



News Release

FOR IMMEDIATE RELEASE

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FDA Grants Merck Animal Health Approval for Two New AQUAFLO[®] Indications

SUMMIT, N.J., March 24, 2014 — Merck Animal Health, known as MSD Animal Health outside of the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has approved two additional indications for AQUAFLO[®] (florfenicol*) Type A Medicated Article. The supplemental approval provides for an increase in the maximum daily dosage for freshwater-reared finfish other than freshwater-reared warmwater finfish to provide a dosage range of 10 – 15 mg/kg body weight/day and changes the conditions of use to permit the use of florfenicol in recirculating aquaculture systems.

AQUAFLO is now approved for use in freshwater-reared salmonids for control of mortality due to furunculosis associated with *Aeromonas salmonicida* and for control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* at a maximum dose rate of 15 mg/kg, which is reflected on the new label as 10-15 mg/kg.

In addition, AQUAFLO can be used for control of mortality due to columnaris disease in all freshwater-reared finfish, including freshwater-reared salmonids. “This new dose rate allows producers of trout and other freshwater-reared salmonids increased flexibility in managing these three important bacterial diseases,” said Tim Kniffen, D.V.M., technical services manager, Merck Animal Health. “We are pleased to be able to continue to offer our customers solutions-focused products that meet the ever-changing needs of their businesses.

AQUAFLO is the first antibiotic licensed for U.S. aquaculture in more than 20 years and addresses the need for a fast-acting, broad-spectrum, highly-palatable, antibiotic premix. It can be top-coated or incorporated in both floating and sinking feeds and is highly palatable, which helps to optimize antibiotic intake.

In support of these new indications, the AQUAFLO website – AQUAFLO-usa.com – has been updated to include the latest product bulletin, as well as new VFD forms. The site continues to

feature scientific articles, educational brochures and industry links, as well as important contact information. For more details about AQUAFLO and VFD protocols, producers also may contact their extension specialist, veterinarian, diagnostician or feed company representative, or call Merck Animal Health at 1-800-521-5767.

*Florfenicol, the active ingredient in AQUAFLO, is a synthetic, broad-spectrum antibiotic shown to be highly effective in *in vitro* and *in vivo* studies against an extensive range of aerobic and anaerobic gram-positive and gram-negative bacteria. Unlike sulfa drugs and tetracyclines, however, florfenicol is used exclusively in farm-raised fish and food animals. It is not used in human medicine.

AQUAFLO is classified by the FDA Center for Veterinary Medicine as a Veterinary Feed Directive (VFD) drug, a category established in 1999 to help the agency more closely control new in-feed therapeutic products, primarily antimicrobials, and their use in food animals. Producers may obtain VFD drugs through normal feed distribution channels, but they do require a signed Veterinary Feed Directive from a licensed veterinarian.

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CAUTION: Federal law limits this drug to use under the professional supervision of a licensed veterinarian. Animal feed bearing or containing this veterinary feed directive drug shall be fed to animals only by or upon a lawful Veterinary Feed Directive (VFD) issued by a licensed veterinarian in the course of the veterinarian's professional practice.

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.

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).