to the issues we had identified. In emails dated August 6 and 9, 2021, we informed you that the amendment did not adequately address the deficiencies we identified. In an email dated August 10, 2021, you requested on behalf of Arla that we cease our evaluation of GRN 000909. In a follow-up email on August 19, 2021, we provided a detailed list of the issues we had identified.

**U.S. Food and Drug Administration**  
**Center for Food Safety & Applied Nutrition**  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000909 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: 2021.09.08  
15:06:21 -04'00'

Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition