



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

Re: GRAS Notice No. GRN 001111

Dear Mr. Trujillo,

The Food and Drug Administration (FDA, we) is granting the request to cease our evaluation of GRN 001111, which we filed on April 28, 2023. We received this request on February 7, 2024.

The subject of the notice is endo-1,4- β -xylanase enzyme preparation produced by *Bacillus subtilis* expressing the gene encoding xylanase from *B. subtilis* (xylanase enzyme preparation) for use as an enzyme at up to 50 mg total organic solids (TOS)/kg raw material in baking, brewing, and in grain processing. The notice informs us of AB Enzymes Inc.'s view that this use of xylanase 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 xylanase enzyme in the preparation, while the information supporting the safety of 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 001111 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 001111.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001111 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
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Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
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