

June 23, 1999

Dockets Management Branch (HFA-305) 5654 '99 JUN 30 A10:07
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: DOCKET #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."**

To Whom it May Concern:

These comments are submitted with regard to the Food and Drug Administration's 64 Fed. Reg. 887, Jan 6, 1999.

The proposed framework 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 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.

Carolyn Mayfield, President
MAYFIELD ENTERPRISES, INC



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