

May 31, 2012

Martha E. Marrapese  
Keller and Heckman LLP  
1001 G Street, N.W.  
Suite 500 West  
Washington, D.C. 20001

Re: GRAS Notice No. AGRN 000-012

Dear Ms. Marrapese:

The Food and Drug Administration (FDA) is responding to the notice, dated August 31, 2011, that you submitted under FDA's Center for Veterinary Medicine (CVM) Pilot Program for substances generally recognized as safe (GRAS) added to food for animals (See 75 FR 31800; June 4, 2010). CVM received the notice on September 1, 2011, filed it on September 29, 2011, and designated it as GRAS Notice No. 000-012.

The subject of your notice is Virginiamycin. The notice informs the FDA of the view of Lallemand Specialties, Inc. that Virginiamycin is GRAS, through scientific procedures, for use as an ingredient in animal feed for livestock animals (beef cattle, dairy cows, broiler chickens, egg-laying chickens, swine, and sheep) and pets (dogs, cats, rabbits, guinea pigs, and horses) as a processing aid in the production of non-food grade and food grade ethanol at a level not to exceed 6 ppm of commercial product (3 ppm Virginiamycin) in the fermentor.

In a letter dated May 7, 2012, you asked that FDA cease to evaluate your notice. Given your letter, we ceased to evaluate your GRAS notice for animal food, effective May 7, 2012, the date that we received your letter.

In accordance with the Federal Register notice announcing the CVM Pilot Program, a copy of the text of this letter responding to AGRN 000-012, and a copy of the information in this notice that conforms to the information described in your GRAS exemption claim is available for public review and copying via the FDA home page at <http://www.fda.gov>. To view or obtain an electronic copy of this information, follow the hyperlinks from the "Animal & Veterinary" topic to the "Products" section to the "Animal Food & Feeds" to the "Generally Recognized as Safe (GRAS) Notifications" page where the Animal Food GRAS Inventory is listed.

If you have any questions about this letter, please contact Dr. M. Thomas Hendricks at 240-453-6869 or by email at [thomas.hendricks@fda.hhs.gov](mailto:thomas.hendricks@fda.hhs.gov). Please reference AGRN 000-013 in any future correspondence regarding this submission.

Sincerely,

/s/

Sharon A. Benz, Ph.D., PAS

Director

Division of Animal Feeds

Office of Surveillance and Compliance

Center for Veterinary Medicine