Natalie Rainer
Keller and Heckman LLP
Three Embarcadero Center, Suite 1420
San Francisco, CA 94111

Re: GRAS Notice No. GRN 001005

Dear Ms. Rainer:

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 001005, which we filed on August 17, 2021. We received this request on January 26, 2022.

The subject of the notice is β-Lactoglobulin from cow milk for use as a source of protein in ready to drink (RTD) sports drinks, RTD "energy" drinks, RTD milk-based drinks, fruit juice drinks, meal replacement and protein shakes, yogurt, and medical foods for management of chronic kidney disease, at levels ranging from 4-25 g/100 mL. The notice informs us of Arla's view that these uses of β-lactoglobulin are GRAS through scientific procedures.

In an email dated January 3, 2022, we informed you that we could not continue our evaluation due to deficiencies identified in the notice. We noted that we still had questions regarding Arla's dietary exposure estimate and manufacturing methods. Furthermore, there was not sufficient information presented to support the safe use of β-lactoglobulin in medical foods consumed by chronic kidney disease patients. Given the substantive nature of these issues, we recommended that Arla request that we cease our evaluation of the notice. We also suggested that Arla request a pre-submission meeting with us prior to submitting a revised GRAS notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001005 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2022.03.03 18:00:55 -05'00'

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