U.S. FOOD & DRUG ADMINISTRATION

April 28, 2024

James La Marta, Ph.D.
Principal Consultant
Splitrock Regulatory Solutions, LLC
107 Decker Road
Boonton, NJ 07005

Re: Animal GRAS Notice No. 65 – Bacteriophage Preparation

Dear Dr. La Marta:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) received a generally recognized as safe (GRAS) notice, dated November 30, 2023, submitted on behalf of your client Proteon Pharmaceuticals S.A. (the notifier). The subject of the submission is a bacteriophage preparation for use to decrease the presence of *Salmonella* species in poultry feed. The submission informs us of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. The notice was filed on December 20, 2023 and designated as animal GRAS notice number (AGRN) 65. In a March 29, 2024 email to you, CVM informed the notifier of questions regarding the notifier's conclusion. Specifically, CVM has questions related to the adequacy of the published utility study to support the intended use and its impact on safety.

CVM is granting your request, on behalf of Proteon Pharmaceuticals S.A., dated April 4, 2024, to cease the evaluation of the AGRN 65.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 65 is accessible to the public on our website for the Current Animal Food GRAS Notices Inventory at https://www.fda.gov/animal-veterinary/generally-recognized-safe-gras-notification-program/current-animal-food-gras-notices-inventory.

If you have any questions about this letter, please contact Ms. Wasima Wahid at (240) 402-5857 or at wasima.wahid@fda.hhs.gov.

Sincerely,

/s/
David Edwards, PhD
Director, Division of Animal Food Ingredients
Office of Surveillance and Compliance
Center for Veterinary Medicine

U.S. Food and Drug Administration
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