

# FDA GRAS



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**Re: GRAS Notice No. GRN 001270**

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001270. We received the GRAS notice dated May 7, 2025 that Gene III Biotechnology Co., Ltd. (Gene III) submitted and filed it on July 8, 2025. We received amendments to the notice on September 15, 2025, and October 3, 2025, that clarified the manufacturing process, potential allergenicity of the enzymes, specifications, stability, dietary exposure, intended uses, and safety information.

The subject of the notice is L-ergothioneine, produced by *Escherichia coli* K-12 MG1655 expressing enzymes encoded by the genes from *Neurospora crassa* and *Mycobacterium smegmatis* MC2 155 (ergothioneine), intended for use as an ingredient in beverages (including coffee, tea, fruit drinks and ades, carbonated soft drinks, sports and energy drinks, and nutritional beverages), protein and nutritional powders, bakery products and other baked goods (including nutrition bars, cereal bars, and sweet bakery products), and candy, at use levels ranging from 8.3 to 150 mg per 100 g of food, with the intention of providing 30 to 150 mg of L-ergothioneine per serving, excluding use in infant formula and in products under the jurisdiction of the United States Department of Agriculture.

Based on the information that Gene III provided, as well as other information available to FDA, we have no questions at this time regarding Gene III's conclusion that ergothioneine is GRAS under its intended conditions of use. This letter is not an affirmation that ergothioneine is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 001270 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).



Sincerely,

Susan J.  
Carlson -S

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