Manki Ho, Ph.D.
Chr. Hansen A/S
Boege Allé 10-12
2970 Hoersholm
DENMARK

Re: GRAS Notice No. GRN 001040

Dear Dr. Ho:

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001040, which we filed on February 28, 2022. We received this request on August 16, 2022.

The subject of the notice is 2′-fucosyllactose (2′-FL) for use as an ingredient in cow milk-based, exempt infant formula for post-discharge preterm infants at a level up to 2.0 g/L, as consumed. The notice informs us of Chr. Hansen's (you, your) view that this use of 2′-FL is GRAS through scientific procedures.

In a teleconference with you on August 3, 2022, we stated that the data and information presented in GRN 001040 are not sufficient to support the conclusion that the intended use of 2′-FL in exempt infant formula for preterm infants (either pre- or post-discharge) is GRAS. We noted that the science surrounding the use of 2′-FL and other human milk oligosaccharides in formula for highly vulnerable preterm infant populations is currently unsettled, and scientific consensus on this issue is lacking among experts in infant health and nutrition. Because the general recognition of safety standard required for a GRAS conclusion has not been met in your notice, we suggested you request that we cease our evaluation of GRN 001040. In an email dated August 16, 2022, you asked that we cease our evaluation of GRN 001040.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001040 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2022.09.12 17:01:57 -04'00'

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