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

Medical, Environmental Groups Petition FDA to Ban Use of Antibiotics as Feed Additives, Citing Noncompliance with FDA Guidance to Protect Human Health

Bipartisan Bill Introduced to Ensure Prompt Removal of Drugs from Market

Washington, DC - Five major medical and environmental groups today filed a formal regulatory petition with the U.S. Food and Drug Administration (FDA) urging the agency to withdraw approvals for seven classes of antibiotics for use as agricultural feed additives, citing those uses' failure to comply with FDA Guidance to protect human health. The petition demonstrates that continued use of these antibiotics as feed additives for chickens, hogs, or beef cattle fails to comply with the safety criteria in the FDA's guidance on agricultural antibiotics, Guidance #152. It designates the seven classes of antibiotics as "critically important" or "highly important" in human medicine.

The petitioners include the American Academy of Pediatrics, American Public Health Association, Environmental Defense, Food Animal Concerns Trust and Union of Concerned Scientists. The petition is available at www.KeepAntibioticsWorking.com. The petition quotes several letters FDA recently sent to manufacturers of certain antibiotic feed-additives, noting that those products are "not considered appropriate" and that existing information "does not alleviate [FDA's] concern about the use of these products and their possible role in the emergence and dissemination of antimicrobial resistance."

Bipartisan legislation that would ensure the prompt removal of the drugs, The Preservation of Antibiotics for Medical Treatment Act, was reintroduced today in both houses of Congress. The bill would phase out use of these drugs as feed additives within two years unless the FDA determines that continued use does not contribute to antibiotic resistance affecting humans. It does not restrict use of these antibiotics to treat sick animals. More than 380 organizations, including more than 100 health groups, endorsed a similar bill in the last Congress.

Senate Governmental Affairs Committee Chair Susan Collins (R-ME) joined lead sponsors Sen. Olympia Snowe (R-ME), chair of the Small Business Committee, and Edward M. Kennedy (D-MA), ranking member of the Senate Health Committee, in sponsoring the Preservation of Antibiotics for Medical Treatment Act. The measure's lead sponsor in the House of Representatives is Rep. Sherrod Brown (D-OH), ranking member of the Commerce Health Subcommittee.

"While we hope that the FDA will quickly grant the petition, history demonstrates that the FDA can take up to 20 years to withdraw an agricultural drug from the market," said Karen Florini, senior attorney with Environmental Defense and the principal author of the petition. "We need

the Preservation of Antibiotics for Medical Treatment Act to ensure that action will be taken promptly to stop the erosion of drug effectiveness.”

“Overuse of antibiotics in food animal production speeds the development of resistance to our dwindling supply of life saving antibiotics,” said Katherine M. Shea MD, MPH, member of the American Academy of Pediatrics, an organization of 60,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health and well being of infants, children, adolescents and young adults. “Given the serious threat that antibiotic resistance poses to human health, especially children who have less-developed immune systems, it’s time to discontinue the feeding of medically important drugs to chicken, hogs and beef cattle.”

“Scientific studies have linked the overuse of antibiotics in animal feed to health risks in humans, including medical treatment failures that sometimes result in death,” said Georges C. Benjamin, MD, FACP, executive director of the American Public Health Association, the oldest organization of public health professionals in the world, representing more than 50,000 members from over 50 occupations of public health. “We strongly support limiting the use of antibiotics in animal feeds to protect the public's health.”

The Union of Concerned Scientists estimates that 70% of the antibiotics used each year in the U.S. are fed to livestock and poultry - not to treat illness, but to promote slightly faster growth and to prevent disease that would otherwise result from crowded, stressful, and unhygienic conditions. More than half of those antibiotics are identical or related to medicines used in human treatments. In March 2003, the National Academy of Sciences called for “substantial efforts” to reduce overuse of antibiotics in agriculture.

Technical addendum:

FDA's Guidance #152 (<http://www.fda.gov/cvm/guidance/fguide152.pdf>) provides a qualitative methodology for assessing the risk that the use of particular types of antibiotics in agriculture promotes the development and spread of antibiotic resistant pathogens that may impair human health. Although the agency has stated several times that the methodology laid out in the Guidance applies to veterinary antibiotics currently on the market, it has yet to initiate formal proceedings to limit uses of any of these drugs. According to the methodology, the safety risk for an antibiotic is ranked as High, Medium, or Low, depending on the results of a specific analytic process laid out in the Guidance. Since the Guidance designates the seven antibiotic classes or class members (penicillins, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides and sulfonamides) covered by the petition as “highly important” or “critically important” in treating human disease, their use in chicken, swine, and beef cattle results in the assignment of a High or Medium overall risk to those drugs. The Guidance further indicates that High and Medium risk drugs should not have a high “extent of use,” which is defined to include use on a herd-wide or flock-wide basis - the manner in which antibiotic feed additives are administered. Thus, application of the methodology leads to the conclusion that feed additive uses of the seven drug classes should not be permitted. While the provisions are not mandatory, the petition demonstrates that the use of the seven medically important classes of drugs in feed is presumptively inconsistent with the Guidance's safety criteria.

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