Arie Carpenter
Chr. Hansen, Inc.
9015 West Maple Street
Milwaukee, WI 53214 – 4298

Re: GRAS Notice No. GRN 000937

Dear Ms. Carpenter:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000937. We received Chr. Hansen, Inc.'s (Chr. Hansen) notice on April 28, 2020 and filed it on August 17, 2020. Chr. Hansen submitted amendments to the notice on January 26, 2021 and February 22, 2021 that provided clarifications on the appendices, description of the ingredient, specifications, and the dietary exposure estimate.

The subject of the notice is *Staphylococcus carnosus* DSM 25010 for use as an ingredient to improve color stability of raw cured meats throughout their shelf life, at levels up to 10^9 colony forming units (CFU)/g of cured meat. The notice informs us of Chr. Hansen's view that this use of *S. carnosus* DSM 25010 is GRAS through scientific procedures.

Chr. Hansen describes *S. carnosus* DSM 25010 as an off-white to brown powder. Chr. Hansen states that *S. carnosus* DSM 25010 is a spherical-coccus that is a facultative-anaerobe, is catalase positive, coagulase negative, and displays a high tolerance to salt. The strain was obtained from the German meat culture producer Rudolf Müller & Co. and is deposited in the strain collection of the Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ) in Braunschweig, Germany with the accession number DSM 25010. Chr. Hansen discusses phenotypic and genotypic characteristics to confirm identity. Chr. Hansen states that *S. carnosus* DSM 25010 is a non-pathogenic and non-toxigenic organism and does not contain any virulence genes or produce biogenic amines.

Chr. Hansen describes the manufacture of *S. carnosus* DSM 25010 by fermentation of a pure culture under controlled conditions. Upon completion of fermentation, the culture is cooled, concentrated by centrifugation, and frozen into pellets. The frozen pellets are immersed in liquid nitrogen, lyophilized, ground to a powder, and mixed with food-grade excipients. Chr. Hansen states that no components of the fermentation medium are allergens or are derived from allergenic sources, and that *S. carnosus* DSM 25010 is manufactured under current good manufacturing practices using food-grade raw materials.

Chr. Hansen provides specifications for *S. carnosus* DSM 25010 that include limits for lead (<0.02 mg/kg)[1] and for microorganisms including, *Salmonella* serovars (absent in 25 g), *Listeria monocytogenes* (absent in 25 g), and *Bacillus cereus* (<100 CFU/1 g). Chr. Hansen provides the results from the analyses of four non-consecutive lots to demonstrate that *S. carnosus* DSM 25010 is manufactured to conform with the provided specifications.[2]

Chr. Hansen uses food consumption data from the 2015-2016 National Health and Nutrition Examination Survey to estimate the dietary exposure to *S. carnosus* DSM 25010 from its intended use. Chr. Hansen determines that the average amount of cured meat products consumed by individuals in the U.S. 2 years and older is 27.2 g/p/d. Chr. Hansen estimates the average dietary exposure to *S. carnosus* DSM 25010 to be 2.7 x 10^{10} CFU/g based on the conservative assumption that all raw cured meat products are consumed raw and will contain *S. carnosus* DSM 25010 at a level of 10^{9} CFU/g. However, Chr. Hansen states that *S. carnosus* DSM 25010 is heat sensitive and would be killed during cooking, and therefore, the dietary exposure to *S. carnosus* DSM 25010 is negligible if cured meat products are cooked prior to consumption.

Chr. Hansen states that there is a history of safe use of *S. carnosus* in fermented foods. Lactic acid bacteria in combination with coagulase-negative staphylococci, such as *S. xylosus* and *S. carnosus*, is a common starter culture used in meat products. Chr. Hansen relies on published literature to support the safety of consumption of *S. carnosus* DSM 25010 and notes that the only pathogenic *Staphylococcus* is the coagulase-positive *S. aureus*. Chr. Hansen further states that there have been no human infections related to ingesting food products containing *S. carnosus*.

Based on the totality of evidence, Chr. Hansen concludes that *S. carnosus* DSM 25010 is GRAS for its intended use.

[1] Chr. Hansen states that heavy metals are unlikely to be present in food cultures and notes that they monitor for heavy metals by selecting products that are representative of the raw materials used in the manufacturing facilities and that heavy metal testing is performed annually.

[2] Chr. Hansen provides the analyses of three batches of food cultures containing the raw materials used in the production of *S. carnosus* DSM 25010 and two batches of a product that is a blend of *L. carnosum* DSM 32756 and *S. carnosus* DSM 25010 to demonstrate that *S. carnosus* DSM 25010 meets the specification for lead.

Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of GRN 000937, we coordinated with the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS determines the efficacy and suitability of ingredients used in meat, poultry, and egg products, and prescribes safe conditions of use. Suitability relates to the ingredient's effectiveness in performing its intended technical effect and the assurance that the ingredient's use will not result in products that are adulterated or misleading for consumers.

FSIS has completed its review and has no objection to the use of *S. carnosus* DSM 25010 as an ingredient to improve the color stability of raw cured meat products throughout the shelf-life at levels up to 10^9 CFU/g of cured meat. Chr. Hansen is required to label the ingredient as "culture," "bacterial culture," "Staphylococcus carnosus culture," or "S. carnosus culture," in the ingredients statement of the products in which it is used.

FSIS requested that we advise Chr. Hansen to seek labeling guidance from Ms. Rosalyn Murphy-Jenkins at (301) 504-0879 or *via* email at Rosalyn.Murphy-Jenkins@usda.gov for questions regarding labeling of *S. carnosus* DSM 25010 used to improve the color stability of raw cured meat products.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (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 Chr. Hansen's notice concluding that *S. carnosus* DSM 25010 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 *S. carnosus* DSM 25010. Accordingly, our response should not be construed to be a statement that foods containing *S. carnosus* DSM 25010, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Chr. Hansen provided, as well as other information available to FDA, we have no questions at this time regarding Chr. Hansen's conclusion that *S. carnosus* DSM 25010 is GRAS under its intended conditions of use. This letter is not an affirmation that *S. carnosus* DSM 25010 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 000937 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
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Susan Carlson, Ph.D.
Director
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