

Utah State UNIVERSITY EXTENSION

DEPARTMENT OF ANIMAL, DAIRY
AND VETERINARY SCIENCES
5600 Old Main Hill
Logan UT 84322-5600

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Phone: (435) 797-1882
Fax: (435) 797-3959
clellb@ext.usu.edu
<http://ext.usu.edu/ag/ah>

December 3, 1998

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

Comments on Docket # 98D-0969

“Draft Guidance for Industry : Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals”

This document, as written, has the potential to cause great suffering and pain for animals due to the loss of antimicrobial drugs, for use in animals.

In the “Conclusion” of the document it states, “FDA recognizes that there is no standardized protocol established for determining the human health impact of the microbial effect(s) on an antimicrobial product, and that one standard protocol is likely to be inappropriate for all intended uses.”

This says, in effect, that the standard is unmeasurable and unknown but FDA is going to require someone in its administration to approve or disapprove products, based on the drug’s potential for harm. This is a definite leap from “science” into politics. It will give assigned FDA personnel almost unlimited authority so they can “stonewall”, retaliate or blackmail a commercial company. It will allow individuals to keep good products off the market and result in needless animal disease and suffering.

Animal producers and veterinarians want to produce safe food products and work hard to do so. But we need good products to use and there are few new products currently available. It is currently very difficult and very expensive to clear a new antimicrobial for use in animals. Incorporating an unmeasurable and unknown requirement into the regulations for antimicrobial approval may well make it unreasonable for companies to even TRY to develop new products.

The ultimate effect may actually be to foster the use of un-approved products. Producers cannot (economically) and will not (morally) stand by and do nothing while their animals sicken and/or die, needlessly. If no approved products are available, some producers will find a product of

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98D-0969

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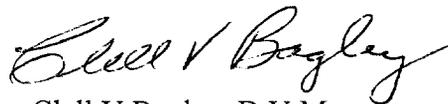
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some kind which they think or hope will make a difference, and use it - even if it is not approved. Practicing veterinarians will have no ability to deter this use with the regulations currently in place. The FDA will not be able to monitor and adequately enforce the regulations.

It would be much wiser to encourage the development of antimicrobial products specifically for use with animals (such as, classes of products of lesser importance in human medicine). And, at the same time, restrict the use of antimicrobial products identified as being very important in human medicine. At the very least, establish some specific standards and tests that could be used by companies seeking approval of an antimicrobial.

Policies do have a major impact on new product development. Please do not implement this policy as currently outlined.

Sincerely,

A handwritten signature in black ink that reads "Clell V Bagley". The signature is written in a cursive style with a large, prominent "C" and "B".

Clell V Bagley, D.V.M.
Extension Veterinarian
Utah Delegate to AVMA

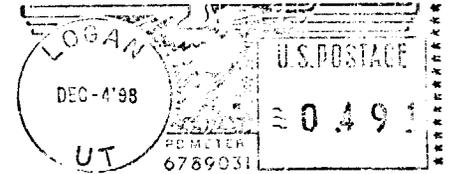
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