



Joab Trujillo
AB Enzymes Inc.
8211 W. Broward Blvd., Suite 375
Plantation, FL 33324

Re: GRAS Notice No. GRN 001150

Dear Mr. Trujillo,


The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001150, which we filed on October 13, 2023. We received this request on February 7, 2024.

The subject of the notice is triacylglycerol lipase enzyme preparation produced by *Trichoderma reesei* expressing a gene for triacylglycerol lipase from *Thermomyces lanuginosis* (lipase enzyme preparation) for use as an enzyme at up to 4 mg Total Organic Solids/kg cereal in the production of baked goods and other cereal based products. The notice informs us of AB Enzymes Inc.'s view that this use of lipase enzyme preparation is GRAS through scientific procedures.

In a teleconference on February 7, 2024, we informed you that we had identified areas of the safety narrative that would require edits beyond the intended scope of the GRAS notice evaluation process. We noted that the focus of the safety narrative should shift to the lipase enzyme in the preparation, while the information supporting the safety the production organism provided in the notice will remain a part of the revised safety narrative. We recommended that you request that we cease our evaluation of GRN 001150 and resubmit a new GRAS notice with a revised safety narrative. In an email dated February 7, 2024, you requested that we cease our evaluation of GRN 001150.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001150 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,
Susan J.
Carlson -S

 Digitally signed by Susan J.
Carlson -S
Date: 2024.02.15 18:57:18
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Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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