



AMERICAN FEED INDUSTRY ASSOCIATION

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May 3, 1999

Dockets Management Branch
Food and Drug Administration
12420 Parklawn Dr. (HFA-305)
Room 1-23
Rockville, Maryland 20857

Comment: FDA Docket No. 98D-1146
*"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."*

Dear Sir/Madam:

The American Feed Industry Assn. (AFIA) welcomes the opportunity to comment upon the aforementioned agency proposal (FDA Docket No. 98D-1146). AFIA is the national trade association representing more than 75% of the commercial primary livestock and poultry feed sold annually in the U.S. AFIA's membership also includes drug and feed additive manufacturers, animal health product distributors, ingredient suppliers, pet food manufacturers and feed manufacturers. AFIA's members control more than 3,000 facilities in 50 states. The Association also enjoys the support of more than 40 state, regional and international associations.

AFIA would first like to stipulate for the docket that it strongly supports the comments filed made by the Animal Health Institute (AHI). AFIA would also like to associate itself with comments filed on behalf of the Animal Health Coalition, an ad hoc coalition of producer groups as well as feed, animal drug and veterinary medical associations which serve the farmer/rancher.

However, as relates to AFIA's parochial interests, we are deeply concerned that the proposed antibiotic framework document, if undertaken, will significantly change the way these and other products are generally reviewed by the Food & Drug Administration (FDA), and we are specifically concerned how these changes may impact the availability and use of antimicrobials in the future.

Such a drastic shift in agency treatment of these important products will result in fewer antimicrobial drugs being approved, as well as greater restrictions on their use. Such an outcome will certainly adversely affect the price of these products to not only the manufacturer of the feed products, but also to the livestock producer. These

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eventualities have implications for the cost of producing meat, milk and eggs, as well as for the overall health and wellbeing of food producing animals should producers choose not to treat their herds and flocks at the first sign of disease

AFIA strongly believes any such far-reaching decision must be based upon significant and detailed formal risk analysis emanating from sound scientific evidence. This science – and its use – must be well accepted by the scientific and/or veterinary communities.

Thank you for the opportunity to submit these comments. AFIA, as always, stands ready to assist the agency in any way it feels appropriate.

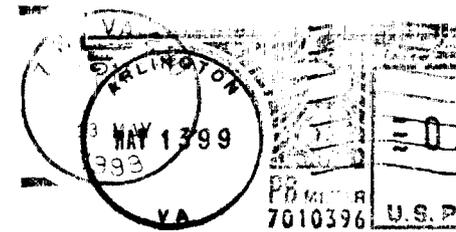
Sincerely,

A handwritten signature in cursive script that reads "Steve Kopperud".

Steven L. Kopperud
Senior Vice President



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