U.S. FOOD & DRUG ADMINISTRATION

September 2, 2026

Keller and Heckman LLP
Attention: Ms. Evangelia Pelonis
Consultant
1001 G Street, N.W.
Suite 500 West
Washington, DC 20001

Re: GRAS Notice AGRN 89 – Hydroxypropyl Cellulose

Dear Ms. Pelonis:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine refers to a generally recognized as safe (GRAS) notice, dated August 14, 2025, and received on September 3, 2025, submitted on behalf of your client, Redbarn Pet Products (the notifier). The subject of the notice is Hydroxypropyl Cellulose (hereafter known as Hydroxypropyl Cellulose or the notified substance) as a film coating and binder of nutrient and flavor additives on dry food and treats for dogs at a maximum inclusion rate of 40 g Hydroxypropyl Cellulose per kg 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 January 5, 2026, that the GRAS notice was acceptable for filing, and the notice was designated as animal GRAS notice number (AGRN) 89. CVM received an amendment, dated May 29, 2026, from the notifier containing additional information. We have completed our evaluation of AGRN 89 and have no questions at this time regarding the conclusion for use of the notified substance as a film coating and binder of nutrient and flavor additives on dry food and treats for dogs at a maximum inclusion rate of 40 g Hydroxypropyl Cellulose per kg food.

To address the identity, method of manufacture, and specifications of the notified substance, the notifier describes the raw materials used in the manufacture, the manufacturing process and controls, analytical methods, and analysis results including composition, and potential impurities and contaminants. The notified substance is produced by etherifying alkali cellulose followed by washing and drying. The analysis results from multiple batches are provided to demonstrate consistency in composition and physical properties, control of undesirable impurities and heavy metals, and conformance to the specifications currently described in 21 CFR 172.870(a)(1) and Food Chemicals Codex specifications for Hydroxypropyl Cellulose. The notifier provides specifications for the notified substance as follows: appearance (white powder), hydroxypropyl groups (53.5% - 80.5%), lead (≤3 mg/kg), loss on drying (≤5.0%), pH of 10 mg/mL solution (5.0 – 8.0), residue on ignition (≤0.5%), viscosity of a 10% solution (200 – 600 cps). The notifier also provides stability and packaging information.

U.S. Food and Drug Administration
Center for Veterinary Medicine
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College Park, MD 20740-3835
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To address the utility of the notified substance, the notifier provides three studies to demonstrate that Hydroxypropyl Cellulose can be combined with other ingredients in an aqueous coating formulation to coat dry pet food and toothbrush treats for dogs. In addition, the notifier describes how publicly available information supports the use as a coating that can affix flavors, nutrients, and other suitable ingredients to the exterior of a dry pet food and toothbrush treats.

To address the target animal safety of the intended use of the notified substance, the notifier provides publicly available information on 1) the toxicological evaluation of modified celluloses conducted by international organizations; 2) published/unpublished studies on the toxicity of Hydroxypropyl Cellulose and other modified celluloses; and 3) the dietary exposure assessment of dogs to Hydroxypropyl Cellulose.

Publicly available studies in rodents, dogs and other animal species orally exposed to modified celluloses evaluated impacts on acute, chronic, sub-chronic, toxicity, genotoxicity, carcinogenesis, and reproductive/developmental toxicity. The notifier used a read-across approach from studies on other modified celluloses to address data gaps in the toxicity profile of Hydroxypropyl Cellulose. The notifier justified the read-across approach given the close structural and physicochemical similarities among cellulose and its substituted analogues. The notifier provided information on the primary mode of clearance for Hydroxypropyl Cellulose being fecal excretion without meaningful systemic absorption in monogastrics including dogs. The notifier also cites that monogastrics lack cellulolytic digestive enzymes and large fermentation chambers.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (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 this notice, concluding that the notified substance 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 submitted by Redbarn Pet Products, and other information available to the FDA, we have no questions at this time regarding the notifier's conclusion that Hydroxypropyl Cellulose is GRAS under the intended conditions of use as a film coating and binder of nutrient and flavor additives on dry food and treats for dogs at a maximum inclusion rate of 40 g of Hydroxypropyl Cellulose per kg food. The Agency has not 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 FD&C Act. As always, it is the continuing responsibility of Redbarn Pet Products to ensure that animal food ingredients that it 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 89 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 or comments, please contact Ms. Megan Hall at animalfood-premarket@fda.hhs.gov.

Sincerely,

/s/
Jeanette Murphy, M.S.
Acting Director
Office of Surveillance and Compliance
Center for Veterinary Medicine