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FOR IMMEDIATE RELEASE:
November 4, 2011

Contact: Zach Goldberg, 202-478-6171
zgoldberg@mrss.com

**KEEP ANTIBIOTICS WORKING QUESTIONS LAST MINUTE
CHANGES TO FDA DATASET ON FARM USE OF
ANTIBIOTICS**

*FDA fails to explain significant revision of drug use data only days after
initial release*

Washington, D.C. – The Keep Antibiotics Working (KAW) Coalition is raising questions about the Food and Drug Administration’s (FDA) downward revision of antibiotic use in its annual report of data on sales of animal antibiotics. The FDA is required to compile and release sales data on animal antibiotics under the Animal Drug User Fee Act (ADUFA). Under that law, sponsors must submit use data to FDA by March 31 of each year.

The FDA’s initial report of the 2010 ADUFA data, posted on its website on Friday, October 28, showed 30.7 million pounds of antibiotics were sold in 2010 in the United States, a 6.7 percent increase over sales reported in 2009, adding to concerns that the already huge proportion (over 80 percent) of antibiotics used in animal agriculture is still growing. Then on Tuesday, November 1, without any notice, the FDA posted a revised ADUFA report in which the total reported sales had decreased by a dramatic 1.5 million pounds from the Friday posting, reducing the percentage increase to only 1.3 percent.

Information on the FDA website indicates that the change was due to a late submission by a drug sponsor, but still failed to explain why the reduction occurred. The FDA did not explain why the data was submitted after the March 31 deadline, how a new submission could result in such a significant decrease in antibiotics use when a late submission would increase the amount or how the submission could account for the large amount of antibiotics involved.

”The FDA’s explanation raises more questions than it answers,” said Steven Roach, Public Health Program Director at Food Animal Concerns Trust (FACT) and a member of Keep Antibiotics Working. “How could a late submission result in such a huge drop in drug sales?”

Roach added: “These data are vital to determining antibiotic use on farms. The scientific consensus is clear that overuse of antibiotics in food animals contributes to antibiotic resistant infections in humans. These data should have been compiled and released to the

public long ago. It is disturbing to see the FDA be so loose in its reporting of this vital information.”

Whether one looks at the original or the revised report, this dataset indicates that antibiotic use in animal agriculture is not going down and is on the rise. Ongoing high level use of antibiotics in animals just adds to the evidence of FDA’s long-term failure to address this important public health problem.

FDA’s release of the ADUFA data and last minute, unexplained revision are in line with the conclusion of a recent report from the Government Accountability Office detailing how the FDA and the U.S. Department of Agriculture have failed for decades to collect the data necessary to effectively reduce antibiotic usage in agriculture.

The FDA also chose not to break the data out by route of administration (feed, water, or injection) or purpose of use (therapy, prevention, or growth promotion). The FDA has the power to do such breakouts and indeed did so with last year’s data, but only in response to a request from U.S. Representative Louise Slaughter (D-NY).

Margaret Mellon, senior scientist at the Union of Concerned Scientist, and a member of KAW, said, “The shoddy treatment of this important dataset is very troubling. FDA prides itself on its high scientific standards, but high quality science demands high quality data. The FDA should be compiling and publishing the data rapidly and breaking the data out in ways that help to address the problem. Instead it is treating this vital dataset like a nuisance.”

KAW supports the Preservation of Antibiotics for Medical Treatment Act (PAMTA), bipartisan legislation that would address the shortcomings in the federal response and reduce antibiotic resistance by phasing out the use of medically important antibiotics in food animals that are not sick.

Keep Antibiotics Working (KAW) is a coalition of health, consumer, agricultural, environmental, humane, and other advocacy groups with more than 11 million supporters.

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