U.S. FOOD & DRUG ADMINISTRATION

December 16, 2022

Elizabeth Lewis, Ph.D.
Scientific & Regulatory Adviser
NutraSteward, Limited
1 Cleddau Bridge Business Park
Pembroke Dock SA72 6UP
United Kingdom

Re: Animal Generally Recognized as Safe Notice No. 59 – Porcine oligosaccharides-peptides complex

Dear Dr. Lewis,

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM or we) refers to a generally recognized as safe (GRAS) notice dated April 7, 2022 submitted on behalf of your client, Gnubiotics Sciences SA (Gnubiotics or the notifier). The subject of the notice is oligosaccharides-peptides complex to be used as a source of amino acids, peptides, and glycopeptides in food for cats and dogs at a level not to exceed 1.5% by weight in complete food. The submission informs us of the notifier's conclusion that the subject of the submission is GRAS through scientific procedures. You were notified in a letter dated May 11, 2022 that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 59. During the evaluation, we received an amendment, dated October 21, 2022, in response to our October 4, 2022 request for more information. We have completed our evaluation of AGRN 59.

Gnubiotics provides information about the identity, method of manufacture, and specifications of the notified substance. The notified substance is produced from protein hydrolysate of porcine intestinal mucosa which is processed to remove heparin for human medical use. It is intended to be used as a source of amino acids, peptides, and glycopeptides in food for cats and dogs at a use level of 1.5% by weight in complete food. The notifier provides a statement that potential viruses are inactivated, especially African Swine Fever Virus (AFSV). The raw materials used are regulated as feeding materials in other jurisdictions such as the European Union and Canada. The notifier provides notified substance specification with test method and acceptance criteria: Appearance (white to yellow powder), pH (2% aqueous solution) 5.0-7.0, Moisture ≤9%, Ash ≤17%, Free amino acids 35-45%, Glycopeptides and peptides 37-47%, Arsenic ≤1 mg/kg, Lead ≤1 mg/kg, Cadmium ≤0.5 mg/kg, Mercury ≤1 mg/kg, Total aerobic plate count ≤2000 CFU/g, Yeast and mold <100 CFU/g, *Salmonella* Negative in 25 g, *Escherichia coli* <10 CFU/g. The notifier provided stability information of the notified substance. The commercial product is the same as the notified substance.

The notifier concludes that information on the physical or other technical effect of the notified substance is not necessary because use of the notified substance as a source of amino acids, peptides, and glycopeptides in food for dogs and cats of all life stages at a level up to 1.5% by weight in complete food does not impact target animal safety.

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To address target animal safety of the intended use of the notified substance, the notifier includes analytical batch data demonstrating compliance with specifications for quality and contaminants, data from feeding studies in adult cats and dogs showing a lack of adverse clinical effects when the notified substance is fed as intended for six months, information demonstrating that the notified substance has a negligible impact on dietary thiamine, and results from studies showing that the notified substance is not genotoxic. The notifier provides additional support for the safety of the notified substance with a literature review examining the safety of the compositionally equivalent source material in swine and the toxicity of mammalian milk oligosaccharides, as well as with calculations comparing the estimated dietary intake of the notified substance and its components in the target animal species with safe consumption estimates from the cited literature.

The Association of American Feed Control Officials publishes in their Official Publication a list of names and definitions for accepted feed ingredients. FDA recognizes these names as being the "common or usual" names for feed ingredients. FDA recognizes "porcine oligosaccharides-peptides complex" as the common or usual name for the notified substance.

Section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Under section 403(a) of the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular. The notifier did not provide any information to demonstrate that the notified substance functions as intended because the notifier concluded that the intended use would not be expected to impact safety. Therefore, we did not evaluate whether the notified substance, porcine oligosaccharides-peptides complex, would achieve the effect claimed for it. However, please note that if products containing the notified substance, porcine oligosaccharides-peptides complex, bear any claims on the label or in labeling regarding the function of the notified substance, these claims should be supported by appropriate data and information. FDA may take enforcement action if any claims on labels or labeling are found to be false or misleading.

Section 301(ll) of the FD&C Act

Section 301(ll) 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(ll) (1)-(4) applies. In our evaluation of Gnubiotics' notice, concluding that the notified substance, porcine oligosaccharides-peptides complex to be used as a source of amino acids, peptides, and glycopeptides in food for cats and dogs at a level not to exceed 1.5% by weight in complete food 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 the notified substance. Accordingly, our response should not be construed to be a statement that foods containing the notified substance if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusion

Based on the information contained in the notice and the amendments submitted on behalf of Gnubiotics Sciences SA, as well as other information available to the FDA, we have no questions at this time regarding the notifier's conclusion that the use of porcine oligosaccharides-peptides complex is GRAS under the intended conditions of use. The agency

has not, however, made its own determination regarding the GRAS status of the intended use of the notified substance in animal food under 21 CFR 570.35. Unless noted above, our evaluation did not address other provisions of the Federal Food, Drug, and Cosmetic Act. As always, it is the continuing responsibility of Gnubiotics to ensure that animal food ingredients that the notifier markets are safe and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with 21 CFR 570.275(b)(2), the text of this letter responding to AGRN 59 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 +1(240) 402-5857 or at wasima.wahid@fda.hhs.gov. Refer to AGRN 59 in any future correspondence regarding this notice.

Sincerely,

/s/
Timothy Schell, Ph.D.
Director
Office of Surveillance and Compliance
Center for Veterinary Medicine