



Melvin S. Drozen  
Keller and Heckman LLP  
1001 G Street NW  
Suite 500 West  
Washington, DC 20001

Re: GRAS Notice No. GRN 000866

Dear Mr. Drozen:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Amano Enzyme, Inc. (Amano) to cease our evaluation of GRN 000866, which we filed on August 1, 2019. We received your request to cease to evaluate the notice on January 13, 2020.

The subject of the notice is acylglycerol lipase enzyme preparation produced by a genetically engineered *Penicillium camemberti* overexpressing the acylglycerol lipase gene (acylglycerol lipase enzyme preparation). You stated that the acylglycerol lipase enzyme preparation is intended for use as an enzyme in dairy, fats, and oil processing at up to 2522 mg Total Organic Solids (TOS)/kg raw material. The notice informs us of Amano's view that the uses of acylglycerol lipase enzyme preparation are GRAS through scientific procedures.

Upon review of your submission we informed you via a teleconference on October 30, 2019, that your GRAS notice included data supporting two acylglycerol lipase enzyme preparations. They are:

1. Acylglycerol lipase enzyme preparation produced by *P. camemberti* and
2. Acylglycerol lipase enzyme preparation produced by a genetically engineered *P. camemberti*.


In the teleconference, FDA discussed that a GRAS notice is designed to describe the safety of uses of a single ingredient. Therefore, we offered you the opportunity to request that we cease our evaluation of GRN 000866. In an email dated January 13, 2020, you requested on behalf of Amano that we cease our evaluation of GRN 000866 and noted that you will submit a separate GRAS notice for the use of each enzyme preparation.

U.S. Food and Drug Administration  
Center for Food Safety & Applied Nutrition  
5001 Campus Drive  
College Park, MD 20740  
[www.fda.gov](http://www.fda.gov)

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000866 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  
Date: 2020.02.05 14:45:24  
-05'00'

Susan Carlson, Ph.D.  
Director  
Division of Food Ingredients  
Office of Food Additive Safety  
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and Applied Nutrition