

Docket No. FDA-2011-D-0889 (Draft Guidance 213)
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

July 12, 2012

Dear Dr. William T. Flynn,

On behalf of the patients and communities we serve, we are writing to respectfully request that the federal government accelerate and expand actions to curtail the overuse and misuse of antibiotics in food animal production. FDA should act on recent court orders to comply with the law's mandate to protect public health from risky uses of antibiotics in animal agriculture and improve its proposed Guidance package (Guidance for Industry No. 209, Guidance for Industry No.213, and Veterinary Feed Directive) in parallel.

Data compiled by the U.S. Food and Drug Administration (FDA) demonstrates that 80 percent of all antibiotics sold in the United States are for food animal production, the vast majority used to compensate for overcrowded and unsanitary conditions and fed to animals for growth promotion rather than any therapeutic need. This contributes to a surge of drug-resistant bacteria, called "superbugs", which can easily make their way out of the farm and spread to humans through infected food, water, and other pathways, putting the health of all Americans at risk for dangerous antibiotic-resistant infections.

Four decades ago, experts began sounding the alarm about these practices. The Centers for Disease Control and Prevention, the FDA, and U.S. Department of Agriculture have all testified before Congress that scientific studies link the routine, non-therapeutic uses of antibiotics on industrial farms and the crisis of antibiotic resistance in humans. Medical and public health institutions have long warned about the dangers of such uses and have called for action. Yet despite the overwhelming scientific evidence about the threat to human health, the routine use of low-dose antibiotics in intensive meat and poultry operations continues unabated and the crisis of antibiotic resistance has grown.

The use of life-saving antibiotics for disease prevention should be a last resort, when all other options have failed, and should not substitute for improved management practices on livestock farms. The medical community is actively working on reducing the inappropriate use of antibiotics in human medicine and has made progress on that front. We now call on FDA and other federal agencies to do their part and take strong action in the interest of the American people to preserve the effectiveness of the vital medicines we depend upon to treat common but dangerous infections.

Rulings by a federal court in New York from March and June of this year have directed the FDA to carry out withdrawal proceedings for penicillin and tetracyclines and to evaluate the safety of using other medically important antibiotics in animal feed. FDA should move ahead with this important process and not replace enforceable limitations on antibiotic use with voluntary guidance.

As a supplement to the actions required by the court, FDA's proposed Guidance package has the potential to help eliminate non-therapeutic uses of antibiotics and ensure more rigorous veterinary oversight of antibiotics used in food animal production, but significant revisions will need to be made.

We hope FDA will act quickly and vigorously to:

- 1) Comply with recent court orders directing the agency to move forward with the process for mandatory regulations to stop the use in animal agriculture of all antibiotics important for human medicine, unless those uses can be proven safe.
- 2) If it chooses to continue in parallel with a voluntary approach, revise its guidance to eliminate loopholes that would allow livestock operators to continue the practice of administering herd-wide or flock-wide doses of antibiotics to animals that are not sick, even if operators call this practice "disease prevention."
- 3) Establish a monitoring program to collect the information from industry needed to evaluate antibiotic use trends, prevalence of high risk practices and incidence of drug resistance.

The development of antibiotics, which have been called "miracle" drugs, represented a huge step forward in human medicine. Now vigilance and strong action is required by FDA to safeguard the effectiveness of these life-saving medicines for when we need them most. Effective FDA leadership on this issue can have huge benefits: healthier meat and poultry products, the elimination of unnecessary suffering and health care costs, and saved lives.

Sincerely,

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