



November 14, 2025

Center for Regulatory Services, Inc.
Attention: Kristi Smedley, Ph.D.
Consultant
1536 Canoe House Road
Jamaica, VA 23079

Re: Animal Food Ingredient Consultation 0001– Rice Protein Concentrate

Dear Dr. Smedley:

The Division of Animal Food Ingredients in the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) received a request, dated October 30, 2024 and submitted on behalf of your client Hill's Pet Nutrition, Inc., in which the firm requested the submission be reviewed under the Animal Food Ingredient Consultation (AFIC) process. You were notified in an email dated January 16, 2025, that CVM received the consultation request. The request was subsequently designated as AFIC 0001 and added to the AFIC Inventory on July 7, 2025.

All issues associated with the consultation of this animal food ingredient have been adequately addressed.

Chemistry, Manufacturing, and Controls

To address the identity, method of manufacture, and specifications of the ingredient, CVM considered the raw materials acceptance criteria, manufacturing process and controls, analytical methods and analysis results including physical properties, composition, and potential impurities and contaminants. The analysis results from multiple batches were provided to demonstrate consistency in composition, microbial parameters, heavy metals (including the inorganic arsenic), pesticides, and mycotoxins. Provided stability data from multiple batches also demonstrate that physical properties, composition, and microbial content are within established specifications throughout the proposed shelf-life under recommended storage conditions.

Intended Use

To address intended use, CVM considered information relative to the amino acid profile of the ingredient and data and information from feeding studies conducted in dogs and cats. Rice protein concentrate is not intended to serve as the sole protein source in dog and cat diets, but digestibility studies conducted by the firm demonstrate that true protein digestibility in adult dogs ranged from 88-94% when the ingredient was included at up to 9.6% of the diet and in adult cats true protein digestibility ranged from 87-100% when included at up to 28% of the diet. The

firm also conducted a 6-month study in kittens fed a diet containing 20% rice protein concentrate, and the adequate growth, normal serum protein concentrations, and good stool quality support the intended use of the ingredient as a protein source for both growing cats and dogs.

Target Animal Safety

To address target animal safety, CVM considered information relative to a safety assessment of potential impurities and contaminants and data and information from feeding studies conducted in dogs and cats. Batch analyses of the ingredient demonstrated that heavy metals, mycotoxins, pesticides, and microbial hazards should not pose a target animal safety concern under the conditions of intended use. Short-term feeding studies conducted by the firm showed adult dogs and cats had acceptable body weight and stool quality and did not experience serious adverse events when fed diets containing up to 28% of the ingredient. In the firm's 6-month feeding study with kittens consuming a diet containing 20% of the ingredient, veterinary physical exams and clinical assessments demonstrated that all kittens remained in good health throughout the study, steadily gained weight, had good stool quality, and experienced no significant abnormalities in hematology, serum chemistry, taurine, or urine analyses.

This letter concludes Hill's Pet Nutrition's consultation with the FDA regarding Rice protein concentrate. The ingredient and its use in animal food are defined as follows:

Rice protein concentrate is the dried protein fraction of the endosperm of the rice grain (*Oryza sativa*). It is obtained during rice starch production by wet milling under alkaline conditions, sieving, separation, precipitation under acidic conditions, and drying. It must contain not less than 70% protein on a dry matter basis and not more than 12% moisture. If a conditioning agent is used, the name of the conditioning agent must be shown as an added ingredient. It is for use in dog and cat foods as a source of protein in accordance with good feeding practices.

At this time, we have no questions or concerns about the safety of this ingredient when used in accordance with the conditions of intended use described in this letter. FDA generally does not anticipate initiating enforcement action with respect to the food additive approval requirements of the Federal Food, Drug and Cosmetic Act for this ingredient or animal food containing this ingredient as long as there continues to be no questions or concerns about the safety of this ingredient. However, it is Hill's Pet Nutrition, Inc.'s continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and otherwise in compliance with all applicable legal and regulatory requirements. A copy of this letter will be made available to the public at [Current Animal Food Ingredient Consultation Inventory | FDA](#).

If you have any questions or comments regarding this letter, please contact Ms. Wasima Wahid at animalfood-premarket@fda.hhs.gov.

Sincerely,

/s/

David Edwards, Ph.D.
Director, Division of Animal Food Ingredients
Office of Surveillance and Compliance
Center for Veterinary Medicine