



FDA News

FOR IMMEDIATE RELEASE
P05-48
July 28, 2005

Media Inquiries:
Rae Jones, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Announces Final Decision About Veterinary Medicine

U.S. Food and Drug Administration (FDA) Commissioner Lester Crawford is announcing the Agency's final decision to no longer allow distribution or use of the antimicrobial drug enrofloxacin for the purpose of treating bacterial infections in poultry. This ruling does not affect other approved uses of the drug. This animal drug belongs to a class of drugs known as fluoroquinolones and is marketed under the name Baytril by Bayer Corporation.

The FDA's Center for Veterinary Medicine (CVM) began proceedings to withdraw use of this animal drug in poultry because of scientific data that showed that the use of enrofloxacin in poultry caused resistance to emerge in *Campylobacter*, a bacterium that causes foodborne illness. Chickens and turkeys normally harbor *Campylobacter* in their digestive tracts without causing poultry to become ill. Enrofloxacin does not completely eliminate *Campylobacter* from the birds' intestinal tracts, and those *Campylobacter* bacteria that survive are resistant to fluoroquinolone drugs. These resistant bacteria multiply in the digestive tracts of poultry and persist and spread through transportation and slaughter, and are found on chicken carcasses in slaughter plants and retail poultry meats.

Campylobacter bacteria are a significant cause of foodborne illness in the U.S. Antimicrobial treatment is recommended for people with severe illness as well as the very young, the elderly, and people with certain medical conditions. Complications of such infections can include reactive arthritis and, more rarely, blood stream infections. Early treatment can mitigate symptoms and may decrease the risk of complications. Fluoroquinolones used in humans are ineffective if used to treat *Campylobacter* infections that are resistant to them. This failure can significantly prolong the duration of the infections and may increase the risk of complications. The proportion of *Campylobacter* infections that are resistant to fluoroquinolones has increased significantly since the use of enrofloxacin in poultry was approved in the U.S.

Bayer Corporation has 60 days from the date of the decision to appeal the withdrawal to a U.S. Court of Appeals. The Final Rule withdrawing approval of the antimicrobial drug enrofloxacin for the purpose of treating bacterial infections in poultry will be effective on September 12, 2005. For the Final Decision please go to www.fda.gov/oc/antimicrobial/baytril.pdf and for the Federal Register documents please go to www.fda.gov/ohrms/dockets.

Press release <http://www.fda.gov/bbs/topics/news/2005/new01212.html>

Final decision <http://www.fda.gov/oc/antimicrobial/baytril.html>