

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

April 16, 1999

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RE: Docket No. 98 D-I 146-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."

To Whom it May Concern:

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 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.

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,



Robin Semeria

98D-1146

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