



May 4, 2018

Thomas Berger, Ph.D.  
Vice President  
G-Science, Inc.  
5500 Highlands Parkway  
Smyrna, GA 30082

Re: GRAS Notice No. AGRN 25

Dear Dr. Berger:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of AGRN 25, which we filed on August 21, 2017. We received your request on April 24, 2018.

The subject of the notice is clinoptilolite of sedimentary origin. The notice informs FDA of G-Science's view that clinoptilolite of sedimentary origin is GRAS, through scientific procedures, for use as an anticaking agent in diets for cattle, swine, goats, sheep, poultry, cats and dogs, regardless of life stages, at a level up to 2% by weight in complete diets.

In teleconferences on January 30, 2018 and April 9, 2018, we discussed issues identified during our evaluation of the notice. In particular, we discussed the published studies reporting the conflicting evidence of changes induced by clinoptilolite in animal serum, and the lack of publicly available information to support the use of 2% clinoptilolite for dogs and cats. We also discussed the use of clinoptilolite at intended 2% by weight in complete diets could cause potential excess levels of aluminum and iron for some species. We discussed the opportunity for G-Science to ask us to cease our evaluation of AGRN 25 and to re-submit a new GRAS notice in the future.

In accordance with 21 CFR 570.275(b)(3), the text of this letter responding to AGRN 25 is accessible to the public on our website for Animal Food GRAS Notices Inventory at <https://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm>.

Sincerely,

/s/

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