

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

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April 5, 1999

Docket Number 98D-1146

A Proposed Framework for Evaluating and Assuring the Human Safety of Antimicrobial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals. ("Framework Document"). Federal Register 64(3): 887-888 (1/6/99)

Alpharma is a manufacturer of human and animal drugs including antibiotics for livestock and poultry.

Alpharma fully supports the testimony presented by the Animal Health Institute (AHI) at the January 25-26, 1999 meeting of the Veterinary Medicine Advisory Committee and the AHI comments submitted to this docket. We believe that a sound scientific basis derived from a comprehensive risk assessment of antibiotic resistant food borne pathogens on human health is necessary and essential before any new requirements are imposed by FDA on sponsors of new animal drug applications for antibiotic animal drugs. Alpharma will support sensible, workable science-based changes in the regulations so long as such changes can be shown to assure continued protection of the public health. To date, however, Alpharma has considerable doubts as to the necessity for the changes envisioned by the Framework Document and their beneficial effect in protecting the public health. That is not to say that Alpharma is unconcerned about the issue of antibacterial resistance; we like others in human and veterinary medicine take it very seriously.

Numerous reports, symposia, and published articles demonstrate the lack of scientific consensus about the magnitude of the contribution from animal antibiotics to the antibacterial resistance problem in human pathogens. For example, a recent study¹ by an independent group of scientists recommends further multi-disciplinary research to fully assess the potential risks to human health, if any, from the use of such drugs in animal feed. Indeed, to quote this report, "Epidemiological data to this date do not show that the use of AGPs [antibiotic growth promoters] in animal rearing compromised the use of related antibiotics in human medicine".

To impose the new requirements outlined in the Framework Document prior to conducting such studies will only add cost and additional delay to the animal drug approval process without a commensurate increase in protection of the public health.

¹ Emergence of a Debate: Antibiotic Growth Promoters and Human Health. HAN Foundation, Amsterdam. 1999

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I will be happy to answer any questions you may have concerning our comments.

Sincerely,



Bruce I. Andrews
President
Animal Health Division

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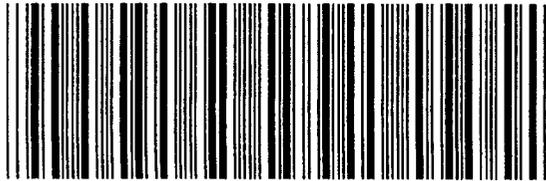
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