



Anguel Jeliaskov
Huve Nutraceuticals Ltd
3a Nikaly Haytov Street
5th Floor, Sofia 1113
Bulgaria

Re: GRAS Notice No. GRN 001209

Dear Mr. Jeliaskov:

The Food and Drug Administration (FDA, we) is granting Huve Nutraceuticals Ltd (HuveNutra)'s request that we cease our evaluation of GRN 001209, which we filed on October 15, 2024. We received this request on April 23, 2025.

The subject of the notice is algal oil ($\geq 35\%$ docosahexaenoic acid) from *Schizochytrium limacinum* CCAP A2 (algal oil ($\geq 35\%$ DHA)) for use as an ingredient in the food categories listed in 21 CFR 184.1472(a)(3) (Menhaden oil)¹ at levels up to 20% of the levels specified for menhaden oil in that regulation. HuveNutra states that if algal oil ($\geq 35\%$ DHA) is blended with another source of DHA or eicosapentaenoic acid (EPA), the total dietary exposure 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. HuveNutra also intends to use algal oil ($\geq 35\%$ DHA) as an ingredient in cow milk-, goat milk-, soy-, amino acid-, and extensively hydrolyzed-protein base, non-exempt infant formula for term infants and in exempt infant formula for pre-term infants at a maximum level of 0.5% (w/w) of total fat as DHA in combination with a source of arachidonic acid (ARA) at a ratio ranging from 1:1 to 1:2 DHA to ARA. The notice informs us of HuveNutra's view that these uses of algal oil ($\geq 35\%$ DHA) are GRAS through scientific procedures.

In an email sent on April 21, 2025, we communicated with you regarding additional information needed to support a GRAS conclusion. We stated that HuveNutra's responses to our initial questions in the March 17, 2025, amendment did not fully address the issues and, in fact, raised a substantial number of new issues. The outstanding issues involve the intended use, manufacturing process, specifications and batch analyses, stability studies, and aspects of the safety narrative. Some examples of outstanding issues include the following: missing information on the impact of optional manufacturing steps on residual levels of heavy metals and other impurities; results of non-consecutive batch analyses were not provided to demonstrate that HuveNutra can manufacture algal oil ($\geq 35\%$ DHA) to meet stated specifications; inconsistent information was provided for quality parameters; and missing information to support

¹ HuveNutra states that algal oil ($\geq 35\%$ DHA) is not intended for use in products under the U.S. Department of Agriculture's jurisdiction.

use in infant formula for infants with cow milk protein allergy.

We have ceased our evaluation of the notice at your request. We remind HuveNutra of a manufacturer's responsibility to ensure the safety and regulatory status of the substances that it markets for use in food or that it uses in food. We also remind HuveNutra that the use of a substance in food that is not GRAS (and is not otherwise excluded from the definition of a food additive), must have pre-market approval by FDA for its use in food (21 CFR 170.30(g)). More information about the criteria for GRAS is available in our regulations (21 CFR part 170).

Your request does not preclude HuveNutra from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that HuveNutra address these issues to adequately support a GRAS conclusion. We recommend HuveNutra request a meeting with us prior to resubmitting. Finally, we remind HuveNutra of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which HuveNutra agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001209 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

 Digitally signed by Susan J.
Carlson -S
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Susan J. Carlson, Ph.D.
Director
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