The Federal Food, Drug and Cosmetic Act and the Bureau of Veterinary Medicine, FDA.

R. A. Baldwin, *D.V.M., M.S.*
Branch Chief
Certifiable Antibiotics Drugs Branch
Division of New Animal Drugs
Bureau of Veterinary Medicine, FDA,
Public Health Service, U.S. Dept. of HEW
Rockville, Maryland 20852

At the Denver meeting in July, I met with the Food and Drug Committee of this association. During this meeting, I explained to the members present how the Federal Food, Drug & Cosmetic Act was enacted and the function of the Bureau of Veterinary Medicine within the Food and Drug Administration. The committee chairman, Dr. Robert Harris, asked that I write a brief article on this subject.

Introduction

Having practiced in Wyoming for fourteen years, I can readily appreciate that most of you who read this article have primary responsibilities to the livestock and pet owner. More especially, your primary concern is for the health and well-being of the animal or groups of animals for which you are called upon to administer services. Acts of Congress, laws, regulations and policies of government only become important when the results of these actions directly affect your relationship with the patient and the client.

Judging from the questions received on a daily basis by all of us in the Food and Drug Administration in direct contact with practicing veterinarians, it appears that there is a lack of understanding of how the Food and Drug Administration originated, what its charge is, and how it operates on a day-to-day basis. It is my hope that this brief presentation will give you a little more understanding of the Food and Drug Administration. This understanding is necessary if all of us are to do the job required in protecting the consumer and the livestock industry of the United States.

The purpose of this paper is to: (1) give you a history of the Food and Drug Administration; and (2) give you a brief outline of the function of the Bureau of Veterinary Medicine within the Food and Drug Administration.

History of the Food and Drug Administration

The Federal Food, Drug and Cosmetic Act (1), passed by Congress, provides authority for the broad and varied regulation of food, drugs, cosmetics and medical devices. The Act prohibits the adulteration or misbranding of all such products. In the case of certain drugs, pesticides, food additives, and color additives, specific premarketing requirements are set forth in the Act.

Most Significant Dates and Amendments to the FD&C Act (2,3)

1. June 23, 1906, Teddy Roosevelt signed the first Federal Food and Drug Act which prohibited interstate shipment of adulterated or misbranded foods and drugs.
2. In 1938 a revised and amended act was passed. It was called the Food, Drug, and Cosmetic Act. This came into being following the "Elixin of Sulfanilamide" disaster in which 107 human lives were lost. It included a most important provision that prohibited traffic of new drugs unless such drugs had been adequately tested to show that they are safe for use under the conditions of use prescribed on their labels. Under this Act also came the authorization to carry out factory inspections and court injunction as an enforcement tool.
3. The 1945 amendment required batch certification of penicillin and later of other antibiotics. It also required proof of safety and efficacy of antibiotics.
4. In 1951 the Durham-Humphrey Amendment required that drugs *which cannot* be safely used without medical supervision be dispensed only upon prescription and bear the Rx legend.
5. In September of 1958 the Food Additive Amendments were enacted, prohibiting the use of *new* food additives until the promoter establishes safety and FDA issues regulations specifying conditions of use.

6. The Kefauver-Harris Drug Amendments of 1962, however, brought the most significant changes in the Act since its passage in 1938. The Amendments provided that new drugs should be evaluated for effectiveness, as well as safety, before they are cleared for the market. FDA was authorized to monitor clinical trials of investigational drugs. Before starting clinical trials, manufacturers must submit reports of preclinical tests, including animal tests, and other information adequate to justify the proposed clinical testing. The amendments also require manufacturers to report promptly to FDA adverse effects and other clinical experience relative to the safety and effectiveness of a drug or antibiotic already on the market.

