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Merck Animal Health Provides Update on Zilmax Five-Step Plan, Announces Next Steps

- Extensive review and analysis of research data completed
- Final stage to focus on planned in-field use studies
- Best Management Practices and Certification Program adopted
- FDA approval of updates to Zilmax label, including new feed delivery method

SUMMIT, N.J., Nov. 5, 2014 – Merck Animal Health (known outside the United States and Canada as MSD Animal Health) is pleased to announce significant progress in the implementation of its Zilmax Five-Step Plan. With insights from the company's advisory board, an extensive assessment and analysis of existing, as well as new product data, was conducted. Additionally, Merck Animal Health obtained the input of industry experts, business partners and customers about the product and its use.

The totality of the comprehensive review supported that Zilmax® (zilpaterol hydrochloride) is safe when used according to the product label and in conjunction with sound animal husbandry practices. The research results and industry data showed that cattle weights, and thus feed consumption rates, have been steadily increasing over time. This created the possibility that certain cattle could consume feed quantities that result in ingestion of Zilmax in an amount that exceeds the approved dose. The review also noted that enhanced label language – coupled with the implementation of comprehensive certification requirements and a thorough best practices program – will ensure that usage of Zilmax remains compliant with the label.

An updated Zilmax label, to include Component Feeding, which is an alternative method of administering Zilmax using a targeted lower dose, was submitted to and approved by the U.S. Food and Drug Administration (FDA). Component Feeding provides cattle feeders with an alternative option to deliver the appropriate dose of Zilmax to cattle every day. The new convenient feed delivery method allows cattle feeders to mix Zilmax in feed to deliver a lower targeted dose of 60 mg/head/day of zilpaterol.

In addition, to help ensure that use of Zilmax is appropriate and consistent with best practices, Merck Animal Health has taken the following steps:

Certification
As previously noted, every feedyard team member, distributor, feed manufacturer, nutritionist and veterinarian who uses Zilmax or provides consultative services on feeding Zilmax to cattle, must complete the Zilmax training program, as well as annual retraining, addressing the proper use of the product. The training will focus on best practices, product handling, mixing protocols, cattle management, product inventory, record keeping and clean-out procedures. Completion and adherence to the program will be a prerequisite for the use of Zilmax. [Certification Program]

Best Management Practices
Merck Animal Health has worked with industry experts to develop comprehensive Best Management Practices. These include best regimens for the feeding of Zilmax, as well as a number of factors that are critical to animal well-being, including animal handling, proper nutrition/feeding protocols, environmental risk factors, transportation, and cattle management and selection. [Best Management Practices Program]

"Emphasizing best management practices illustrates our commitment to our industry partners by helping set benchmarks for animal mobility, mitigating risk factors, and reinforcing the significant role of nutrition and handling in animal performance," said KJ Varma, BVSc, Ph.D., Diplomate ACVCP, Senior Vice President Global R&D, Merck Animal Health. "We remain committed to working closely with our customers to maintain the highest standards of care for the health and well-being of cattle."

Planned In-Field Use Studies
Merck Animal Health also maintains its commitment to sound science – a cornerstone of the Five-Step Plan. The significant advances noted have enabled the company to move forward with the next step – the In-Field Use Studies, for which we will seek the participation of industry partners. Given the addition of Component Feeding to the label, the planned In-Field Use Study design and protocols will be reviewed before the studies commence. As previously noted, these studies will be overseen by an independent third-party and will extend into the high heat months. The guiding principles of the studies remain the same:

- Observing cattle throughout the system – before and after receiving Zilmax – at the feedyard and at the packing plant;
- Evaluating the mobility of cattle by trained third-party experts utilizing an established mobility scoring system; and
- Reviewing potential confounding factors, such as nutrition, transportation, receiving facilities, flooring surfaces and, cattle management and handling practices, given that mobility issues can be the result of numerous issues or even multifactorial in nature.

For the duration of the Planned In-Field Use Studies, Zilmax will be made available only to cattle feeders that can meet and maintain all conditions of the Best Management Practices initiative and the Certification Program, as well as fully comply with all protocols of the In-Field Use Studies. We believe the results of the In-Field Use Studies will help support the return of Zilmax to the market place in the future.

Additional Label Modifications
In addition to Component Feeding, the FDA has approved a revision to the existing Complete Feed indication in the label. The current Complete Feed label dose for zilpaterol is 6.8 grams/ton to provide 60 to 90 mg/head/day. The label will now include an updated caution statement that notes cattle should not be fed Zilmax in excess of 90 mg/head/day. If pen consumption of complete feed exceeds 26.5 lb/head/day (90% on a dry matter basis), zilpaterol should not be fed in complete feed. This additional language will further ensure that Zilmax use remains compliant with the label, regardless of the delivery feed method chosen.

"We are pleased to announce the addition of Component Feeding to the Zilmax label, and are equally excited to note we are moving ahead with the Five-Step Plan," said Dr. Varma. "The work supporting Zilmax has been complex and time intensive, and we appreciate the time and efforts of the Merck Animal Health Advisory Board, the input and continued support of our customers, and the FDA for its commitment to science and advancing animal well-being."

Merck Animal Health has recently filed a label update submission in Canada. Click here to view the updated U.S. Zilmax label.

Zilmax has a withdrawal period of 3 days prior to harvest. Not for use in animals intended for breeding. Do not allow horses or other equines access to feed containing zilpaterol. Do not use in veal calves. Not to be fed to cattle in excess of 90 mg/head/day in complete feed. If pen consumption of complete feed exceeds 26.5 lb/head/day (90 percent dry matter basis), zilpaterol should not be fed in complete feed. For complete information, refer to the product label.

About Merck Animal Health

Today's Merck is a global healthcare leader working to help the world be well. Merck Animal Health, known as MSD Animal Health outside the United States and Canada, is the global animal health business unit of Merck. Through its commitment to the Science of Healthier Animals™, Merck Animal Health offers veterinarians, farmers, pet owners and governments one of the widest range of veterinary pharmaceuticals, vaccines and health management solutions and services. Merck Animal Health is dedicated to preserving and improving the health, well-being and performance of animals. It invests extensively in dynamic and comprehensive R&D resources and a modern, global supply chain. Merck Animal Health is present in more than 50 countries, while its products are available in some 150 markets. For more information, visit www.merck-animal-health.com or connect with us on LinkedIn and Twitter at @MerckAH.

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Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2013 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).