Susan S. Cho, Ph.D.
AceOne RS, Inc.
5903 Hampton Forest Way
Fairfax, VA 22030

Re: GRAS Notice No. GRN 001156

Dear Dr. Cho:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Runke Bioengineering (Fujian) Co., Ltd. (Runke) to cease our evaluation of GRN 001156, which we filed on October 19, 2023. We received this request on February 5, 2024.

The subject of the notice is algal oil (≥35% docosahexaenoic acid) from *Schizochytrium* sp. "FJRK-SCH3" (algal oil (≥35% DHA)) for use as an ingredient in the same food categories as those listed in 21 CFR 184.1472(a)(3) (Menhaden oil)[1] at use levels that are no more than 28.57% of the levels specified for menhaden oil in that regulation. Runke states that if algal oil (≥35% DHA) is blended with another source of DHA or eicosapentaenoic acid (EPA), the levels will be no more than 1.5 g of DHA/person (p)/d and no more than 3.0 g/p/d of DHA and EPA combined. Algal oil (≥35% DHA) is also intended for use as an ingredient in cow milk-, goat milk-, soy-, amino acid-, and extensively hydrolyzed protein-based, non-exempt infant formula for term infants and exempt infant formula for pre-term and low birthweight infants, at a maximum level of 0.5% (w/w) of total fat as DHA in combination with a safe and suitable source of arachidonic acid (ARA) at a ratio ranging from 1:1 to 1:2 of DHA to ARA. The notice informs us of Runke's view that these uses of algal oil (≥35% DHA) are GRAS through scientific procedure.

In an email dated January 10, 2024, and during a subsequent teleconference held on January 18, 2024, we informed you that we had concerns regarding deficiencies identified in the safety narrative, particularly regarding the data and information used to support use in pre-term infants, as well as how information was incorporated from prior notices in general.

[1] Runke states that algal oil (≥35% DHA) is not intended for use in products under the U.S. Department of Agriculture's jurisdiction.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001156 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2024.02.08 18:35:15 -05'00'

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