

United States Senate

WASHINGTON, DC 20510

August 13, 2012

The Honorable Margaret A. Hamburg, M.D.
Commissioner, U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner Hamburg:

We write to commend the FDA for releasing Guidance for Industry 209—which proposes voluntary reductions in the use of antibiotics in food animal production—and to urge you to further strengthen the document.

FDA's Guidance 209 and its accompanying blueprint for implementation, Draft Guidance 213, make two important recommendations which we support in principle:

- Revise veterinary antibiotic labels to eliminate the use of antibiotics for “growth promotion”; and,
- Increase and improve veterinary oversight of antibiotics used in food animal production.

However, because the Guidance documents allow for the continued use of antibiotics for “disease prevention,” there is considerable ambiguity about the actual impact of this guidance. If broadly defined, “disease prevention” could allow the continued use of antibiotics in ways not consistent with the FDA's vision for “judicious use.” This could include inappropriate and ineffective practices that merely mask underlying production problems such as poor hygiene or animal overcrowding.

In addition, Draft Guidance 213 lacks a plan for monitoring and evaluating implementation of this important initiative. By the FDA's own admission, the “FDA does not have detailed drug use data that would enable us to estimate

quantitatively the reduction in the total volume of use that would be expected with phasing out the production or growth promotion uses of medically important drugs." This is of great concern to us, and we urge the agency to design a system with relevant agencies and stakeholders for gathering and analyzing necessary information to assess the effectiveness of the new policies. Should you find any critical gaps in your statutory authority, we would welcome the opportunity to work with you to provide additional authorities and resources.

Thank you again for beginning the process of addressing the issue of antibiotic resistance. As the FDA has previously stated, a wide body of evidence confirms that the overuse of antibiotics in the food animal industry is a key factor in the development of antibiotic resistance in humans. We look forward to working with you on this important issue and hope that you will give serious consideration to our request for a stronger, more effective guidance document.

Sincerely,

Denise Stein

Frank R. Lautenberg

Herb Kohl

Ben Sanders

Susan M Collins

John J. Kerry

Patrick Leahy

Kirsten E. Gillibrand

Bob Casey

Joe Lieberman

Jack Reed

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