CVM Milestones

1906
Congress passed the Pure Food and Drugs Act, prohibit adulteration or misbranding of any food or drugs made for man or animals.

1927
The Food, Drug, and Insecticide Administration (known as the Food and Drug Administration (FDA) as of 1930) was formed. The agency employed its first veterinarian, Dr. Henry Moskey, to evaluate vitamins and minerals in light of their claimed nutritional and treatment uses.

1938
The Federal Food, Drug, and Cosmetic Act (FFDCA) was enacted. For the first time, manufacturers were required to provide evidence of product safety before distributing new drugs. Animal drugs were regulated under two sections of the Act—new drugs under Section 505, or antibiotics under Section 507.

1940
FDA was transferred from USDA to the Federal Security Agency, and the Office of Commissioner of Food and Drugs was established.

1951
The Durham-Humphrey Amendment of 1951 [§503; 21 U.S.C.§353], required that human (not animal) drugs which cannot be safely used without medical supervision must be dispensed only on the prescription of a licensed practitioner, and must bear the Rx legend. The veterinary prescription legend was subsequently affected through a rulemaking procedure.

1953
The Federal Security Agency became part of the Department of Health, Education and Welfare (DHEW), and the following year FDA was organized into five Bureaus, including a Bureau of Medicine. With the establishment of this Bureau, a Veterinary Medical Branch was created with Dr. John Collins as the first chief. The Branch's primary function was to determine the safety of animal drugs, both for animals and for consumers of food derived from medicated animals.

The great expansion in the development and use of animal drugs and medicated feeds during this period presaged the increasingly prominent role that veterinary medicine was to play in FDA and in animal and human health.

1958
The Food Additive Amendments of 1958 [P.L. 85-929, 21 U.S.C. 321(s)] expanded regulatory authority over animal food additives and drug residues in animal-derived foods. It added Section 409 to the Food, Drug, and Cosmetics Act, defining food additives and creating a third regulatory pathway for the approval of medicate feeds.

1959
The Veterinary Medical Branch was elevated to a Division, headed by Dr. Charles G. Durbin.

1962
Enactment of the Kefauver-Harris Drug Amendments of 1962 brought the most significant and sweeping changes in the Act since its passage 24 years earlier. These Amendments authorized FDA to monitor the clinical trials of investigational drugs and strengthened the agency's factory inspection authority. For the first time, manufacturers were required to test new drugs for effectiveness as well as safety before they could be sold to American patients. The Amendments also imposed a retroactive efficacy requirement for drugs previously approved for safety alone. Furthermore, the Amendments required manufacturers to report promptly to FDA any adverse effects and other clinical experiences relative to the safety and efficacy of drugs detected in clinical trials or post-marketing.

1965
In September, recognizing the importance of animal health to the welfare of the country, the Secretary of DHEW established the Bureau of Veterinary Medicine (BVM). Dr. M.R. Clarkson was the Bureau's first Director.

1967
Dr. C. D. Van Houweling succeeded Dr. Clarkson as Director of the Bureau of Veterinary Medicine. At this time the major units within the Bureau were the Division of Veterinary Medical Review, Division of Veterinary New Drugs, and the Division of Veterinary Research.

1968
The Animal Drug Amendments to the Food, Drug, and Cosmetic Act added Section 512, which created a unique regulatory pathway for animal drugs (distinct from those for human drugs).

1970
The Secretary of DHEW approved a reorganization of BVM on October 23, 1970, which established two new divisions— the Division of Compliance and the Division of Nutritional Sciences.

1976
Within six years, the burden of increased responsibility and an ever-growing workload necessitated another major reorganization of the Bureau. This reorganization which went into effect on May 26, 1976 , divided the activities of the Bureau into four principal areas: (1) Pre-clearance review of applications and petitions for drugs and feed additives; (2) Post-marketing surveillance and compliance activities; (3) Research; and (4) Administration.

