William Turney
Kerry Ingredients & Flavors, Inc.
3400 Millington Rd.
Beloit, WI 53511

Re: GRAS Notice No. GRN 000955

Dear Mr. Turney:

The Food and Drug Administration (FDA, we) completed our evaluation of Kerry Ingredients & Flavors, Inc.'s (Kerry) supplement to GRN 000955. We received the supplement on December 16, 2022. The supplement addresses the increased use level of *Bacillus subtilis* BS-MB40 PTA-122264 spore preparation from a maximum level of 2 x 10^9 colony forming units (CFU)/serving to 1 x 10^{10} CFU/serving. Kerry submitted clarifying information on May 19, 2023, and June 5, 2023, which included information regarding the licensing agreement between Kerry and the notifier of GRN 000955, BIO-CAT Microbials, LLC (BIO-CAT), revised heavy metal specifications, and an updated literature search.

We previously responded to GRN 000955 on March 26, 2021. We stated that we had no questions at that time regarding BIO-CAT's conclusion that *B. subtilis* BS-MB40 PTA-122264 spore preparation is GRAS for use as an ingredient at a maximum level of 2 x 10^9 CFU/serving in baked goods and baking mixes; beverage and beverage bases, nonalcoholic; breakfast cereals; cheeses; chewing gum; coffee and tea; condiments and relishes; confections and frostings; dairy product analogs; fats and oils; fruit juices; frozen dairy desserts and mixes; fruit and water ices; gelatins, puddings, and fillings; grain products and pasta; hard candy and soft candy; herbs, seeds, spices, seasonings, blends, extracts, and flavorings; jams and jellies; milk and milk products; nut and nut products; plant protein products; processed fruits and fruit juices; processed vegetables and vegetables juices; snack foods; soups and soup mixes; sugar and sugar substitutes; and sweet sauces, toppings, and syrups.[1]

In the supplement dated December 13, 2022, Kerry informs us of its view that *B. subtilis* BS-MB40 PTA-122264 spore preparation is GRAS, through scientific procedures, for use as an ingredient at a maximum level of 1 x 10^{10} CFU/serving in the same food categories described in GRN 000955.

Kerry states that the identity, the food categories in which the ingredient is intended to be used, and the method of manufacture are the same as discussed in GRN 000955 and

[1] BIO-CAT states that *B. subtilis* BS-MB40 PTA-122264 spore preparation is not intended for use in infant formula or in any products under the jurisdiction of the United States Department of Agriculture (USDA).

its amendments. Kerry states that all specifications for *B. subtilis* BS-MB40 PTA-122264 spore preparation are the same as described in GRN 000955 and its amendments except for the specifications for lead, cadmium, arsenic, and mercury, which were each revised from <0.5 mg/kg to <0.25 mg/kg.

Kerry states that based on the maximum servings of food consumed per day for males aged 51 years and older of 18.2 servings per day and a maximum use level of 1×10^{10} CFU/serving, the maximum dietary exposure to *B. subtilis* BS-MB40 PTA-122264 spore preparation from the intended uses is 1.82×10^{11} CFU/d.

Kerry conducted a literature review through May 2023 and concludes that the safety of *B. subtilis* continues to be confirmed and that there is an absence of adverse effects.

Based on the data and information presented in the supplement, Kerry concludes that *B. subtilis* BS-MB40 PTA-122264 spore preparation is GRAS for its intended use.

Standards of Identity

In the notice, Kerry states its intention to use *B. subtilis* BS-MB40 PTA-122264 spore preparation in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

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 *B. subtilis* BS-MB40 PTA-122264 spore preparation 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 the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition (CFSAN). The Office of Food Additive Safety (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.

Allergen Labeling

The FD&C Act requires that the label of a food that is or contains an ingredient that contains a "major food allergen" declare the allergen's presence (section 403(w)). The FD&C Act defines a "major food allergen" as one of nine foods or food groups (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame) or a food ingredient that contains protein derived from one of those foods. *B. subtilis* BS-MB40 PTA-122264 spore preparation may require labeling under the FD&C Act because it may contain protein derived from soy and milk. Questions about petitions or

notifications for exemptions from the food allergen labeling requirements should be directed to the Division of Food Ingredients in OFAS. Questions related to food labeling in general should be directed to ONFL in CFSAN.

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 Kerry's supplement concluding that *B. subtilis* BS-MB40 PTA-122264 spore preparation is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing *B. subtilis* BS-MB40 PTA-122264 spore preparation. Accordingly, our response should not be construed to be a statement that foods containing *B. subtilis* BS-MB40 PTA-122264 spore preparation, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Kerry provided, as well as other information available to FDA, we have no questions at this time regarding Kerry's conclusion that *B. subtilis* BS-MB40 PTA-122264 spore preparation is GRAS under its intended conditions of use. This letter is not an affirmation that *B. subtilis* BS-MB40 PTA-122264 spore preparation 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 the supplement to GRN 000955 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2023.09.11 14:30:21 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition