



Ray A. Matulka, Ph.D.
Director of Toxicology
Burdock Group Consultants
859 Outer Road
Orlando, FL 32814

Re: GRAS Notice No. GRN 00716

Dear Dr. Matulka:

This letter corrects our letter in response to GRN 000716 dated January 30, 2018. The purpose of this revised letter is to correct the date on which you asked FDA to cease to evaluate GRN 000716.

The Food and Drug Administration (FDA, we) is granting Arla Foods Ingredients Group PIS (AFI)'s request to cease our evaluation of GRN 000716, which we filed on August 3, 2017. We received your request on December 13, 2017.


The subject of the notice is bovine whey-derived osteopontin (bOPN) for use as an ingredient in milk-based, non-exempt infant formulas for term infants and in powdered beverages at levels up to 138 mg/L as consumed. The notice informs us of AFI's view that this use of bOPN is GRAS through scientific procedures.

On October 3, 2017, we sent questions to AFI. After reviewing AFI's responses, we have questions regarding the intended use of bOPN in infant formulas. In a telephone conversation with Burdock Group Consultants (Burdock Group) on November 9, 2017, and in a telephone conversation with Burdock Group and AFI on November 20, 2017, we discussed our outstanding questions. We explained that the amendment we received from AFI on October 20, 2017, did not fully address our questions. The amendment included information on the intended use level and resulting exposure to bOPN in infants. The amendment also included information on the bioequivalence of human OPN and bOPN. We also discussed the opportunity for AFI to ask us to cease our evaluation of GRN 000716.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000716 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S



Digitally signed by Susan J. Carlson -S
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