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# KAW DENOUNCES RECENT FDA APPROVAL OF HUMAN ANTIBIOTIC FOR ANIMAL AGRICULTURE

## *Leading coalition highlights potential risk to human health and calls for thorough review of the regulatory agency's decision*

Washington, D.C. – Keep Antibiotics Working (KAW), a coalition of consumer, environmental, science and humane organizations, this week strongly criticized the Food and Drug Administration's (FDA) recent decision to approve without limitation the use of enrofloxin, a fluoroquinolone drug used to treat foodborne and other serious human infections, in swine.

In a letter to the FDA Commissioner, Dr. Andrew von Eschenbach, the coalition highlighted that such use of the drug could compromise its effectiveness in humans and is inconsistent with FDA guidelines and recent rulings. KAW also calls for a Veterinary Medicine Advisory Committee (VMAC) review to reassess the FDA's approval of enroflaxin and ultimately, given the public health risks associated with its use in animal agriculture, reverse the decision.

"The FDA continues to ignore the mounting body of evidence about the dangerous use of human antibiotics in animal production," noted Richard Wood, Executive Director of Food Animal Concerns Trust. "Commissioner von Eschenbach must stop this hazardous trend. A welcome first step would be to order a Veterinary Medicine Advisory Committee review of the decision to allow enrofloxacin use in swine before finalizing the approval."

The FDA and the World Health Organization have classified fluoroquinolone drugs as "critically important," the rank of drugs most likely to cause human health problems when used in animals. Consistent with this ruling, in 2005, the FDA withdrew approval of the use of enrofloxacin in poultry amidst the clear risks to human health associated with its use in livestock.

The FDA, however, failed to consider these past rulings when it decided on March 14, 2008 to allow the use of enrofloxacin in swine. The FDA also made this approval despite the risk management controls under the Agency's own Guidance #152 for high risk drug approvals such as enrofloxacin. The Guidance is a qualitative risk assessment tool with which the agency determines the safety of antibiotic use in animal agriculture by looking at how important the proposed drug is to human medicine, the likely resistance patterns to the drug and, finally, human exposure levels to livestock in question.

KAW's letter urged the FDA not to approve a veterinary drug use where all three component assessments in Guidance #152 rate "high." Since Guidance #152 came into effect, no drug important to human medicine has been approved flock or herd-wide for use as a growth promoter or for disease prevention — until now.

"The FDA has simply not given full consideration of the risks and has not followed appropriate risk management protocol under its own guidelines. Without such action, the reputation of Guidance #152 as an adequate regulation for the protection of the public health is at stake," noted Richard Wood. "In light of the World Health Organization's well documented position on fluoroquinolones and the FDA's own record on the issue, it is clear that the Agency was and continues to be aware of the controversy that has existed around the use of this class of drugs in food animals. Given this reality, the FDA's failure to hold a VMAC hearing on the use of enrofloxacin in swine is unconscionable."

A recent report by the Pew Commission on Industrial Farm Animal Production highlights the needless squandering of human antibiotics in animal agriculture and provides several recommendations, many of which are included in The Preservation of Antibiotics for Medical Treatment Act (PAMTA) currently before Congress.

The Pew report, "Putting Meat on the Table: Industrial Farm Animal Production in America," is the result of more than two years of research about industrial farm systems, and it is just the latest of many studies coming to similar conclusions. In fact, last year the National Institutes of Health's *Environmental Health Perspectives* journal reported similar bad news on the public health front — the ongoing, routine use of antibiotics in livestock production contributes to the rise in antibiotic-resistant germs that are transferred to humans via our food, air and water.

PAMTA, which would phase out within two years the use as animal feed additives of antibiotics that are also important in human medicine, such as penicillin, is sponsored by Senate Health Committee Chairman Edward Kennedy (D-MA) and Senators Olympia Snowe (R-ME), Susan Collins (R-ME), Sherrod Brown (D-OH) and Jack Reed (D-RI) in the Senate (S. 549) and Rep. Louise Slaughter (D-NY), the only microbiologist in Congress, and 38 other House members in the U.S. House of Representatives (H.R. 962).

The coalition's letter to Commissioner von Eschenbach is available at http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=102952.

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