



Susan Cho, Ph.D.
NutraSource, Inc.
6309 Morning Dew Ct.
Clarksville, MD 21029

Re: GRAS Notice No. GRN 00860

Dear Dr. Cho:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Hubei Fuxing BioTechnology, Co., Ltd. (Hubei Fuxing) to cease our evaluation of GRN 000860, which we filed on July 3, 2019. We received this request on August 20, 2019.

The subject of the notice is algal oil ($\geq 36\%$ docosahexaenoic acid) from *Schizochytrium* sp. strain DHF (algal oil ($\geq 36\%$ DHA)) for use as an ingredient in the same food categories as those currently listed in 21 CFR 184.1472(a)(3) (Menhaden oil),¹ at use levels of algal oil ($\geq 36\%$ DHA) that are no more than 27.775% of the levels specified for menhaden oil in that regulation. Hubei Fuxing also intends to use algal oil ($\geq 36\%$ DHA) as an ingredient in exempt and non-exempt, soy-, whey-, cow's milk-, amino acid-, and hydrolyzed protein-based infant formula for pre-term and term infants at a maximum level of 0.5% 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 Hubei Fuxing's view that these uses of algal oil ($\geq 36\%$ DHA) are GRAS through scientific procedures.

In an email dated August 20, 2017, we informed Hubei Fuxing that we could not continue our evaluation due to the poor quality of the notice, which included the following deficiencies: incorrect references and citations to both prior GRAS notices and the literature; inaccurate or missing information on the intended use, identity, manufacturing, specifications, and exposure; inaccurate descriptions of cited studies; incorrect reporting of NOAEL values; incorrect or inconsistent units; and typographical errors throughout the notice that impacted its readability. Given the extent of the changes that would be necessary to continue our evaluation, we recommended that Hubei Fuxing request that we cease our evaluation of the notice. In an email dated August 20, 2019, Hubei Fuxing requested that we cease our evaluation of GRN 000860. In a follow-up email on August 21, 2019, we provided to Hubei Fuxing a detailed list of the deficiencies we identified in the notice.

¹ Hubei Fuxing states that algal oil ($\geq 36\%$ DHA) is not intended for use in products under the U.S. Department of Agriculture's jurisdiction or products defined in 21 CFR 170.3(n)(13).

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000860 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan
J. Carlson -S
Date: 2019.09.03 13:54:01
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**Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
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