



Generally Recognized as Safe (GRAS) Determination for:

- **Intentional use of Lactrol's Virginiamycin as a processing aid**
- **Distillers grains containing virginiamycin residues up to 1 PPM**

Phibro Ethanol Performance Group has successfully completed the review process for Lactrol's virginiamycin, resulting in a GRAS (Generally Recognized as Safe) determination as regulated by the Food, Drug and Cosmetic Act. Virginiamycin is the active ingredient in Lactrol®, the market-leading antimicrobial for renewable fuels production.

Since its introduction in 1993, Lactrol® has proven to be a safe product for use in renewable fuels production and distillers' grain production. It was previously sold under the FDA's letter of no objection as well as at the "regulatory discretion" of the FDA's Center for Veterinary Medicine (CVM).

Phibro has consistently been at the forefront of regulatory compliance with the FDA. A number of years ago, under the guidance of the FDA, Phibro began preparing essential scientific data and research necessary to secure long-term regulatory compliance for Lactrol's virginiamycin. During that process, Phibro learned the FDA's Food Additive Petition (FAP) process would not guarantee safekeeping of Phibro's confidential data. This presented a significant financial and research risk for the company; as the only manufacturer of Lactrol's virginiamycin, security of intellectual property is critical.

To meet FDA requirements and protect Lactrol's proprietary active ingredient, Phibro pursued a GRAS determination, an equally acceptable option for regulatory compliance. Phibro compiled virtually the same data needed for the FAP process and formed an independent expert panel to review the scientific data and determine the compliance status of Lactrol's virginiamycin.

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The panel—**Dr. Lester Crawford, Dr. Kristi Smedley, Dr. Peter Silley, Dr. Richard Kraska, and Dr. Jerry Shurson**—agreed, based on the following conclusions, that virginiamycin is Generally Recognized as Safe (GRAS) as defined by the Food Drug and Cosmetic Act.

- There is a long history of safe use of virginiamycin at higher levels as an animal drug in livestock and the major regulatory agencies agree that virginiamycin is a safe animal drug.
- There are sufficient data in the public domain to judge the safety of virginiamycin.
- It is highly unlikely that resistant pathogens will develop from the use of virginiamycin as a processing aid in fermentation.
- The presence of a maximum level of 1 ppm in animal feed is not harmful to livestock or other animals.
- The residues expected in meat and other animal products used as human food are negligible and present no risk to consumers.

With the increasing reliance on distillers' grains in the marketplace, the FDA has elevated its oversight in this arena. The FDA's Center for Veterinary Medicine has regulatory and enforcement responsibility for distillers' grains. Under the current FDA policies, Phibro believes it has successfully satisfied its data privacy needs while achieving long-term regulatory compliance for the use of Lactrol in ethanol production.

On the animal health side, the active ingredient virginiamycin, formulated specifically for animal feeds, has been used successfully and safely since the 1970s for growth promotion, disease prevention and control in farm animals. In addition, antibiotics (such as Lactrol) are a widely used and critical tool for infection management in renewable fuels production. Through the use of small amounts of antibiotics such as Phibro's Lactrol® antimicrobial, the United States renewable fuels industry continues to improve the United States' progress toward energy independence and safety.