

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 98D-1146-Discussion Paper: "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals."

Gentlemen:

These comments are submitted with regard to the Food and Drug Administration's "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (64 Fed. Reg. 887, Jan. 6, 1999).

The proposed Framework (1) describes a pre-approval system under which the FDA will consider the potential of new uses of antibiotics in animal agriculture to exacerbate problems of antibiotic resistance in human pathogens, and (2) outlines requirements for post-approval studies and monitoring of resistance levels for new uses of antibiotics in animal agriculture.

I have read various articles on the Internet and in news magazines such as Newsweek and US News which have outlined the problems we are now seeing with bacteria that is seemingly immune to some our stronger antibiotics. I have to go with current logic that continued use in livestock severely threatens the ability of current antibiotics to keep us safe.

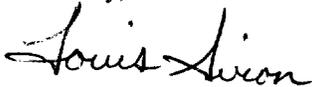
It is my belief that the FDA should restrict the use of antibiotics in food-animal production based on concerns about antibiotic resistance.

The FDA's proposed scheme for categorizing antibiotics does not adequately protect human health.

The FDA should require that drug-sales information be submitted to the agency.

Thank you for your consideration.

Sincerely,

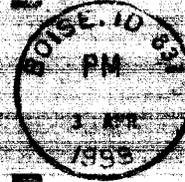


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