U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Dylan Fronda
Dicentra LLC
7 St Thomas St #603
Toronto, Ontario M5S 2B7
CANADA

Re: GRAS Notice No. GRN 001237

Dear Mr. Fronda:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Erbslöh GmbH (Erbslöh) that we cease our evaluation of GRN 001237. We received this request on August 28, 2025. We received Erbslöh's notice on November 20, 2024 and filed it on April 10, 2025.

The subject of the notice is β-glucanase enzyme preparation produced by *Talaromyces versatilis* (β -glucanase enzyme preparation) for use as an enzyme at up to 50 mg Total Organic Solids (TOS)/kg raw material in brewing, wine making, and fruit, vegetable, and yeast processing. The notice informs us of Erbslöh's view that these uses of β -glucanase enzyme preparation are GRAS through scientific procedures.

In a phone conversation on July 18, 2025, we spoke with you as Erbslöh's representative regarding additional information needed to support a GRAS conclusion. Data and information that form the basis for Erbslöh's view that endo-1,3(4)-β-glucanase enzyme preparation from *Talaromyces versatilis* is safe under the conditions of its intended use needs to be publicly available. This can be corroborated by the application of unpublished data and information. Additionally, more specific information on the enzyme needs to be included in the safety narrative.

We have ceased our evaluation of the notice at your request on behalf of Erbslöh. We remind Erbslöh of a manufacturer's responsibility to ensure the safety and regulatory status of the substances that it markets for use in food or that it uses in food. We also remind Erbslöh that the use of a substance in food that is not GRAS (and is not otherwise excluded from the definition of a food additive), must have pre-market approval by FDA for its use in food (21 CFR 170.30(g)). More information about the criteria for GRAS is available in our regulations (21 CFR part 170).

Your request on behalf of Erbslöh does not preclude Erbslöh from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that Erbslöh address these issues adequately to support a GRAS conclusion. Finally, we remind Erbslöh of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which Erbslöh agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001237 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2025.09.22 10:20:32 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary Supplements, and Innovation
Human Foods Program