



DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

September 22, 1977

A. T. Blades
Preston, Maryland 21655

Dear Mr. Blades:

Your letter of August 24, 1977 to the Commissioner of Food and Drugs has been referred to this office for reply. We also have a copy of the U.S. Department of Agriculture letter of September 2, 1977 for further response. The USDA letter to you dated September 2, 1977 is not representative of the facts of the Food and Drug Administration's intentions regarding the use of antibiotics in livestock feeds.

Contrary to the impression conveyed by the USDA letter, the Food and Drug Administration (FDA) is not intending to propose a total ban on the use of antibiotics in treating livestock. The study cited (Gilliam and Martin, Journal of Animal Science, Vol. 40:1241 - 1975) was done in abstract, unrelated to any specific proposals. Our announced intention is to withdraw the use of penicillin and certain uses of the tetracyclines (chlortetracycline and oxytetracycline) from livestock feeds for which there are effective alternative drugs being marketed for use in feeds. The purpose of these intended actions is to decrease the unnecessary use of these drugs because of the risk of resistant plasmids being transferred from animals to man resulting in antibiotic resistance in humans.

Furthermore, the intended actions do not affect the use of antibiotics and other drugs in the treatment of mastitis by the dairy industry. Mastitis is ordinarily treated by direct intramammary infusion, and not by the administration of drugs through feed. Chlortetracycline will continue to be available for important diseases addressed in the USDA letter, such as anaplasmosis in beef cattle. We are preparing an economic impact analysis of our proposed actions which will be available at the time our proposal is published in the Federal Register.

There is some evidence that the addition of certain antibiotics to animal feeds aids in improving production efficiency and probably helps prevent infection. It is our belief that these results are obtained at risks to the public health, and that the laws regarding safety of animal drugs require us to act to restrict that risk. Our intention to restrict the uses of the tetracyclines and penicillin in animal feed is based upon extensively documented scientific evidence of a significant potential public health problem as summarized in the enclosure. We recognize that the scientific

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conclusions are in some respect controversial among scientific experts. However, because of the public health significance of the issue, it is incumbent upon this Agency to propose actions to effectively deal with the issue.

The proposal to eliminate the use of penicillin in animal feeds was published in the Federal Register on August 30, 1977 for public review and comment. We expect to publish proposals to restrict use of the tetracyclines in livestock feeds in the near future. We believe these proposals will enable us to obtain the widest possible spectrum of comments for evaluation in reaching a final decision. Thoughtful analyses of their contents will be welcomed from members of the public and from all quarters of the scientific and agricultural communities.

We hope these comments will be helpful in establishing the proper perspective and facts of our announced intentions. We appreciate the opportunity to express our comments on this important issue.

Sincerely yours,

Edward J. Ballitch
Acting Deputy Director
Division of Compliance
Bureau of Veterinary Medicine

Enclosure: Antibiotics in Animal Feed
Federal Register Notice - Penicillin
in Animal Feed (8/30/77)

cc: HF-1(2)
HFC-20(w/cy inc)
HFV-231
HFA-224
EBallitch 9/22/77-jms

September 2, 1977

Mr. A. T. Blades
Preston, Maryland 21655

Dear Mr. Blades:

Thank you for your letter to Secretary Bergland in which you enclosed a copy of your letter to Dr. Donald Kennedy, Commissioner, Food and Drug Administration. Your interest in subtherapeutic levels of antibiotics in animal feeds is appreciated.

Feed additives, such as antibiotics, have been widely used in animal nutrition and veterinary medicine for over 25 years. Antibiotics are used in beef to prevent liver abscesses and anaplasmosis and in swine to prevent and control baby pig diseases, increase rate of growth, and improve feed efficiency. In swine, the low-level feeding of antibiotics will increase the growth rate by 10 percent and improve feed efficiency by 5 percent. Recent studies show that the banning of antibiotics in cattle, calves, and swine would cost \$3 billion annually. Estimated annual increases in production costs and cost costs are approximately \$1.5 billion for cattle and calves, and \$1.4 billion for swine. (Source: Gilliam and Martin. J. Anim. Sci. 40:1241. 1975).

The most extensive use of drugs and chemicals, including antibiotics, by the dairy industry is in the treatment of mastitis. Mastitis is an inflammation of the mammary gland, and is estimated to cost the dairy industry \$118 per cow, or well over \$1 billion per year. In dairy calves, responses have been variable, but improvements in gain up to 20 percent have been observed when antibiotics are fed up to 90 days of age. Under some circumstances, antibiotics have a beneficial effect in the prevention and control of scours in dairy calves.

The low-level feeding of antibiotics will increase egg production in layers and turkey breeders 1 to 3 percent. In turkey poult and broilers, rate of gain is increased 5 to 7 percent. The Food and Drug Task Force Report (1970) estimated that the use of antibiotics in turkey and broiler rations saved \$50 million annually. Because of the increase in the price of feed, the estimated annual savings in 1977 is about \$75 million.

Antibiotics play an important role when used at subtherapeutic levels in animal feeds. We realize these benefits must be weighed against the theoretical risks of creating some infections and viable drug-resistant organisms in the future that may be harmful to the health of man or animal.

Mr. A. T. Blades

2

Primary responsibility for administering laws related to the safety of drugs, such as antibiotics, used in animal production rests with the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare under the provisions of the Federal Food, Drug and Cosmetic Act. All of the efficacy information concerning antibiotics based on research conducted by the Agricultural Research Service and other research agencies—Federal, State, and private—is available to FDA.

Enclosed for your information is a USDA news release by the Department of Agriculture concerning the issue.

Thank you again for sharing your thoughts with us on this important issue.

Sincerely,

Andrew J. Kral, Jr.

Andrew J. Kral, Jr.
Program Correspondence Specialist
Livestock & Veterinary Sciences

Enclosure

cc: Secretary's Records 06-04899V
LSAS
Edward Ballitch, FDA

ARS:NPS:LVS:AJKral, Jr.:adb: ext. 42087 9/2/77

A. T. BLADES
PRESTON, MARYLAND 21655

August 24, 1977

Control No. 06 - 04899
Referred to:
Date: ARS
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Hon. Robert S. Bergland
Secretary, Agriculture Department
14th Street and Independence Avenue, S.W.
Washington, D.C. 20250

Dear Mr. Bergland:

I am attaching copy of a letter written to Dr. Donald Kennedy, Commissioner, Food and Drug Administration, which I feel needs your urgent attention.

Yours very truly,



A. T. Blades

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SECTION
SECRETARY'S RECORDS
AGRICULTURE

A. T. BLADES
PRESTON, MARYLAND 21655

August 24, 1977

Dr. Donald Kennedy, Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Kennedy:

Being located in an area that is heavily orientated toward the production of broilers, I am disturbed that you plan to restrict the use of tetracycline and penicillin antibiotics in livestock and poultry feeds for disease prevention and plan to put them on a list of products which must be prescribed by a veterinarian and then only for the treatment, not prevention, of disease.

I can appreciate your concern with the theory that tetracycline gives rise to population of bacteria which are resistant to penicillin, tetracycline and other antibiotics and that this resistance might interfere with subsequent treatment of sick livestock or for that matter transfer to humans, thus leading to the possibility of untreatable disease.

It would seem to me that your department should have a lot more factual information before issuing an order that could cripple the broiler industry in the United States based on theory but not facts.

Yours very truly,

A. T. Blades

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