July 25, 2012

Mr. Devon W. Hill
Keller and Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001

Re: GRAS Notice No. AGRN 000-013

Dear Mr. Hill:

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. 000-013.

The subject of your notice is isobutanol distillers grains (“IDG”). The notice informs FDA of the view of Gevo, Inc. that IDG, including up to 100 ppm isobutanol is GRAS through scientific procedures, for use as a nutritional component in animal feed. IDG collectively includes distillers dried grains, distillers dried grains with solubles, condensed distillers solubles, wet distillers grains, and wet distillers grains with solubles. IDG is intended for food-producing animals (beef cattle, dairy cows, broiler chickens, egg-laying chickens, swine, and sheep) and companion animals (dogs, cats, rabbits, guinea pigs, and horses).

In an email dated July 25, 2012, you asked that FDA cease to evaluate your notice. Given your letter, we ceased to evaluate your GRAS notice for animal food, effective July 25, 2012, the date that we received your letter.

In accordance with Federal Register notice announcing the CVM Pilot Program, a copy of the text of this letter responding to AGRN 000-013, 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. Andrea Krause at 240-276-9768 or by email at andrea.krause@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