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*The Campaign to End Antibiotic Overuse*

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## **FDA Commended for Acknowledging Need To Re-Evaluate Safety of Agricultural Antibiotics**

### ***But New Guidance Flawed by Absence of Timetable for Taking Action***

**Washington, DC** – The Food and Drug Administration’s (FDA’s) new guidance on evaluating the safety of agricultural antibiotics (<http://www.fda.gov/OHRMS/DOCKETS/98fr/98d-1146-gdl0001.doc>) has both strengths and weaknesses, according to Keep Antibiotics Working (KAW), a coalition of health, consumer, environmental, humane, and other advocacy groups ([www.KeepAntibioticsWorking.com](http://www.KeepAntibioticsWorking.com)).

“Although it has a number of important limitations, this long-awaited document signals FDA’s increasing recognition that overuse of antibiotics in agriculture plays a significant role in the growing public-health crisis of antibiotic resistance,” said Tamar Barlam, M.D., an infectious disease physician who directs the Antibiotic Resistance Project at the Center for Science in the Public Interest.

“The major weakness is that FDA’s new guidance focuses primarily on procedures for reviewing applications for approving additional drugs in the future,” said Margaret Mellon, Ph.D., J.D., head of the Food and Environment Program at the Union of Concerned Scientists. “While that issue certainly warrants attention, the elephant in the room is the vast quantity of antibiotics already administered to farm animals. In fact, an estimated 70% of antibiotics used in the U.S. each year are fed to healthy farm animals, and half of these are identical or nearly identical to antibiotics used in treating sick people.

“The 48-page guidance document contains less than two pages on re-evaluating the safety of already-approved agricultural antibiotics,” said Karen Florini, Senior Attorney with Environmental Defense. “Even more troubling is the lack of any timetable for completing, or even initiating, such re-evaluations. And that’s only the start of a lengthy process – FDA’s prior proceedings to withdraw other agricultural drugs have taken up to 20 years to complete for a single drug class. Clearly, Congress needs to take action to get the ball moving much faster.”

Legislation introduced by Senator Edward M. Kennedy, D-MA, (S. 2508) and by Representative Sherrod Brown, D-OH, (H.R. 3804) would automatically phase out the routine feeding of medically important antibiotics to healthy farm animals two years after enactment unless FDA determined that there is enough scientific information to show continuation of such use would not contribute to antibiotic resistance in humans. That legislation has been endorsed by the American Medical Association, American Public Health Association, American Academy of Preventive Medicine, KAW, and dozens of other groups.

KAW also has a number of additional concerns about the guidance, which it will detail in comments to be submitted to the FDA shortly.