



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

Re: GRAS Notice No. GRN 001162

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 November 7, 2023. We received this request on February 5, 2024.

The subject of the notice is fungal oil ($\geq 38\%$ arachidonic acid (ARA)) from *Mortierella alpina* "FJRK-MA01" (*M. alpina* oil) 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 level of 0.75% and 0.50% (w/w) of total fatty acids for term and pre-term or low-birthweight infants, respectively, and in combination with a safe and suitable source of docosahexaenoic acid (DHA) at a ratio ranging from 2:1 to 1:1 of ARA to DHA. The notice informs us of Runke's view that these uses of *M. alpina* oil 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 and the increased ARA use level, as well as how information was incorporated from prior notices in general.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001162 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 18:36:01
-05'00'

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

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov