

Merck Animal Health Scientific Studies on Animal Safety and Well-Being

As a leader in animal health, we are committed to ensuring the well-being of animals, supporting the cattle farmers who use our products, as well as sharing the available data. During the last 30 years, Merck Animal Health has conducted numerous animal safety and well-being trials with cattle fed Zilmax, including rigorous animal safety and well-being studies submitted to, and reviewed by, FDA and other international regulatory authorities (Canada, Mexico and South Africa). In support of the product, we have conducted additional animal well-being studies with well-respected universities and third-party experts. These comprehensive studies evaluated locomotion, movement, pain and stress, lameness, feeding behavior, and various physiological parameters (heart rate, body temperature, panting, drooling, water intake, and blood chemistry) in cattle fed Zilmax. The results of more than 30 studies, totaling 65,000 cattle, show Zilmax, when used according to label directions, does not impact the safety or well-being of cattle.¹

Among the numerous studies confirming Zilmax's safety and well-being profile are the following:

1. Lowe et al (2012) evaluated locomotion scores before and after feeding Zilmax in cull dairy cows and there were no differences. The results of this study were published in a peer-reviewed journal, *The Professional Animal Scientist*.
2. Two PAACO audits (Professional Animal Auditor Certification Organization) one at a large feedlot and packing plant in a large randomized trial of over 950 head of cattle and one observational audit at a different packing plant were conducted by a trained, PAACO-accredited professional. The results of these audits demonstrated no differences between Zilmax-fed animals and controls in

lameness scores (both at the feedyard and plant), slips and falls during loading and unloading, vocalization, and first stun efficiency.

3. Merck Animal Health conducted several studies with West Texas A&M and University of Nebraska using accelerometer pedometers, which show Zilmax-fed steers take an equal number of steps per day, and laying down and standing times are also equal throughout the day when compared to controls.
4. Pain/stress markers (substance P, haptoglobin and cortisol levels) were measured and no differences were found between Zilmax-fed animals and controls. The studies were conducted by a researcher at West Texas A&M University and independently analyzed by researchers, including experts at Kansas State University.
5. FDA target animal safety studies, conducted prior to product approval, included an evaluation of locomotion and behavior by a trained veterinarian and the results showed no differences between Zilmax-fed animals and controls.
6. Researchers at New Mexico State University conducted research to measure the time it took for animals to move from their home pen to the scale. They observed no difference in time of movement from pen to scale for Zilmax-fed cattle and controls.

Zilmax has been used in more than 25 million cattle since its first market approval. Merck Animal Health has monitored carefully the performance of the product in those cattle, including the thorough investigation of the extremely infrequent serious adverse events that have been reported. Moreover, when these very infrequent reports have occurred, Merck Animal Health has worked closely with feeders to resolve the issues through various farm management practices and protocols that ensured proper usage of the product. It is a responsibility we take very seriously.

In addition to demonstrating the strong body of evidence that supports Zilmax's record for animal safety and well-being, it is important to note the benefits of the product. Zilmax helps improve cattle's natural ability to convert feed into more lean beef instead

of excess fat and as a result, requires less use of natural resources.² These data have been published in the *Journal of Animal Science*.

“We remain confident in the safety of Zilmax and the well-being of animals that receive it,” said KJ Varma, BVSc, Ph.D., Diplomate ACVCP, Senior Vice President Global R&D, Merck Animal Health. “We are committed to continuous improvement and reinforcement of best management practices – nutrition, animal handling, low-stress environments and transportation – all of which impact animal health.”

Zilmax has a withdrawal period 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. For complete safety information, refer to product label and Zilmax website.

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. 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.

Merck Forward-Looking Statement

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. If underlying

assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

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's 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 2012 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).

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¹ FDA. 2006. Freedom of information summary. Original new animal drug application NADA 141-258. Zilmax (zilpaterol hydrochloride) Type A medicated article for cattle fed in confinement for slaughter. <http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm051412.pdf>. Accessed Apr. 26, 2007.

² Capper, J.L. 2011 The environmental impact of beef production in the United States: 1977 compared with 2007. *Journal of Animal Science* 89:4249-4261.