



August 30, 2010

The Honorable Margaret A. Hamburg, MD  
Commissioner  
c/o Division of Dockets Management (HF A305)  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

ATTN: Comment Docket No. FDA-2010-D-0094

Dear Commissioner Hamburg and Principal Deputy Commissioner Sharfstein:

I welcome FDA's draft guidance, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" as a step forward in articulating FDA's opinion on what more can be done to preserve the effectiveness of antibiotics through limiting the emergence of antimicrobial resistance in farm animal husbandry. Key elements of the two new principles FDA is proposing contribute to laying the groundwork to build consensus among major stakeholders – public health and agribusiness: 1) limiting the use of medically important antimicrobial drugs to treat sick animals through inclusion of veterinary oversight; and 2) removing antibiotics for production purposes, i.e., promotion of growth and feed efficiency.

Aspects of the principles that are less subject to consensus concern preventive use of antibiotics. In this case, animals who are not sick are receiving antibiotics. These diseases may have been avoided by other alternatives, such as animal hygiene, less crowding of cages/pens, and alternative management strategies (in-all-out). The fact that FDA considers mass administration of antibiotics to herd/flock through feed and water as a viable prevention strategy is cause for concern. An impact on the microbiology of the environment will certainly occur given the duration and doses practiced.

That FDA has taken an initiative regarding antibiotic use in food-producing animals is indicative of its foresight in carrying out its mission to safeguard both animal and public health. However, even if finalized- the guidance is purely voluntary, and I fear, will exact no compliance from the agricultural industry to eliminate inappropriate use of antibiotics. Without mandating the termination of injudicious use and establishing a system to monitor compliance, I believe that the new FDA guidance will be to no avail: agribusiness will continue its practice of feeding animals antibiotics non-therapeutically.

Thank you for consideration of my comments. I shall be happy to answer any questions that you may have.

Sincerely,

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