U.S. FOOD & DRUG ADMINISTRATION
Human Foods Program

Dietrich Conze, Ph.D.
Spherix Consulting Group, Inc.
751 Rockville Pike, Unit 30-B
Rockville, MD 20852

Re: GRAS Notice No. GRN 001259

Dear Dr. Conze:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001259. We received the notice that you submitted on behalf of ATK Biotech Co., Ltd. (ATK Biotech) on January 28, 2025, and filed it on June 27, 2025. ATK Biotech submitted an amendment to the notice on December 3, 2025, that clarified the identity, specifications, and aspects of the safety narrative.

The subject of the notice is fungal oil (≥40% arachidonic acid (ARA)) from *Mortierella alpina* TKA-1 (*M. alpina* oil) for use as an ingredient in cow milk- and soy-based, non-exempt infant formula for term infants at levels providing up to 0.75% of fatty acids as ARA and in exempt infant formula for pre-term infants at levels providing up to 0.40% of fatty acids as ARA. ATK Biotech states that *M. alpina* oil will be used in combination with a safe and suitable source of docosahexaenoic acid (DHA) at a ratio ranging from 1:1 to 2:1 ARA:DHA. The notice informs us of ATK Biotech's view that these uses of *M. alpina* oil are GRAS through scientific procedures.

Our use of the term, "*M. alpina* oil," in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with FDA's labeling requirements. Under 21 CFR 101.4, each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence. The Office of Pre-Market Additive Safety (OPMAS) did not consult with ONFL regarding the appropriate common or usual name for "*M. alpina* oil."

ATK Biotech describes *M. alpina* oil as a clear, light-yellow oil that is ≥40% by weight of total fatty acids (TFA) as ARA. ARA is an omega-6 fatty acid with a carbon chain length of 20 and four *cis*-double bonds (20:4 n-6). The chemical name is (all *cis*)-5,8,11,14-

eicosatetraenoic acid. The predominant fatty acids and their concentrations[1] in *M. alpina* oil include palmitic acid (5.0-5.4%), stearic acid (7.5-8.9%), oleic acid (7.3-11.5%), linoleic acid (7.4-18.7%), gamma-linolenic acid (1.7-2.1%), eicosapentaenoic acid (1.5-1.8%), dihomo-gamma-linolenic acid (1.3-1.6%), lignoceric acid (1.1-1.4%), arachidic acid (0.8-1.0%), and ARA (40.8-52.8%). Based on the results of batch data, ATK Biotech reports that the total sterols present in *M. alpina* oil are 1.3-1.5% (by weight).

ATK Biotech describes the manufacture of *M. alpina* oil produced by fermentation using the production strain *M. alpina* TKA-1, deposited at the China Center for Type Culture Collection under deposit number CGMCC 21442. *M. alpina* is fermented under controlled conditions and monitored to ensure consistent pH, aeration rate, and temperature. After fermentation is complete, the biomass is filtered from the medium and washed with water, dried, and extracted with butane to yield crude *M. alpina* oil. After evaporation of the butane, the crude oil is degummed with hot water and citric acid, neutralized with sodium hydroxide, and additional hot water is then added and the mixture separated by centrifugation. The resulting oil is bleached using activated clay (Bentonite) and is then filtered and deodorized with steam under vacuum. Tocopherols and ascorbyl palmitate are added as antioxidants. ATK Biotech notes that sunflower oil may be added to standardize the ARA content. The refined oil is then filtered to obtain the final *M. alpina* oil product. ATK Biotech states that *M. alpina* oil is produced in accordance with current good manufacturing practices and that raw materials, processing aids, and food contact substances used in the manufacturing process are food grade and are safe and suitable for their intended use, are used in accordance with applicable U.S. regulations, or are GRAS for their intended use.

ATK Biotech provides specifications for *M. alpina* oil that include the minimum content of ARA (≥40% of TFA) and limits for acid value (≤1.0 mg potassium hydroxide/g), free fatty acids (≤0.45% as oleic acid), peroxide value (≤5.0 milliequivalents/kg), *p*-anisidine value (≤20), unsaponifiable matter (≤1.5%), moisture and volatiles (≤0.5%),[2] arsenic (≤0.1 mg/kg), cadmium (≤0.1 mg/kg), lead (≤0.1 mg/kg), mercury (≤0.05 mg/kg), and microorganisms, including *Cronobacter* spp. (absent in 10 g), *Listeria monocytogenes* (absent in 25 g), and *Salmonella* serovars (absent in 25 g). ATK Biotech provides the results of five non-consecutive batch analyses to demonstrate that *M. alpina* oil can be manufactured to meet these specifications. ATK Biotech provides the results of a stability study conducted with *M. alpina* oil stored at -18 and 4 °C under nitrogen for up to 24 months. Based on the results of the study, ATK Biotech reports that *M. alpina* oil is stable under the conditions tested.

ATK Biotech estimates the dietary exposure to ARA and *M. alpina* oil from the intended

[1] The ranges listed for the content of fatty acids is based on the fatty acid profile of three non-consecutive batches of *M. alpina* oil provided by ATK Biotech.

