SAMPLE INTERPRETIVE SUMMARY

Alternatives to conventional antibiotics: Immune system stimulants

Marcus E. Kehrli, Jr., Pfizer, Inc.

The promise of immune modulation has been around for decades. Many immune modulators have been tested and found to not provide sufficient benefit to justify commercial investment in obtaining regulatory approval. However, there are many product opportunities created by livestock production management practices and some would argue we have barely scratched the surface in this area with today's technologies. Most infectious diseases livestock encounter are precipitated by immune suppression associated with natural stresses (e.g., parturition effects on the mother, naïve and immature immune capacity in neonates). There are also stresses brought on by management practices (e.g., weaning, co-mingling & transport). All of these provide opportunities for immune modulation with compounds that combat or restore immune capacity to a level where disease incidence and/or severity is reduced.

Nutritional approaches to immune modulation are ever popular but fall short of restoring immune function when immune suppression is not caused by nutritional deficiencies. Genetic approaches to immune modulation are also highly desirable because they offer a permanent change in the genetic resistance to disease. However, genetic approaches to immune modulation are in the hands of the animal breeders and not a realistic approach for pharmaceutical or biological companies.

Importantly, if immune modulators are ever to come into fruition, the producer, regulatory, scientific and industry communities must first recognize that immune modulators are NOT just another antibiotic. Effective immune modulators will reduce the incidence and severity of disease episodes in populations of livestock that are immunologically impaired. They will do so against an array of opportunistic pathogens without necessarily effecting microbiological cures. Immune modulators will also require unique approaches to label claims and regulatory issues, which set them apart from traditional approaches for antibiotic approvals. Immune modulators, by definition, have an immune specific mechanism of action - which suggests one regulatory path. However, regulatory decisions are not that simple. Effective immune modulators should reduce our reliance on antibiotics by reducing therapeutic and metaphylactic use of antibiotics.

Kehrli, Marcus E., Jr., Future address: Virus and Prion Diseases of Livestock Research Unit, USDA, Agricultural Research Service, National Animal Disease Center, Ames, IA 50010, Tel: (515) 663-7254, email: mkehrli@nadc.ars.usda.gov