



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

Re: GRAS Notice No. GRN 000827

Dear Mr. Homer:

The Food and Drug Administration (FDA, we) completed our evaluation of OmniLytics Inc.'s (OmniLytics) supplement to GRN 000827. We received the supplement on September 10, 2019. The supplement addresses additional uses for a preparation containing three bacterial monophages (MLF4, OLB35 and OLB145) specific to *Escherichia coli* (*E. coli* phage preparation).

We previously responded to GRN 000827 on August 12, 2019. We stated that we had no questions at that time regarding OmniLytics's conclusion that *E. coli* phage preparation is GRAS for use as an antimicrobial agent to control specific *E. coli* serotypes on fruits, vegetables, eggs, fish (excluding Siluriformes), and shellfish, when applied to food surfaces at up to 10^8 plaque-forming units (PFU)/g food. The notice originally included uses in products under USDA jurisdiction. Thus, as provided under 21 CFR 170.270, during our evaluation of GRN 000827, we coordinated with USDA/FSIS. However, during this coordination, in an amendment dated July 23, 2019, OmniLytics requested that the uses on products under the jurisdiction of USDA be excluded from consideration.

In the supplement received September 10, 2019, OmniLytics' informs us of its view that *E. coli* phage preparation is GRAS, through scientific procedures, for use as an antimicrobial agent to control specific *E. coli* serotypes when used as aqueous solution containing up to 10^8 PFU/g applied using a surface spray, dip or wash on red meat carcasses, parts, and trim (prior to grinding). This is a result of FSIS' reconsideration of its evaluation of GRN 000827 and subsequent letter to the notifier dated September 6, 2019, which stated that it had no objections to the use of the *E. coli* phage preparation when used as '[A]n aqueous solution containing up to 1×10^8 PFU per gram applied using a surface spray, dip or wash on red meat carcasses, parts, and trim (prior to grinding).' Stemming from FSIS's letter to OmniLytics, the intended uses include use as an antimicrobial agent to control specific *E. coli* serotypes on red meat carcasses, parts, and trim (prior to grinding) in addition to the previously considered intended uses on fruits, vegetables, eggs, fish (excluding Siluriformes), and shellfish when applied to food surfaces at up to 10^8 plaque-forming units (PFU)/g food.¹

¹ We note that the original notice, which we received on October 4, 2018, included poultry products, which

The changes in the intended uses do not affect the identity, method of manufacture, specifications, and safety of the product. However, the estimated dietary exposure is adjusted to reflect the uses restored in this supplement. Based on data from USDA's Economic Research Service (2017), OmniLytics provided an initial exposure estimate for *E. coli* phage preparation based on an average *per capita* dietary exposure to the selected food categories of 727 g/person(p)/day(d), resulting in a dietary exposure to *E. coli* phage preparation of 7.3×10^{10} PFU/p/d.² Our letter dated August 12, 2019 reflected the removal of all food categories under USDA jurisdiction, resulting in a reduced dietary exposure to the remaining food categories of 565 g/p/d, resulting in an exposure to the *E. coli* phage preparation of 5.7×10^{10} PFU/p/d. Because the supplement restores uses for some products under USDA jurisdiction, the estimated dietary exposure to food categories treated with *E. coli* phage preparation is 654 g/p/d, resulting in an exposure to the *E. coli* phage preparation of 6.5×10^{10} PFU/p/d.

Based on the totality of the evidence, OmniLytics concludes that the intended use on red meat carcasses, parts, and trim (prior to grinding) under the jurisdiction of FSIS are GRAS.

Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of the supplement to GRN 000827, we coordinated with USDA/FSIS. 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 completed its evaluation and stated that it had no objection to the use of *E. coli* phage preparation as an antimicrobial agent when used as an aqueous solution containing up to 10^8 PFU/g applied using a surface spray, dip or wash on red meat carcasses, parts, and trim (prior to grinding).

FSIS requested that we advise you to seek regulatory guidance from its Risk, Management, and Innovations Staff (RMIS) about the use of the *E. coli* 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

were not reconsidered by FSIS in its September 6, 2019 letter to OmniLytics.

² OmniLytics states that the working solution of the *E. coli* phage preparation is 10^9 PFU/mL, and it is applied at a maximum rate of 0.1 mL/food to achieve 10^8 PFU/g food.

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's supplement concluding that the *E. coli* 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 *E. coli* phage preparation. Accordingly, our response should not be construed to be a statement that foods containing *E. coli* 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's conclusion that *E. coli* phage preparation is GRAS under its intended conditions of use. This letter is not an affirmation that *E. coli* 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 000827 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan
J. Carlson -S
Date: 2019.10.09 16:37:08
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Susan Carlson, Ph.D.
Director
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cc: Melvin Carter, Ph.D.
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