



J. Mason Weeda
OFW Law
2000 Pennsylvania Ave., NW
Suite 3000
Washington, DC 20006

Re: GRAS Notice No. GRN 000888

Dear Mr. Weeda:

The Food and Drug Administration (FDA, we) is granting your request on behalf of Gum Products International (Gum Products) to cease our evaluation of GRN 000888, which we filed on December 13, 2019. We received your request on February 25, 2020.

The subject of the notice is a preparation containing three bacteriophages specific to *Salmonella* serovars (*Salmonella*-specific phage preparation) for use as an antimicrobial on food, including meat, poultry and egg products, at a level of no greater than 1×10^{10} plaque-forming units (PFU)/g of food. The notice informs FDA of Gum Product's view that *Salmonella*-specific phage preparation is GRAS through scientific procedures.

In response to our questions seeking clarification on identity, additional manufacturing specifications, clarification on the intended use, and the data used to estimate the dietary exposure of *Salmonella*-specific phage preparation, Gum Products provided an amendment received on February 15, 2020, that included a revised notice that had been edited and reformatted. In an email sent to you on February 20, 2020, we recommended that Gum Products request that we cease our evaluation of GRN 000888 so that Gum Products may resubmit the revised dossier as a new notice. In an email dated February 25, 2020, you requested that we cease our evaluation of GRN 000888.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740
www.fda.gov

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000888 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -

Digitally signed by Susan J.

Carlson -S

Date: 2020.02.28 13:18:06 -05'00'

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Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

cc: Melvin Carter, Ph.D.
Director
USDA/FSIS/OPPD/RMIS
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