   Other provisions of the amendments strengthened FDA's factory inspection authority and authorized the agency to issue Good Manufacturing Practices Regulations to assure adequate quality controls in drug plants. (Feed manufacturers are considered in the same category as drug manufacturers whenever they are producing feeds containing drugs of any kind.) The amendments stipulated that new drugs may not be cleared for marketing if the labeling is in any way *false or misleading.*
7. The 1962 Amendments were enacted in the wake of the thalidomide tragedy in Europe. Thousands of babies had been born malformed because their mothers took this seemingly mild sedative during pregnancy. The drug had not reached the market in this country, but the experience with the drug in Europe showed the need for tighter controls over investigational drugs.
8. In addition to requiring evidence of the effectiveness of new drugs marketed since 1962, the Amendments authorized a review of the efficacy of new drugs cleared for safety alone since 1938. The National Academy of Sciences—National Research Council began this review in mid-1966 under contract with FDA. About 3,000 human drugs and over 700 veterinary drugs were involved. Recommendations are now being implemented by FDA and the results of the reviews have been published in the FEDERAL REGISTER[4] over the past four years.
9. In 1965, Congress enacted the drug abuse control amendments to curb the illegal traffic in stimulant, depressant, and hallucinogenic drugs. The Bureau of Drug Abuse Control was established within FDA in 1966, but has since been transferred to the Department of Justice. It is now called the Drug Enforcement Agency (DEA).
10. Under the Federal Food, Drug and Cosmetic Act, the Bureau of Veterinary Medicine is charged by the Commissioner of Food and Drugs with ensuring the wholesomeness of our food, and with providing the maximum benefit to the producers of our nation's livestock and poultry and to our animal pet owners.
11. The Animal Drug Amendment of 1968 was a consolidation of Sections 505, 507 and 409 into one section of the FD&C Act regarding new animal drugs (Section 512).

The Food and Drug Administration is the agency which enforces the Act. It does this through regulations and policies; relying upon the Act for its authority. The regulations and policies currently in effect are found in the Code of Federal Regulations, Title 21. Title 21 is broken down into parts from 1 to 1299. The main parts dealing with drugs used in veterinary medicine are 121, 135, and 146.

The Code of Federal Regulations (5) are a codification of documents of general applicability and future effect. The Code is published *yearly* by the office of the Federal Register, National Archives and Records Service, General Services Administration. Since regulations and policies are constantly being promulgated and placed into effect, this is done on a *daily* basis through the FEDERAL REGISTER.

Following is a diagram of how the "will of the people" is carried out and communicated to interested parties in the case of animal drugs.

Functions of the Bureau of Veterinary Medicine and its Five (5) Divisions

I. Bureau of Veterinary Medicine—Overall Functions.

a. Develops and recommends the veterinary medical policy of the Food and Drug Administration with respect to the safety and efficacy of veterinary preparations and devices.

b. Evaluates proposed use of veterinary preparations for animal safety and efficacy.

c. Coordinates the veterinary medical aspects of the FDA inspection and investigational programs and provides veterinary medical opinion in the drug hearings and court cases.

d. Plans, directs, and evaluates FDA's surveillance and compliance programs relating to veterinary drugs and other veterinary medical matters.

II. Division of New Animal Drugs—Overall Functions.

Vetisulid®
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gives them a chance

Rapid absorption... rapid excretion

Baby calves have a chance when you use Vetisulid to fight *E. coli* organisms that attack these young animals.

In addition to the 90%-plus effectiveness of Vetisulid *in vitro* against *E. coli*, Vetisulid acts rapidly. And once it has acted, it is rapidly excreted. Effective and out. That's Vetisulid.

In calves, Vetisulid reaches maximum blood level concentrations in one to three hours following administration. Rapid excretion occurs within 18 hours after intravenous administration. Vetisulid is readily soluble at normal urine pH, so free and acetylated crystallization is unlikely.

Bile concentrations in laboratory animals are high; liver and kidney concentrations closely parallel that of the blood, demonstrating excellent tissue penetrating power of Vetisulid.

Vetisulid is available in three forms for calves: Injection (100 ml. and 250 ml. vials); Powder (5.4 g. packets and 54 g. bottles); Boluses (packages of 40 two-gram boluses).

Remember, the quicker you act against *E. coli* organisms, the better. Do it with rapid absorption, rapid excretion Vetisulid. Give them a chance.

