



Alexander Sulakvelidze, PhD
Intralytix, Inc.
701 E Pratt St
Baltimore, MD 21202

Re: GRAS Notice No. GRN 000435

Dear Dr. Sulakvelidze:

The Food and Drug Administration (FDA, we) completed our evaluation of Intralytix, Inc.'s (Intralytix's) supplement to GRN 000435. We received the supplement on January 31, 2019. The supplement addresses additional uses for a preparation consisting of six bacterial monophages specific to *Salmonella enterica* (monophage cocktail). Intralytix submitted additional information on June 5, 2019, which included data on efficacy and information about shelf life. On August 1, 2019, Intralytix requested to exclude from consideration uses in ground red meat.

We previously responded to GRN 000435 on February 22, 2013. We stated that we had no questions at that time regarding Intralytix's conclusion that monophage cocktail is GRAS for the intended use as an antimicrobial for the treatment of certain poultry products, fish, shellfish, and fresh and processed fruits and vegetables at 10^7 plaque-forming units (PFU) per g of food. Subsequently, on February 13, 2015, FDA responded with no questions to a supplement to GRN 000435 from Intralytix, dated October 28, 2014, for use of monophage cocktail as an antimicrobial for the treatment of raw poultry in general at 10^7 PFU/g of food.

In the supplement received January 31, 2019, Intralytix informs us of its view that monophage cocktail is GRAS, through scientific procedures, for use as an antimicrobial for the treatment of ready-to-eat and raw red meat carcasses, subprimals, and trimmings at 10^7 PFU/g of food, as clarified on August 1, 2019.

Intralytix states that the identity, method of manufacture, and estimates of dietary exposure are the same as discussed in GRN 000435. Intralytix conducted a review of the literature in February and March 2018 and concludes that the safety of phage continues to be confirmed and that there is an absence of adverse effects. To support use on red meat products, Intralytix's supplement includes supporting data examining the efficacy of monophage cocktail.

Based on all the available scientific information, Intralytix concludes that monophage cocktail is GRAS for its intended uses.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
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www.fda.gov

Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of this supplement to GRN 000435, 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 expanding the use of monophage cocktail as an antimicrobial for the treatment of ready-to-eat and raw red meat carcasses, subprimals, and trimmings at 1×10^7 PFU/g of treated food. Regarding labeling, FSIS would consider the substance a processing aid that does not require labeling when it is used for ready-to-eat and raw red meat carcasses, subprimals, and trimmings at 1×10^7 PFU/g of treated food.

FSIS requested that we advise you to seek regulatory guidance from its Risk Management and Innovations Staff (RMIS) about the use of monophage cocktail 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(II) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(II) 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(II)(1)-(4) applies. In our evaluation of Intralytix's supplement concluding that monophage cocktail is GRAS under its intended conditions of use, we did not consider whether section 301(II) or any of its exemptions apply to foods monophage cocktail. Accordingly, our response should not be construed to be a statement that foods containing monophage cocktail, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).

Conclusions

Based on the information that Intralytix provided, as well as other information available to FDA, we have no questions at this time regarding Intralytix's conclusion that monophage cocktail is GRAS under its intended conditions of use. This letter is not an affirmation that monophage cocktail 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 000435 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
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
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cc: Melvin Carter, Ph.D.
Director
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