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Bayer Threatens Human Health by Seeking Stay of FDA's 1st Ever Ban of Agricultural Drug Due to Human Antibiotic-Resistance Concerns

Groups Urge FDA to End Bayer's Five Year Legal Battle to Keep Drug on Poultry Market Linked to Antibiotic Resistance Increase in Humans

Washington D.C. — The Bayer Corp. is endangering public health by seeking to stay the September 12 effective date of the first-ever ban for an agricultural antibiotic by the U.S. Food and Drug Administration (FDA) because of concerns about antibiotic resistance affecting human health. That's the conclusion of comments filed today with the FDA by the Keep Antibiotics Working coalition (KAW) regarding Bayer's attempt to delay the effective date for FDA Commissioner Lester Crawford's July 28 decision to withdraw approval for use of Cipro-like antibiotics in poultry (see KAW comments on Bayer's FDA petition for a stay at www.keepantibioticsworking.com/new/resources_library.cfm?refID=76521 and news release about FDA decision at www.fda.gov/bbs/topics/news/2005/new01212.html). Two similar requests for a stay were filed, one by Animal Health Institute (an agricultural drug trade group), and the other by the poultry-veterinarian groups. Each petition asks that FDA allow the drugs to remain on the market for an indefinite period while Bayer seeks judicial review of the Commissioner's decision. Such a review would take many months, and possibly several years, to complete. Many major medical groups, including the American Medical

Association and the Infectious Disease Society of America, have publicly supported banning fluoroquinolone use in poultry.

"This proceeding has already dragged on for nearly five years, during which time a growing number of people have suffered from Cipro-resistant food poisoning associated with poultry," said Karen Florini, senior attorney with Environmental Defense. "It's just appalling that Bayer is pushing to leave these Cipro-like poultry drugs on the market for several more months or years, condemning more people to hard-to-treat illnesses. In their motion for a stay, Bayer and its allies are simply rehashing the same unpersuasive arguments expressly rejected by both an FDA administrative law judge and the Commissioner himself."

Commissioner Crawford, who holds a Doctor of Veterinary Medicine degree as well as a Ph.D. in pharmacology, issued a 126-page final decision banning use of Cipro-like antibiotics in chickens and turkeys because of concerns about antibiotic resistance affecting human health (the entire 126-page decision is available at <http://www.fda.gov/oc/antimicrobial/baytril.pdf>). The FDA first proposed the ban in October 2000, but took nearly five years to finalize it because of numerous procedural delays created by Bayer, the only manufacturer of the drug, whose trade name is Baytril. Both Baytril and Cipro are members of the fluoroquinolone class of antibiotics.

The FDA concluded that using Baytril in poultry reduces the effectiveness of Cipro in treating people who have severe food poisoning caused by *Campylobacter*, one of the most common causes of severe bacterial food poisoning. The most recent data from the Centers for Disease Control and Prevention show that resistance to Cipro in *Campylobacter* in humans has risen to 21 percent as of 2002; when fluoroquinolones were first approved for use in poultry in 1995, such resistance was negligible. Although Bayer claims that Baytril is critical for poultry production, most top poultry producers have announced that they no longer use these drugs in chickens produced for human consumption, including Tyson, Gold Kist, Perdue, Foster Farms, and Claxton. Major chicken purchasers, including McDonald's, Wendy's,

Dairy Queen, Burger King, Domino's, Hardee's, Popeye's, Subway, and Bon Appetit have instructed their suppliers to stop using fluoroquinolones in chickens they purchase.

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