Dietrich B. Conze, Ph.D.
Spherix Consulting Group, Inc.
11821 Parklawn Drive, Suite 310
Rockville, MD 20852

Re: GRAS Notice No. GRN 000924

Dear Dr. Conze:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Jennewein Biotechnologie GmbH (Jennewein) to cease our evaluation of GRN 000924, which we filed on May 18, 2020. We received this request on October 29, 2020.

The subject of the notice is 2′-fucosyllactose (2′-FL) for use as an ingredient in cow milk-based, non-exempt infant formula for term infants at a level of 3.64 g/L of reconstituted formula. The notice informs us of Jennewein's view that this use of 2′-FL is GRAS through scientific procedures.

In response to our questions seeking clarification on the intended use level, information of the production microorganism, manufacturing specifications and the data used to estimate the dietary exposure for 2′-FL, Jennewein provided an amendment received on August 19, 2020 that included clarifying information on the intended use level, production microorganism, manufacturing specifications and dietary exposure.

In an email to Jennewein on September 14, 2020, we discussed our concerns regarding the GRAS notice. We explained that we had outstanding questions and suggested that Jennewein request that we cease our evaluation of GRN 000924. In a letter sent to us on October 5, 2020, Jennewein provided additional information regarding the intended use level. We followed up with an email on October 15, 2020 and reiterated that Jennewein should provide a scientifically justified explanation in support of their intended use level. Our October 15, 2020 email also provided a summary of our remaining questions, including our request for updated specifications, analytical methods, results from batch analyses for the 2′-FL, and an appropriately-estimated dietary exposure.

In an email dated October 29, 2020, you requested on behalf of Jennewein that we cease our evaluation of GRN 000924.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000924 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2020.11.23 17:34:12 -05'00'

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