Administratively, the structure of the Bureau was as follows: The preclearance functions were directed by the Associate and Deputy Associate Directors for Scientific Evaluation. Under them were the Division of Drugs for Non-Food Animals, Division of Drugs for Ruminant Species, Division of Drugs for Avian Species, and the Division of Drugs for Swine and Minor Species. The Associate and Deputy Associate Directors for Surveillance and Compliance directed the postmarketing activities. These were carried out by the Division of Compliance, Division of

Surveillance, and the Division of Animal Feeds. The research activities remained under the Division of Veterinary Medical Research, and the administrative functions were handled by the Associate Director for Administration.

1978
In August 1978, Dr. Lester M. Crawford succeeded Dr. Van Houweling as the Director of BVM and continued to serve in that role until 1985.

1984
BVM became the Center for Veterinary Medicine.

1984
The Veterinary Medicine Advisory Committee (VMAC) was chartered under standards in Public Law 92-463. VMAC advises the Commissioner in discharging his responsibilities as they relate to assuring safe and effective drugs, feeds and feed additives, and devices for animal use, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal diseases and increased animal production, and makes appropriate recommendations to the Commissioner of Food and Drugs regarding scientific issues and regulatory policies.

1986
Dr. Gerald B. Guest served as Acting Director of CVM from January 1986 to October 1986. He then served as Director of CVM from October 1986 to April 1993.

1988
Congress passed the Generic Animal Drug and Patent Term Restoration Act (GADPTRA). Under GADPTRA, the sponsor of a generic animal drug product is required to submit an Abbreviated New Animal Drug Application (ANADA) for review and approval before the product can be legally marketed. The generic product and its uses must be the same as those of an approved animal drug, with certain exceptions, and it must be demonstrated that the generic product is bioequivalent to the approved product.

1993
Dr. Richard Teske served as Acting Center Director of CVM from April 1993 to May 1994.

1994
Dr. Stephen F. Sundlof became the Director of CVM in 1994.

1994
Congress passed the Animal Medicinal Drug Use Clarification Act (AMDUCA), allowing veterinarians to prescribe extra label uses of certain approved animal drugs and approved human drugs for animals under certain conditions.

1996

Congress passed the Animal Drug Availability Act (ADAA) which provides for improvements in the process of approving and using animal drugs, and for other purposes. The ADAA was designed to increase the number of animal drugs on the market, without compromising FDA's mission to promote and protect the public health. It was the culmination of collaboration between FDA, a coalition of animal industry groups, and manufacturers of animal drugs. This passed with strong bipartisan support.

2003
Congress passed the Animal Drug User Fee Act (ADUFA), which authorizes FDA to collect fees for certain animal drug applications, as well as establishment license fees.

2004
Congress passed the Minor Use and Minor Species Animal Health Act (MUMS) to make more medications legally available to veterinarians and animal owners to treat minor animal species and also uncommon diseases in the major animal species. This legislation provides innovative ways to bring such products to market and is designed to help pharmaceutical companies overcome the financial roadblocks they face in providing limited-demand animal drugs. The animal drugs measure is expected to benefit people who own small or unusual pets such as guinea pigs or ornamental fish, and it will likely be a great help to zoo veterinarians. Before this legislation, pharmaceutical companies could rarely afford to bring to market drugs for rare pets and zoo animals, because the markets were too small to generate an adequate financial return.

Present
Today one of CVM's highest priorities is assuring the safety of the food supply. And, because of the Center's work and the cooperative efforts of all FDA employees, the American food supply is among the safest in the world. The responsibilities of CVM have a direct effect on the safety of the human food supply and on the safety to animals of veterinary products.

CVM works to educate consumers as well as regulated industry; evaluates data on proposed veterinary products carefully before permitting them to be marketed; identifies problematic products through post-market surveillance and adverse-event reporting programs; and conducts research to support Center activities. Whether developing and disseminating information, approving animal drug products for marketing, monitoring marketed animal drug products, or conducting research, CVM is committed to the important goal of protecting animal and human health throughout the United States.