

Post Approval Monitoring and Review Ensures Continued Safe Use of Antibiotics

As with human medicines, all animal medicines, including antibiotics, are subject to careful monitoring after they have been approved by the Food and Drug Administration and marketed.

Risk assessment is an important tool used by federal agencies to make public policy decisions about health and safety. It is a tool allowing policymakers to measure and quantify the risks involved in taking or not taking a particular action. FDA, company sponsors, and researchers have conducted post-approval risk assessments on many antibiotic compounds used in animal agriculture, and findings consistently demonstrate very low risk to human health as a result of using medicines, such as antibiotics, to help animals recover from illness or help to prevent illness or maintain their health:

- Researchers at the University of Georgia found that carcasses from harvested poultry sick with airsacculitis were more likely to be contaminated with *E. coli* and *Campylobacter* which could lead to a greater number of food borne infections (Russell SM., Poultry Science 2003; 82 (8): 1326-1331)
- A follow-up risk assessment using the Russell data found withdrawing antibiotics for animals can cause far more human illness-days than it would prevent. The estimated human BENEFIT:RISK health ratio for the impact of continued animal antibiotic use on human health exceeds 1000:1 in many cases. (Cox LA Jr, Popken DA, Risk Analysis 2006; 26(1): 135-46)
- A Georgetown University risk assessment on the use of fluoroquinolones in beef cattle and the resulting human health risk of fluoroquinolone resistant *Campylobacter* on beef estimated the risk to humans to be 40 additional hospitalizations and 1 case of mortality over 10 years of use in cattle (Anderson SA, et. al., Food Control 2001; 12(1):13-15.)
- An FDA risk assessment on the use of fluoroquinolones in poultry estimated a risk level of 0.0019% for the average U.S. citizen. This work was used to remove from market a fluoroquinolone product to treat airsacculitis in poultry. (Vose, et al, <http://www.fda.gov/cvm/Documents/RevisedRA/pdf.>)
- University researchers conducted a risk assessment of macrolide antibiotics used in animal agriculture, using the general outline of FDA's Guidance 152, finding the risk probabilities of less than 1 in 107 million for macrolide-resistant *Campylobacter* infections in humans from the use of macrolides in pigs. (Hurd, HS, et. al, Journal of Food Protection 2004; 67:980-992)
- FDA conducted a risk assessment on the use of Virginiamycin, concluding that "assuming a food pathway attribution of 10%, the average risk to a random member of the US population of having SREF (streptogramin-resistant *E. faecium*) attributable to animal uses of virginiamycin and that may result in impaired Synercid therapy ranges from 7 chances in 1 billion to 14 chances in 100

million in one year.

http://www.fda.gov/cvm/Documents/SREF_RA_FinalDraft.pdf

Risk assessment, combined with risk communication, is the proper tool for making public policy decisions (risk management decisions) about the use of antibiotics in animal agriculture. Risk analysis, which combines risk assessment, risk communication and risk management, allows policymakers to measure the potential consequences of actions. Actions taken without using risk analysis are likely to result in negative, unintended consequences.

A recent report by the Institute of Food Technologists (Comprehensive Reviews in Food Science and Food Safety, Vol. 5, 2006) made the following recommendation: “Determine the public health impact of antimicrobial resistance on the basis of risk assessment, and consider resistance on the basis of an individual microorganism exposed to a specific agent under a specific condition of use.”

Adverse reactions to the marketed product are collected and analyzed by the Food and Drug Administration, just as with human medicines. When appropriate this information is used to require companies to change the label directions or marketing patterns of the product.