

October 15, 2015

Dr. James La Marta
DSM Nutritional Products
45 Waterview Boulevard
Parsippany, New Jersey 07054

Re: GRAS Notice No. AGRN 000-018

Dear Dr. La Marta:

The Food and Drug Administration (FDA) is responding to the notice, dated September 17, 2014, and the additional information dated November 13, 2014, 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 19, 2014, and the additional information on November 20, 2014, filed the notice on December 22, 2014, and designated it as GRAS Notice No. 000-018. You amended your notice on July 31, 2015.

The subject of your notification is inactivated modified *Saccharomyces cerevisiae* as a component of animal feed when used in the fermentation of corn to produce ethanol. The target animal species are poultry (broilers, layers, breeding chickens and turkeys), swine (piglets, growers, finishers, gestating and lactating sows), bovines (beef and dairy), fish (salmonoids, catfish, and tilapia), minor species (ducks, quail, sheep and goats) and pets. The notice informs FDA of the view of DSM Nutritional Products that inactivated modified *Saccharomyces cerevisiae* is GRAS, through scientific procedures, in feeds for target animal species when used as a single feed ingredient or as a portion of distillers dried grains with or without solubles (DDG/DDGS) at up to 20% of the dry solids.

In a letter dated October 8, 2015, you asked that FDA cease to evaluate your notice. We ceased to evaluate your GRAS notice for animal food, effective October 8, 2015.

In accordance with the Federal Register notice announcing the CVM Pilot Program, a copy of the text of this letter, as well as 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 "Safe Feed" webpage (www.fda.gov/safefeed) under the Seek Ingredient Approval section to "Generally Recognized as Safe (GRAS) Notification Program" where the Animal Food GRAS Inventory is listed.

If you have any questions about this letter, please contact Dr. M. Thomas Hendricks at 240-204-5925 or by email at thomas.hendricks@fda.hhs.gov. Please reference AGRN 000-018 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