KEEP ANTIBIOTICS WORKING

The Campaign to End Antibiotic Overuse

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**Contact: Sean Crowley, 202-478-6128 or 202-550-6524 (c) or scrowley@mrss.com**

# Keep Antibiotics Working Groups Testify Against Pfizer Bid for Off-Label Use of Animal Drug under New FDA Antibiotic Resistance Guidance

## *Cites Pfizer's Own Risk Assessment Concluding that Drug Has "High Risk" of Causing Antibiotic Resistance to Similar Drugs in Human Medicine*

**Rockville, MD** – Citing Pfizer's own risk assessment that its animal drug, tulathromycin, has a "high risk" of causing antibiotic resistance to similar drugs used in human medicine, members of the Keep Antibiotics Working Coalition testified in opposition to Pfizer's application for off label use of the drug at a public hearing before the Food and Drug Administration yesterday. It was the FDA's first public hearing about a drug application under the public health agency's new antibiotic resistance guidance for approving agricultural antibiotics (Guidance #152). The guidance was finalized last October.

Tulathromycin is labeled to treat respiratory disease in swine and cattle, and is administered by injection. Like erythromycin, it is a macrolide antibiotic. The FDA considers erythromycin to be critically important to human medicine because it is used to treat campylobacter, the second most common cause of bacterial infections from food in the U.S., and because it is used to treat Legionnaires Disease and mycobacterium infections.

"Given the importance of macrolides to treat campylobacter infections, we believe that extra label use restriction as suggested by Guidance 152 be required," testified Steve Roach, Food Safety Program Manager for Food Animal Concerns Trust. "Pfizer argues that extra label restrictions are unnecessary because many other macrolides already are approved, but Pfizer's own risk assessment clearly shows that many of these other approvals would not be allowed if Guidance 152 were applied to them."

"We agree with the FDA's assessment that macrolide use in human medicine is 'critically important' and that there is an overall 'high' risk estimation for this drug," testified Susan Prolman, Esq., Washington Representative of the Union of Concerned Scientists' Food & Environment Program. "We recommend that if the FDA chooses to approve tulathromycin, the approval should be limited to the treatment of animals diagnosed with the disease and others at imminent risk of contracting the disease. In no case should approval extend to preventative treatment that would be given to animals on a routine basis."

"It has been almost a year since the final guidance was published and this is the first time that its implementation has been applied to a drug," testified Larissa Mckenna, Coordinator of the Keep Antibiotics Working Coalition. "There are over 50 drugs currently approved for use in feed and water for food animal production. At the rate of one drug per year, it will take the agency over half a century to complete the risk assessments for the list of drugs already approved."

As a result of the FDA's inability to take action in a timely manner, KAW supports the bipartisan "Preservation of Antibiotics for Medical Treatment Act" (S.1460/H.R.2932). It would phase out over a two year period the non-therapeutic use of eight classes of antibiotics that are important in human medicine as feed additives to promote growth and compensate for unsanitary conditions on factory farms. The bill does not restrict use of these antibiotics to treat sick animals or their non-routine use to control the spread of disease. More than 360 organizations, including the American Medical Association and the American Public Health Association, have endorsed the legislation.

*Keep Antibiotics Working (www.KeepAntibioticsWorking.com) is a coalition of health, consumer, agricultural, environmental, humane and other advocacy groups with more than nine million members dedicated to eliminating a major cause of antibiotic resistance: the inappropriate use of antibiotics in farm animals.*

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