

## Lactoside V™ obtains “enforcement discretion” letter from FDA

### FOR IMMEDIATE RELEASE:

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Further to our initial announcement, Lallemand Ethanol Technology (LET) is pleased to confirm that its virginiamycin based antibiotic (**Lactoside V™**) received an “enforcement discretion” letter from the FDA’s Center for Veterinary Medicine (CVM) for use in ethanol production, dated January 9, 2009.

This followed a period of working closely with the CVM to ensure the correct paperwork was filed and that all conditions set forth by them for obtaining the discretion letter were met.

An extract from the letter states; “At this time, based on our review of the information submitted by Lallemand Ethanol Technology, if Lactoside V’s use is limited to its addition to a fermentor at levels of up to 6 ppm maximum, we would not anticipate recommending or initiating enforcement action against Lallemand Ethanol Technology’s virginiamycin based product, Lactoside V, or any distiller by-product and/or non medicated finished feed containing residues of up to 0.5 ppm of virginiamycin during the period of time Lallemand Ethanol Technology is diligently pursuing the approval of virginiamycin through a Food Additive Petition (FAP).”

LET takes note of CVM’s extensive outreach since June 2008, to place the entire U.S. ethanol industry on notice that “[t]he Federal Food, Drug, and Cosmetic Act requires that any substance added to animal feed be approved as a food additive or considered generally recognized as safe (GRAS).” We understand this requirement to apply to all ingredients in ethanol production, including antibiotics, which are reasonably expected to become a component of the distiller grain by-product. Currently, there is no formal FDA food additive regulation for this intended use for any virginiamycin product or for any other antibiotic product. Lallemand Ethanol Technology’s letter from CVM is one of the very few enforcement discretion letters issued for the continued supply of antibiotics within the ethanol industry while this regulatory requirement, which applies to all producers in the industry, is being met.

We want to make it clear that we are well underway to obtaining the necessary data needed for a successful FAP submission for Lactoside V™. Our anticipated submission deadline is June 28, 2010. However, we expect submission well before this date.

We also fully support the method development work that CVM has completed to date. We believe that the LC-MS method utilizes the best available technology and will deliver significantly more accurate residual measurements than traditional methods. LET is developing a similar LC-MS method that is being used to gather data for our FAP submission. Our method detects both virginiamycin sub-units with a high degree of accuracy.

For those customers that require it, a copy of the letter is available upon request.

For more information, please contact Craig Pilgrim at (815) 986-8443 or [cpilgrim@lallemand.com](mailto:cpilgrim@lallemand.com).

Lallemand Ethanol Technology is a Milwaukee, WI based, leading supplier of fermentation ingredients (yeast, yeast nutrition and antimicrobials) and value-creating services to the fuel ethanol industry. Lallemand Ethanol Technology is a business unit of Lallemand Inc., the Canadian-based yeast and bacteria producer.