Benjamin L. England, Esq.
Benjamin L. England & Associates
810 Landmark Drive, Suite 126
Glen Burnie, MD 21061

Re: GRAS Notice No. GRN 001128

Dear Mr. England:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Jiangsu Grand Xianle Pharmaceutical Co., Ltd. (Jiangsu) to cease our evaluation of GRN 001128, which we filed on July 5, 2023. We received this request on October 30, 2023.

The subject of the notice is algal oil (≥35% docosahexaenoic acid) from *Schizochytrium* sp. (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) at use levels that are no more than 20% of the levels specified in the menhaden oil regulation. Jiangsu 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. The notice informs us of Jiangsu's view that this use of algal oil (≥35% DHA) is GRAS through scientific procedures.

In a phone call on October 30, 2023, we noted that we identified a variety of substantive issues in our evaluation of Jiangsu's GRAS notice. These issues included, but were not limited to, the following: the description of the oil as semi-refined; the use of cobalt (II) chloride in the method of manufacture without confirming the absence of cobaltous salts in the final product (foods containing cobaltous salts and its derivatives are deemed adulterated per 21 CFR 189.120); potential variable levels of DHA as evidenced by the batch analyses; insufficient characterization of the fatty acid profile of algal oil (≥35% DHA) and the formulation of the powder form of the ingredient; the lack of dietary exposure estimates for the oil and powder forms of the ingredient; inconsistencies regarding the presented specifications and results of the batch analyses; lack of clarity regarding the identity of the production organism; the lack of citations for a variety of statements made by the notifier in the safety narrative; and insufficient incorporation of information by reference in the safety narrative. We recommended that Jiangsu request that we cease to evaluate GRN 001128. We noted that, following receipt of this request, we would provide a list of deficiencies that were identified during the evaluation of the notice. In an email dated October 30, 2023, you requested on behalf of Jiangsu that we cease our evaluation of GRN 001128.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001128 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2023.12.13 16:10:08 -05'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
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cc: Stephanie Hretz, M.P.H.
Deputy Director
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