Claire L. Kruger, PhD, DABT, CFS
Spherix Consulting Group, Inc.
11821 Parklawn Drive, Suite 310
Rockville, MD 20852

Re: GRAS Notice No. GRN 000958

Dear Dr. Kruger:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Hubei Fuxing Biotechnology Co., Ltd (Hubei Fuxing) to cease our evaluation of GRN 000958, which we filed on October 14, 2020. We received this request on March 22, 2021.

The subject of the notice is fungal oil (≥40% arachidonic acid (ARA)) from *Mortierella alpina* strain AF (ARA oil) for use as an ingredient in cow milk- and soy-based, non-exempt infant formula for term infants at levels of 0.75 g/100 g total fat and exempt infant formula for pre-term infants at levels of 0.40 g/100 g total fat. Hubei Fuxing states that ARA oil will be used in combination with a safe and suitable source of docosahexaenoic acid (DHA) at ratios ranging from 2:1 to 1:1 ARA to DHA. The notice informs us of Hubei Fuxing's view that these uses of ARA oil are GRAS through scientific procedures.

In an email dated March 15, 2021, and teleconference on March 22, 2021, we informed you that we could not continue our evaluation due to issues identified in the amendment submitted on February 2, 2021. These include questions about the identity of the ARA oil with respect to sterol levels, the increased use level of ARA from 0.40 to 0.50 g/100 g total fat in formula for pre-term infants, the narrative used to support the safety of this higher use level, and whether the GRAS panel had reviewed data supporting this higher use level in pre-term infants. We recommended that Hubei Fuxing request that we cease our evaluation of the notice. In an email and letter dated March 22, 2021, Hubei Fuxing requested that we cease our evaluation of GRN 000958. We agreed to send our list of remaining questions to Hubei Fuxing, who intends to submit a revised GRAS notice at a later date.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000958 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2021.03.26 17:25:12 -04'00'

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