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**FDA FINALLY ACTS TO BAN UNAPPROVED USE
IN FOOD ANIMALS OF CRITICAL HUMAN
ANTIBIOTICS**

***KEEP ANTIBIOTICS WORKING CALLS ON FDA TO ACT
FURTHER TO PROTECT ANTIBIOTICS***

Keep Antibiotics Working (KAW) today applauded the Food and Drug Administration (FDA) for prohibiting some off-label or “extralabel” use of cephalosporin antibiotics in food-producing animals, more than three years after that order was first issued but withdrawn. At the same time, KAW renewed its calls for the agency to take immediate and forceful action to further address the misuse of antibiotics in agriculture, which has led to the development and spread of resistant bacteria that cause difficult-to-treat infections. Today’s decision follows repeated inaction by the FDA to protect the public health. In December, the FDA withdrew longstanding proposals – dating back to 1977 – to remove approvals for two antibiotics, penicillins and tetracyclines, used in livestock feeds.

Today’s prohibition will still allow cephalosporin antibiotics to be used in food-producing animals, but puts new restrictions on how they can be used in cattle, swine, and poultry. The extralabel prohibition, which public health, patient advocacy, and food safety groups had urged for years, is a fairly easy step for FDA to take compared with the more difficult process of withdrawing a drug from the market altogether.

The FDA announcement can be found here: <http://www.gpo.gov/fdsys/pkg/FR-2012-01-06/pdf/2012-35.pdf>.

“While we welcome FDA’s belated action, the delay is shocking. Tens of thousands of people continued to become ill from cephalosporin-resistant *Salmonella* when there was clear evidence the extra-label use of these drugs contributes to the spread of these and other resistant superbugs,” said David Wallinga, MD, a physician at the Institute for Agriculture and Trade Policy and a member of the Keep Antibiotics Working coalition.

“FDA’s work is by no means over. Overuse of antibiotics in animal agriculture – such as the routine administration of antibiotics through animal feed – also promotes the epidemic of antibiotic resistance, an ever greater threat to us as a nation,” Wallinga added.

Cephalosporin antibiotics are currently used extralabel for numerous purposes. For example, chicken hatcheries in the U.S. often inject eggs with cephalosporin antibiotics to reduce mortality caused by bacteria introduced from the shell into the egg when vaccines are administered, even though this use has not been evaluated by the FDA. Science has shown that injecting eggs with

antibiotics leads to antibiotic resistant bacteria in the hatched chickens. These resistant bacteria can spread to and infect humans.

The FDA first proposed a prohibition on extralabel use in July 2008 in response to scientific evidence showing that misuse of these critically important antibiotics in livestock was threatening their effectiveness in treating serious *Salmonella* infections, including in children. Cephalosporins are the treatment of choice for pediatric *Salmonella* infections. Subsequent studies have shown that cephalosporin use in animals contributes to the spread of resistant *E. coli* infections as well.

However, the FDA withdrew its extralabel ban in November 2008, just weeks before it would have taken effect. Americans have since continued to become ill from cephalosporin-resistant infections, including a recent outbreak associated with multi-drug resistant *Salmonella* Typhimurium in ground beef. Keep Antibiotics Working had repeatedly urged the FDA to reissue the ban.

According to the FDA's own data, released in December 2010, almost 80 percent of antibiotic drugs in the United States were sold for use in food animals – most of them not to treat animal illness, but to promote slightly faster growth and to compensate for crowded, stressful, and unhygienic conditions at industrial-scale livestock and poultry facilities. Animals at these facilities are given low doses of antibiotics virtually every day of their lives – a recipe for developing resistant “superbugs” – without so much as a veterinarian's prescription. Many of the antibiotics fed to animals are the same as those Americans depend on in human medicine.

As the Government Accounting Office recently revealed, the FDA faces opposition for removing animal drugs from the market when they contribute to human antibiotic resistance, leading to a protracted process. The agency has responded by trying to address the problem with voluntary actions by the pharmaceutical companies it regulates.

KAW continues to call on the Administration and Congress to prohibit giving antibiotics to food animals for reasons other than disease treatment if the same or related drugs are also used in human medicine. KAW supports legislation introduced in both the House and Senate that would make it easier for the FDA to withdraw antibiotics from the market when the FDA finds their use leads to the development and spread of resistant bacteria.

The rising epidemic of antibiotic resistance was recently illustrated by the antibiotic-resistant *Salmonella* outbreak that sickened 129 people and killed one who had eaten ground turkey.

“The extralabel prohibition on cephalosporins in food-producing animals was warranted and long past due,” said Richard Wood, Executive Director of the Food Animal Concerns Trust and Chair of KAW's Steering Committee. “Further FDA action is vital to safeguard the American public from ever-more costly drug-resistant infections. This means prohibiting livestock producers from giving these vital drugs when animals are not sick.”

[Update: January 6, 2012 Federal Register Notice now available:
<http://www.gpo.gov/fdsys/pkg/FR-2012-01-06/pdf/2012-35.pdf>]

Keep Antibiotics Working (KAW) is a coalition of health, consumer, agricultural, environmental, humane, and other advocacy groups with more than 11 million supporters.

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