



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

Re: GRAS Notice No. GRN 000829

Dear Dr. Heimbach:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement you submitted on behalf of Cura Global Health, Inc. (Cura) to GRN 000829. We received the supplement on March 5, 2020. The supplement addresses an additional use for powdered *Aspergillus oryzae* grown with one or more added minerals (powdered *A. oryzae* with minerals). Cura submitted additional information on April 6, 2020 and April 13, 2020, which included a statement regarding the identity and method of manufacture, as well as an updated literature search.

We previously responded to GRN 000829 on December 9, 2019. We stated that we had no questions at that time regarding Cura's conclusion that powdered *A. oryzae* with minerals are GRAS for their intended use in conventional foods, including nonalcoholic, non-carbonated beverages; breakfast cereals and bars; rice and pastas; powdered milk and yogurts; condiments; processed fruits and fruit juices; processed vegetables and vegetable juices; soups and soup mixes; and nutritional drinks, at a level that provides 25% of the Daily Value (DV) for each mineral contained in the product, up to 250 mg powder per serving.¹

In the supplement received March 5, 2020, Cura informs us of its view that powdered *A. oryzae* with minerals are GRAS, through scientific procedures, for use in meat analogs at a level that provides 25% of the DV for each mineral contained in the product, up to 250 mg powder per serving.

Our use of the term, "powdered *A. oryzae* with minerals" in this letter is not our recommendation of that term as an appropriate common or usual name for declaring the substance in accordance with FDA's labeling requirements. Under 21 CFR 101.4, each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for nonstandardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under the purview of the Office of Nutrition and Food Labeling

¹ For adults and children ages four years and older, as established in FDA's 2016 Food Labeling Final Rule (81 FR 33742; May 27, 2016).

(ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety (OFAS) did not consult with ONFL regarding the appropriate common or usual name for “powdered *A. oryzae* with minerals.”

Cura states that the identity and method of manufacture are the same as discussed in GRN 000829. To support the additional use in meat analogs, Cura’s supplement includes a comparison of the dietary exposure for the current uses to that from the current and intended uses of powdered *A. oryzae* with minerals. The difference between the two estimates shows a negligible increase in exposure from the intended use. Cura also conducted an updated review of the scientific literature through March 2020 and concludes that the safety of powdered *A. oryzae* with minerals continues to be confirmed and that there is an absence of any reported adverse effects.

Based on the totality of data and information summarized above, Cura concludes that powdered *A. oryzae* with minerals are GRAS for their intended use.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products containing powdered *A. oryzae* with minerals bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of ONFL in the Center for Food Safety and Applied Nutrition. OFAS did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Section 301(ll) of the FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of Cura’s supplement concluding that powdered *A. oryzae* with minerals are GRAS under their intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing powdered *A. oryzae* with minerals. Accordingly, our response should not be construed to be a statement that foods containing powdered *A. oryzae* with minerals, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Cura provided, as well as other information available to FDA, we have no questions at this time regarding Cura's conclusion that powdered *A. oryzae* with minerals are GRAS under their intended conditions of use. This letter is not an affirmation that powdered *A. oryzae* with minerals are 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 the supplement to GRN 000829 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by
Susan J. Carlson -S
Date: 2020.05.18
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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