

Docket No. FDA-2011-D-0889 (Draft Guidance 213)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

Dear Dr. William T. Flynn,

On behalf of our suppliers, employees and customers, we are writing to respectfully request that the U.S Food and Drug Administration (FDA) accelerate its efforts to curtail the 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).

As businesses that have demonstrated leadership in reducing antibiotic use in our supply chains, we know firsthand that switching away from dependency on these pharmaceuticals is the right thing to do. Data compiled by the FDA reveals that 80 percent of all antibiotics sold in the United States are used not to treat people, but in food animal production—the vast majority to promote more rapid animal growth or prevent disease associated with overcrowded and unsanitary conditions. This is a major contributor to a surge of drug-resistant bacteria, often 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.

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.

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.

We have enormous respect for the farmers and ranchers who supply our businesses. Every day they prove that we can raise healthy farm animals without depending on antibiotics for non-therapeutic uses. FDA can support them, our customers, and our communities by moving animal agriculture away from the misuse of antibiotics and ensuring that we safeguard the effectiveness of these life-saving medicines for the public health.

Sincerely,

Steve McDonnell, CEO
Applegate

Fedele Bauccio, CEO
Bon Appétit Management Company

Steve Ells, Founder, Chairman & Co-CEO
Chipotle Mexican Grill, Inc.

Paul Willis, Founder and Manager
Niman Ranch Pork Company

George Siemon, CEO
Organic Valley

Gary Hirshberg, Co-Founder and Chairman
Stonyfield Farm, Inc.