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Keep Antibiotics Working Coalition Applauds FDA's Issuance of Final Guidance But Criticizes Failure to Set Timetable for Action and Other Weaknesses

Washington, DC – The Keep Antibiotics Working Coalition (KAW) applauded the efforts of the U.S. Food and Drug Administration to release a final Guidance Document (Guidance #152) on agricultural antibiotics today. However, KAW expressed its deep disappointment that FDA failed to provide a timetable for taking action to reduce the massive amounts of medically important antibiotics that are now routinely fed to livestock and poultry. As a result, the Guidance will not suffice to help preserve the effectiveness of medically important antibiotics for treating human illness. (While the Guidance itself does not appear to expressly state that FDA will review existing approvals, the agency's briefing materials on the Guidance state that it "will lead to review of all existing approvals.") KAW also voiced concerns about certain aspects of the Guidance as revised.

An estimated 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.

"The FDA missed a crucial opportunity to improve on the earlier draft of the guidance by setting specific timeframes to act on the overuse of antibiotics in animal agriculture," said Margaret Mellon, Ph.D. from the Union of Concerned Scientists. "By the agency's own admission, FDA's current process takes six to twenty years to remove a single agricultural drug or drug class from the market. So business-as-usual means it would take a half-century or more to address the eight classes of medically important antibiotics that are now used as feed additives. FDA's complete silence as to when it will even initiate – much less complete – reviews for antibiotic feed additives altogether misses the 800-pound gorilla in the room."

"The real test will be in how the guidance is applied," added Mellon.

Because of FDA's inability to take action in a timely manner, KAW supports "The Preservation of Antibiotics for Medical Treatment Act" (S.1460/H.R.2932), introduced by Senators Edward Kennedy (D-MA) and Olympia Snowe (R-ME) and Congressmen Sherrod Brown (D-OH) and Wayne Gilchrest (R-MD). The legislation creates a two-year phase out for the eight classes of medically important antibiotics now used as feed additives for farm animals, but does not restrict use of these antibiotics to treat sick animals or their non-routine use to control the spread of disease. More than 280 organizations, including the American Medical Association and the American Public Health Association, have endorsed the legislation since its introduction in July.

In addition to its serious concern about the Guidance's lack of specific timelines for action on already-approved antibiotics, KAW noted that the final Guidance has some significant weaknesses. "While the Guidance sets out a sensible conceptual strategy for evaluating the safety of antibiotic use in agriculture, there are some serious weaknesses in it," said John Balbus, M.D. of Environmental Defense. "It fails to address certain key issues, notably non-food pathways such as environmental contamination. Nor does it appear to adequately provide for consideration of co-selection and cross-resistance, or to assure protection of highest-value drugs that don't happen to be used in treating food-borne illness. And the timing issues for existing approvals remain urgent."

Keep Antibiotics Working (www.KeepAntibioticsWorking.com) is a coalition of health, consumer, agricultural, environmental, humane and other advocacy groups with more than nine million members dedicated to eliminating a major cause of antibiotic resistance – the inappropriate use of antibiotics in farm animals.