



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 15 2000

Food and Drug Administration
Rockville MD 20857

Joan Dye Gussow, Ed.D.
563 Piermont Ave.
Piermont, NY 10968

Dear Dr. Gussow:

This is in response to your letter dated June 1, 2000, addressed to Commissioner Henney, concerning antibiotics used in livestock.

The Center for Veterinary Medicine (CVM) is a public health organization under the Food and Drug Administration (FDA) that helps to ensure the safety of the food supply and assists in providing for the health care needs of animals through the approval and post-approval monitoring of safe and effective animal drugs, medical devices, and feeds.

Thank you for sharing your concerns with us. The use of drugs in livestock and poultry is strictly regulated. Before any drug intended for use in animals is approved, it must undergo extensive chemical and toxicological testing which must demonstrate that the food from these animals is safe for human consumption. Withdrawal periods for drugs in edible tissues, which are based upon the depletion and elimination of the drug to a safe residue level in those tissues, ensures that the food we eat is safe. In addition, milk discard times are established to ensure that any drug residues in milk are not harmful for human health. If an illegal drug residue is detected, FDA investigates the matter and takes regulatory action, if necessary. FDA believes that our residue monitoring program effectively protects the public from any potentially unsafe residue of animal drugs in meat and milk.

FDA is taking a close look at the rules for approving antibiotics for food animal use in the U.S. Enclosed please find a copy of the "Framework Document," which explains FDA's concept of the best regulatory approach for antimicrobial approvals, as well as a chronology on the use of antibiotics in animal feeds. Please be assured that we take our responsibility to ensure the safety of the food supply very seriously. I am forwarding your letter to Dockets Management Branch for inclusion in Docket Number 99P-0485 -- Rescind Approval of Subtherapeutic Antibiotic Use in Livestock. If you have access to the Internet, please visit our Home Page at <http://www.fda.gov/cvm>.

Sincerely yours,

Karen A. Kandra
Consumer Safety Officer
Center for Veterinary Medicine

Enclosures

99P-0485

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