



Joanne Lasrado, Ph.D.  
Director, Regulatory Affairs and Quality Assurance  
Kemin Foods, L.C.  
2100 Maury Street  
Des Moines, IA 50317

Re: GRAS Notice No. GRN 000697

Dear Dr. Lasrado:

The Food and Drug Administration (FDA, we) is granting Kemin Foods, L.C. (Kemin)'s request to cease our evaluation of GRN 000697, which we filed on April 20, 2017.<sup>1</sup> We received the request on May 8, 2017.

The subject of the notice is dried biomass of *Euglena gracilis* ATCC PTA-123017 (dried *E. gracilis*). The notice informs FDA of Kemin's view that dried *E. gracilis* is GRAS, through scientific procedures, for use as an ingredient in baked goods and baking mixes, beverages and beverage bases, cereal and cereal products, dairy product analogs, milk and milk products, processed fruits and fruit juices, soft candy, and soup and soup mixes at use levels up to 500 mg/serving.

In telephone conversations on April 26, 2017 and May 1, 2017, we discussed the information needed to complete the submission of GRN 000697 with Kemin as the notifier. We explained that FDA would need additional documentation from Kemin besides the letter provided on May 8, 2017 with updated contact information if they chose to complete the filing process for GRN 000697. We also discussed the opportunity of asking us to cease our evaluation GRN 000697 and resubmitting a GRAS notice for dried *E. gracilis*. Kemin mentioned their concern that there are certain data and information that Kemin would consider trade secret and wanted to confirm this with their patent attorney.

In a letter dated May 8, 2017, Kemin requested that FDA cease the evaluation of GRN 000697. Kemin mentioned that they had acquired the assets of Algal Scientific (the original submitter for GRN 000697) on March 28, 2017. Kemin also mentioned that they would like to recast GRN 000697 under Kemin's name and resubmit the GRAS

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<sup>1</sup> The filing date for GRN 000697 is based on a letter from Kemin dated April 20, 2017, confirming an April 13, 2017, email from Robert Levine of Algal Scientific informing FDA of Kemin's acquisition. The April 20, 2017, letter also provided updated contact information.

notice at a later date. Kemin also noted that they view certain details to be trade secret and submitted a redacted copy.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000697 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S  
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ou=People, 0.9.2342.19200300.100.1.1=2000419015,  
cn=Susan J. Carlson -S  
Date: 2017.07.19 15:54:25 -04'00'

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