

Comments on the FDA document entitled "A proposed Framework for Evaluating and Assuring Human Safety of the Effects of Antimicrobial New Animal Drugs Intended for Use in Food Producing Animals".

Docket Number: 98D-1146

Clyde Thornsberry 1/28/99

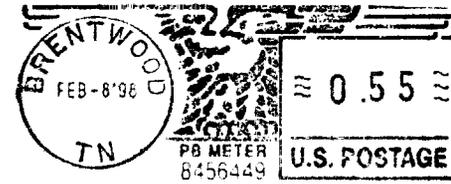
1) Statement of purpose. There are a number of statements concerning resistance and the effect on humans that I do not agree with or are unproven but I understand that to be outside the permissible comments. Nevertheless, it can be said that anything society does has the potential to cause harm to the society and statutes cannot change that. One must be careful that regulation does not create a state of paralysis which would be counter-productive, in this case no new drugs for therapy of animals. We delude ourselves in thinking this would never happen, but companies will weigh carefully how much money they put into developing a drug, particularly an innovative one, if there is a significant chance it will not be approved. Why put the money into veterinary medicine when the likelihood of approval is much greater for a human drug and the return on money much more substantial.

I am reluctant to accept enteric bacteria as the only organism that will be used as indicator species. It seems to me that the document is much too closely tied to *Salmonella* and by inference to fluoroquinolones. I believe this is short-sighted.

I also have reservations about how you would establish the pathogen load in animals and, particularly, how you would relate this to transfer to humans. Would you

98D-1146

CI



MRL
PHARMACEUTICAL SERVICES

7003 CHADWICK DRIVE, SUITE 235
BRENTWOOD, TENNESSEE 37027

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD. 20852

HFA 305