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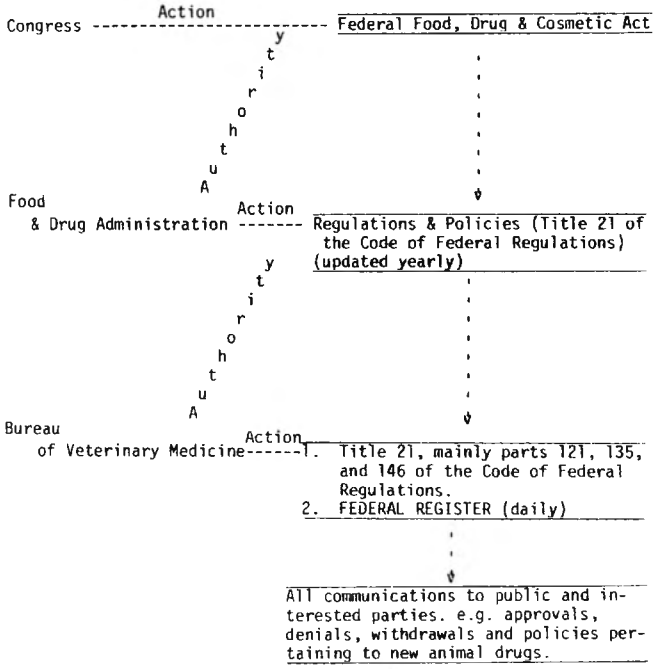


a. Evaluates for animal safety and efficacy *proposed* new therapeutic, reproductive and prophylactic veterinary preparations. Reviews the use of such preparations in veterinary medical practice to determine the effect on animals. (If the preparation is administered to food producing animals, the use of the product is evaluated as it relates to safety in humans.)

b. Evaluates *proposed* labels to assure that they clearly indicate the use and limitations of the product.

c. Evaluates manufacturing facilities and procedures as described in the application to assure that such controls are adequate.

d. Recommends action to be taken on *proposed* new therapeutic, reproductive and prophylactic veterinary preparations submitted for FDA review.

e. Determines data required to establish safety and efficacy and provides such information to investigators and manufacturers.

f. Recommends research projects, to be conducted by the Division of Veterinary Research, to gain further information on new drugs.

III. Division of Veterinary Medical Review—Overall Functions.

a. Conducts continuing surveillance and evaluation of veterinary preparations and devices for safety, efficacy and reliability and recommends action to correct significant hazards or potential dangers.

b. Evaluates drug experience reports, establishment inspection information, advertising, and other clinical or research data bearing on *marketed veterinary preparations.*

c. Evaluates and recommends action on medicated feed applications for those preparations that have been approved for marketing.

d. Recommends or supports regulatory and research activity.

e. Prepares veterinary medical reports for the Post Office Department in support of postal laws and regulations.

f. Develops and carries out programs designed to encourage compliance by industry on a voluntary basis.

g. Monitors and evaluates professional journal advertising, and promotional and related labeling to determine veracity of claims.

IV. Division of Veterinary Research—Overall Functions.

a. Conducts studies to evaluate the validity of data supporting the safety and efficacy of veterinary drugs intended for the prevention or treatment of animal diseases.

b. Conducts acute and chronic toxicity studies in large domestic animals following reports of animal feeds contamination, such as heavy metals, pesticides, etc.

c. Studies the therapeutic properties of specific products and substances, and the experimental reproduction of various disease conditions.

d. Cooperates with other parts of FDA in the development of actual evidence based on animal experimentation to support legal action under the Federal Food, Drug and Cosmetic Act.

e. Directs research to develop methods for studying the effects of therapeutic agents and various disease conditions.

f. Conducts experiments to develop information regarding food additive problems arising from the use of drugs in veterinary medicine.

g. Maintains colonies of laboratory animals for experimental tests and studies.

V. Division of Nutritional Sciences—Overall Functions.

a. Evaluates for animal safety and efficacy *proposed new nutritional drug substances* and other non-drug nutrient substances relating to feed efficiency and growth promotion. Reviews the use of such preparations in animal production and veterinary medical practice to determine the effect on animals. (If the preparation is administered to food producing animals, the use of the product is also evaluated as it relates to safety in humans.)

b. Evaluates *proposed* labels to assure that they clearly indicate the use and limitations of the

product.

c. Evaluates manufacturing facilities and procedures as described in the application to assure that such controls are adequate.

d. Recommends action to be taken on proposed new nutritional drug substances and other non-drug nutrient substances relating to feed efficiency and growth promotion submitted for FDA review.

e. Determines data required to establish safety and efficacy and provides such information to investigators and manufacturers.

f. Recommends research projects to gain further information on new nutritional drugs.

g. Provides Bureau-wide mathematical and statistical support to determine the adequacy of proposed scientific studies and to evaluate data collected in conjunction with various scientific studies.