[2] ATK Biotech states that butane is the only solvent used in the manufacture of *M. alpina* oil and is not expected to be present in the final product due to butane's low boiling point (-1 °C) and the temperatures used during the refining steps (>80 °C). ATK Biotech provides the results of three batch analyses of *M. alpina* oil to demonstrate that butane is not detectable in *M. alpina* oil with a limit of detection of 0.1 mg/kg.

uses of *M. alpina* oil based on the following assumptions: (1) term infants consume 100 kilocalories (kcal)/kg body weight (bw)/d and pre-term infants consume 120 kcal/kg bw/d, (2) fat comprises 50% of the available energy in infant formula, and (3) 1 g of fat is equivalent to 9 kcal. ATK Biotech estimates that term infants consume 5.6 g fat/kg bw/d and pre-term infants consume 6.7 g fat/kg bw/d. Based on the intended use of *M. alpina* oil, ATK Biotech estimates the dietary exposure to ARA to be 42 mg/kg bw/d for term infants and 27 mg/kg bw/d for pre-term infants and the dietary exposure to *M. alpina* oil to be 105 mg/kg bw/d for term infants and 67 mg/kg bw/d for pre-term infants.[3] ATK Biotech notes that these use levels and dietary exposures to ARA are consistent with those reported in previous GRAS notices (GRNs 000326 and 000963).[4]

ATK Biotech discusses the publicly available data and information supporting the safety of *M. alpina* oil. ATK Biotech states that the subject of this notice is compositionally similar to other *M. alpina* oils that were the subjects of prior notices; therefore, ATK Biotech incorporates into the notice the available scientific data and information supporting the safety of *M. alpina* oil discussed in GRNs 000041, 000080, 000094, 000326, 000730, 000963, and 001115.[5] This includes published subchronic and reproductive and development toxicity studies in rats and mice, along with published genotoxicity and neonatal piglet tolerance studies. Across all studies, the results consistently demonstrated no test article-related adverse effects. To further support the safe use of *M. alpina* oil, ATK Biotech also incorporates into the notice and summarizes clinical studies in infants that were previously discussed in GRNs 000326, 000730, and 001115. ATK Biotech concludes that the use of *M. alpina* oil is well-tolerated and safe in both term and pre-term infants. ATK Biotech states that an updated literature search through November 2025, identified no additional studies or safety concerns.

ATK Biotech provides a detailed analysis of the fatty acid and sterol composition of *M. alpina* oil. ATK Biotech concludes that the fatty acid profile is similar to the fatty acid profiles of other ARA-rich oils that were the subjects of prior GRAS notices, and notes that minor differences are not expected to alter the safety of this *M. alpina* oil. Further, ATK Biotech states that the dietary exposure to sterols from infant formula containing this *M. alpina* oil are comparable to dietary exposures from other *M. alpina* oils that are GRAS for use in term and pre-term infant formula.

Based on the totality of the data and information, ATK Biotech concludes that *M. alpina* oil is GRAS for its intended use.

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[3] ATK Biotech estimates the dietary exposure to *M. alpina* oil on page 3 of the notice based on a specified minimum content of 40% ARA. We note that the dietary exposure estimate on page 20 of the notice incorrectly used 50% ARA.

[4] ARA-containing *M. alpina* oils are the subjects of GRNs 000326 and 000963. We evaluated these notices and responded in letters dated February 16, 2011, and October 19, 2021, respectively, stating that we had no questions at that time regarding the notifiers' GRAS conclusions.

[5] ARA-containing *M. alpina* oils are the subjects of GRNs 000041, 000080, 000094, 000730, and 001115. We evaluated these notices and responded in letters dated May 17, 2001, December 11, 2001, April 18, 2006, March 30, 2018, and September 18, 2023, respectively, stating that we had no questions at that time regarding the notifiers' GRAS conclusions.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, & Cosmetic (FD&C) Act, a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products containing *M. alpina* oil bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of ONFL. OPMAS did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Intended Use in Infant Formulas

Under section 412 of the FD&C Act, a manufacturer of a new infant formula must make a submission to FDA providing required assurances about the formula at least 90 days before the formula is marketed. Our response to ATK Biotech's GRAS notice does not alleviate the responsibility of any infant formula manufacturer that intends to market an infant formula containing *M. alpina* oil to make the submission required by section 412. Infant formulas are the purview of the Office of Critical Foods in the Nutrition Center of Excellence.

Section 301(ll) of the FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of ATK Biotech's notice concluding that *M. alpina* oil is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing *M. alpina* oil. Accordingly, our response should not be construed to be a statement that foods containing *M. alpina* oil, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that ATK Biotech provided, as well as other information available to FDA, we have no questions at this time regarding ATK Biotech's conclusion that *M. alpina* oil is GRAS under its intended conditions of use. This letter is not an affirmation that *M. alpina* oil is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 001259 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2026.01.07 20:21:40 -05'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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