



James T. Heimbach, Ph.D.
JHeimbach LLC
923 Water Street #66
Port Royal, VA 22535

Re: GRAS Notice No. GRN 001028

Dear Dr. Heimbach,

The Food and Drug Administration (FDA, we) is granting the request on behalf of Danstar Ferment AG to cease our evaluation of GRN 001028, which we filed on January 14, 2022. We received this request on September 27, 2022.

The subject of the notice is *Metschnikowia pulcherrima* DANMET-A and *M. fructicola* DANMET-B (yeast) for use individually and in combination at a maximum level of 1 g yeast/kg fresh coffee cherries, post-harvest, to provide up to 2×10^7 colony forming units/g coffee. The notice informs us of Danstar's view that this use of *M. pulcherrima* DANMET-A and *M. fructicola* DANMET-B is GRAS through scientific procedures.

In a telephone discussion on April 20, 2022, we informed you of the following:

- We have some administrative comments about the formatting of the notice.
- We noted that the two species of microorganisms are not closely enough related to be evaluated together and thus would necessitate two separate GRAS notices.
- The intended use of the two microorganisms was unclear and would need to be clarified.
- We indicated that the notice did not address the potential presence of microbial secondary metabolites, pulcherrimin and pulcherrimic acid in food related to the intended use of *Metschnikowia pulcherrima* DANMET-A and *M. fructicola* DANMET-B. Furthermore, no information was described to establish safe levels of these metabolites in food.
- The antimicrobial effects of *M. pulcherrima* and *M. fructicola* indicate the potential for effects on resident microbial populations and the potential perturbations of host-microbiome homeostasis.
- We noted that the use of *M. pulcherrima* and *M. fructicola* as a processing aid in winemaking may not support the safety of intended use as an ingredient in food consumed by the general population.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

- We noted that safety evaluations (EFSA/EPA) related to use of *Metschnikowia* species as a pesticide or plant protectant do not establish the safety of the intended uses in food. Notably, the EFSA dossier cited in the notice identified numerous data gaps regarding *Metschnikowia fructicola* NRRL Y-27328 and toxicological reference values for pulcherrimin.

In an email dated August 8, 2022, we recommended that you request that we cease to evaluate GRN 001028 due to the concerns that we conveyed in our April 20, 2022 discussion. In an email dated September 27, 2022, you requested that we cease our evaluation of GRN 001028.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001028 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.

Carlson -S

Susan Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

Digitally signed by
Susan J. Carlson -S
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