VI. Division of Compliance—Overall Functions.

a. Advises the Bureau Director and other FDA officials on regulatory problems and administrative policies concerning FDA's regulatory responsibilities relating to new animal drugs.

b. Directs, designs and monitors studies to develop facts necessary for determination of medical policy and to support regulatory action on violative animal drugs.

c. Develops compliance and surveillance programs covering regulated industries in animal drug and related areas.

d. Develops or coordinates the development of regulations and other standards covering practices of the animal drug industry and fosters development of good manufacturing practices.

e. Provides support and guidance upon request to the District Offices in the handling of legal actions and provides headquarters case development, coordination, and contested case assistance.

f. Develops and coordinates studies to measure degree of compliance by regulated industries with statutes and regulations enforced by FDA.

VII. Assistant Director for Management.

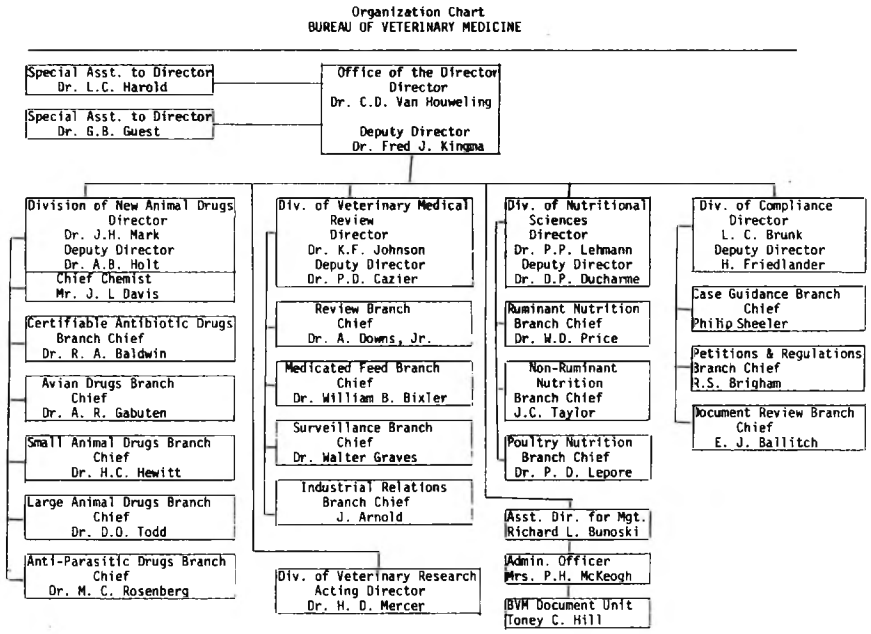
a. Serves as the principal advisor to the Director on all phases of management within the Bureau. Plans and administers a Bureau-wide system of planning, programming, and budgeting; operates a general services program for the Bureau.

b. Provides Bureau-wide systems analysis support for the maintenance and refinement of various information retrieval systems maintained as operational tools of the Bureau.

The BVM has a staff of approximately 180 people, with approximately 50 veterinarians, many of whom are specialists in their field of assignment; plus chemists, statisticians, pharmacologists, toxicologists, nutritionists, technicians, consumer safety officers, clerical, executive and administrative personnel.

Regional Offices

In addition to the organization outlined above, there are presently ten regional offices, which include the 16 former district offices of FDA, strategically located throughout the U.S. These district and regional offices are staffed with inspectors, chemists, and the usual executive and administrative personnel. They are charged with the field management program of FDA, including the inspection of medicated feeds mills and



establishments producing medical preparations, and investigation into the misuse of drugs. At the present time there are eight veterinarians assigned to the district offices who assist the directors with veterinary activities and affairs.

In summary, our total effort is for the single purpose of safeguarding the health of our animal population and the wholesomeness of foods of animal origin. We have available the combined talents of industry, the veterinary medical profession, and government. Each must do his share, and each must be alert to the responsibilities and the legitimate interests of the other. As servants of the people, we in FDA have a public trust which must be met at all costs. As practitioners, you can accept no lesser responsibility in serving the public.

Please note: The Food and Drug Administration has no control over veterinary biologics. These are regulated by the U.S. Department of Agriculture.

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