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Keep Antibiotics Working Coalition Disappointed in FDA's Long-Delayed Guidance 213 Voluntary Plan to Address Antibiotic Use in Food Animals Relies on Drug Companies to Police Themselves

Washington, DC -- The Food and Drug Administration (FDA) today released a long-delayed final version of Guidance 213, a limited voluntary plan that depends on the pharmaceutical industry taking action to reduce antibiotic overuse in food animals. When the draft guidance was first proposed, Keep Antibiotics Working (KAW), a coalition of health, consumer, agricultural, environmental, humane, and other advocacy groups, criticized the Agency for taking this voluntary approach instead of using its legal authority to remove from the markets drugs that are creating a human health problem. KAW is equally skeptical of the final version.

“KAW is happy that the FDA has finalized this document, so that we can see whether it actually works,” said Steven Roach, Senior Analyst for Keep Antibiotics Working. “Our fear however is that there will be no reduction in antibiotic use as companies will either ignore the plan altogether or simply switch from using antibiotics for routine growth promotion to using the same antibiotics for routine disease prevention.”

FDA allows antibiotics to be given to food animals in the absence of diagnosed illness either for growth promotion (using antibiotics to reduce the cost of raising animals) or for disease prevention (antibiotics given to animals because they might get sick). While KAW supports the use of antibiotics for treating illness and for preventing disease in animals when disease is spreading through a flock or herd, it opposes the use of medically important antibiotics on a regular basis to compensate for poor animal husbandry.

Preventive antibiotics are often administered to counter problems caused by poor diets, overcrowding, and unsanitary conditions on farms. Right now many of the drugs approved for growth promotion are approved at the same dose and duration for disease prevention. Therefore even if all the companies agree to stop selling the drugs as growth promoters they could change the label and continue selling them for disease prevention, resulting in little public health impact. The companies themselves have stated that they do not expect impacts on their sales.

The FDA today also released proposed language loosening restrictions on how drugs in animal feeds that require a veterinarian's approval can be used. For feed drugs, instead of a prescription, vets provide veterinary feed directives (VFDs). But currently, most drugs approved for use in animal feeds do not require veterinary approval at all. FDA is apparently hoping that loosening the rules on VFDs will make it more likely that drug companies will shift their feed drugs to require vet approval.

“That FDA felt it needed to greatly weaken the VFD rules on how much contact a vet has to have with the animals before approving a feed antibiotic is not a good sign for the success of the voluntary program,” added Roach. “This is just one more sign that this program is not likely to reduce antibiotic

use in a significant way. Without reductions in use, there can be no health benefit, which is the whole purpose of the plan.”

Without clear leadership on the part of the FDA, stronger Congressional action is essential, which is why KAW has been advocating for swift action on the recently introduced [Preventing Antibiotic Resistance Act](#) (PAR) and its companion bill in the House, the [Preservation of Antibiotics for Medical Treatment Act](#) (PAMTA). The bills, which would help curb routine antibiotic misuse on the farm by requiring the FDA to phase out the use of medically important antibiotics in food animals that are not sick unless such use is proven to be safe, face an uphill battle against the deep pockets of the agricultural and pharmaceutical lobbies.

If you'd like to connect with Steven Roach or other members of the Keep Antibiotics Working coalition for comment, please contact Katie Andriulli at kandriulli@mrss.com or [\(202\) 478-6138](tel:2024786138).

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