



Deepti Sood  
Advanced Enzyme Technologies Ltd.  
5<sup>th</sup> Floor, Sun Magnetica LIC Service Road  
Louiswadi, Thane West, Maharashtra,  
400604, INDIA

Re: GRAS Notice No. GRN 000708

Dear Ms. Sood:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of GRN 000708, which we filed on July 19, 2017. We received your request on August 18, 2017.

The subject of the notice is triacylglycerol lipase enzyme produced by *Aspergillus niger* expressing a triacylglycerol lipase gene from *Rhizopus oryzae* (triacylglycerol lipase enzyme preparation)<sup>1</sup> for use as an enzyme in the production of cocoa butter substitutes at a maximum level of 1 kg of triacylglycerol lipase enzyme preparation per ton of fat raw material. The notice informs us of Advanced Enzyme Technologies Ltd.'s view that this use of triacylglycerol lipase enzyme preparation is GRAS through scientific procedures.

In an email exchange on August 14, 2017, followed by a telephone conversation on September 6, 2017, we discussed items requiring further clarification that were identified during our evaluation. We discussed a new submission made by you dated May 18, 2017, after we filed GRN 000708. The subject of this submission is the same ingredient as that described in GRN 000708 to modify lipids, only the intended use is in infant formula. We advised Advanced Enzyme Technologies Ltd. to resubmit a new GRAS notice with all uses combined into a single submission.

We also discussed the use of octadecyl methacrylate as an immobilizer/carrier of the triacylglycerol lipase enzyme in the preparation, seeking clarification on the use and removal of octadecyl methacrylate during the enzyme manufacturing process. Additional guidance regarding regulatory authorization for immobilizers/carriers that Advanced Enzyme Technologies Ltd. intends to use in its products may be obtained from our office's Division of Food Contact Notifications. Advanced Enzyme Technologies Ltd can reach the Division of Food Contact Notification at [premarkt@fda.hhs.gov](mailto:premarkt@fda.hhs.gov).

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<sup>1</sup> FDA considered the subject of GRN 000708 to be an immobilized enzyme preparation.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000708 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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Susan J. Carlson, Ph.D.

Director

Division of Biotechnology

and GRAS Notice Review

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition