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 $1 \times 10^{10}$ 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.
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'

Susan J. 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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