Karen Sabo
1428 Christy Ave.
Louisville, KY 40204

2639 '99 MAY 19 P4:43

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 Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals."

To Whom it May Concern:

I am writing concerning the FDA'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)

As I understand it, the proposed Framework (a) 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 (b) outline requirements for post-approval studies and monitoring of resistance levels for new uses of antibiotics in animal agriculture.

THE FDA SHOULD RESTRICT OR BAN, AS EUROPEAN COUNTRIES HAVE DONE, THE USE OF ANTIBIOTICS IN FOOD-ANIMAL PRODUCTION BASED ON CONCERNS ABOUT ANTIBIOTIC RESISTANCE.

THE FDA'S PROPOSAL FOR CATEGORIZING ANTIBIOTICS DOES NOT ADEQUATELY PROTECT HUMAN HEALTH, PARTICULARLY OF CHILDREN, OUR MOST VULNERABLE GROUP.

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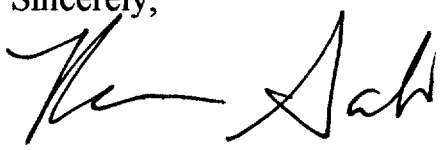
THE FDA SHOULD REQUIRE THAT DRUG-SALES INFORMATION BE SUBMITTED TO THE AGENCY.

I am writing simply because I am interested in the health of my unborn child.

Thank you for your consideration.

Sincerely,



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