Tyler Homer
OmniLytics, Inc.
9075 South Sandy Parkway
Sandy, UT 84070

Re: GRAS Notice No. GRN 000752

Dear Mr. Homer:

The Food and Drug Administration (FDA, we) completed our evaluation of OmniLytics, Inc.'s (OmniLytics) supplement to GRN 000752. We received the supplement on October 22, 2020. The supplement addresses the use of a flexible bacteriophage (phage) preparation containing two to eight phages specific to *Salmonella enterica* (flexible *Salmonella* phage preparation). OmniLytics submitted clarifying information on March 4, 2021, January 4, 2022, and January 5, 2022 which included information regarding the specifications, references to citations in 21 CFR, the date the updated literature search was performed, and confirmation of the notifier's identity.

We previously responded to GRN 000752 on July 13, 2018. We stated that we had no questions at that time regarding Phagelux (Canada) Inc.'s (Phagelux)[1] conclusion that a preparation containing two bacterial monophages (BP-63 and LVR 16-A) specific to *S. enterica* (*Salmonella* phage preparation) is GRAS for use as an antimicrobial agent to control *Salmonella* when applied at up to 10^8 plaque-forming units (PFU)/g of food in ready-to-eat meat and poultry products; meat and poultry carcasses and parts; egg products; fresh and processed fruits; fresh and processed vegetables; and fish (excluding Siluriformes) and shellfish.

In the supplement dated October 22, 2020, OmniLytics informs us of its view that flexible *Salmonella* phage preparation is GRAS, through scientific procedures, for use as an antimicrobial agent to control *Salmonella* when applied at up to 10^8 PFU/g of food in ready-to-eat meat and poultry products; meat and poultry carcasses and parts; egg products; fresh and processed fruits; fresh and processed vegetables; and fish (excluding Siluriformes) and shellfish.

OmniLytics states that the intended use, food categories, use level, method of manufacture, and specifications are the same as discussed in GRN 000752. OmniLytics explains that the introduction of new phages will not alter the safety of flexible *Salmonella* phage preparation. OmniLytics intends to produce flexible *Salmonella* phage preparations containing a mixture of two to eight double-stranded DNA, lytic phages specific to *S. enterica*, and subject to the same manufacturing and safety

[1] FDA notes that OmniLytics is part of Phagelux.

standards as described in GRN 000752.

OmniLytics conducted a literature review through October 2020 and concludes that the safety of phage continues to be confirmed and that there is an absence of adverse effects.

Based on the data and information presented in the supplement, OmniLytics concludes that flexible *Salmonella* phage preparation is GRAS for its intended use.

Standards of Identity

In the supplement, OmniLytics states its intention to use flexible *Salmonella* phage 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.

Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of the supplement to GRN 000752, 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 of the supplement to GRN 000752. As described above, OmniLytics intends to produce phages that are not identified in GRN 000752. These additional phages must comply with the conditions described in GRN 000752 to add to the existing phage preparation. FSIS requires an additional review of these phages for inclusion into the FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products to demonstrate both efficacy and suitability in USDA-regulated products.

FSIS requested that we advise you to seek regulatory guidance from its Risk Management and Innovations Staff (RMIS) about the use of flexible *Salmonella* phage preparation in meat, poultry, and egg products. You should direct such an inquiry to Dr. Melvin Carter, Director, RMIS, Office of Policy and Program Development, FSIS by email at Melvin.Carter@fsis.usda.gov.

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 OmniLytics' supplement concluding that flexible *Salmonella* phage 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 flexible *Salmonella* phage preparation. Accordingly, our response should not be construed to be a statement that foods containing flexible *Salmonella* phage preparation, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that OmniLytics provided, as well as other information available to FDA, we have no questions at this time regarding OmniLytics' conclusion that flexible *Salmonella* phage preparation is GRAS under its intended conditions of use. This letter is not an affirmation that *Salmonella* phage 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 000752 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2022.01.07 18:27:42 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
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cc: Melvin Carter, Ph.D.
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