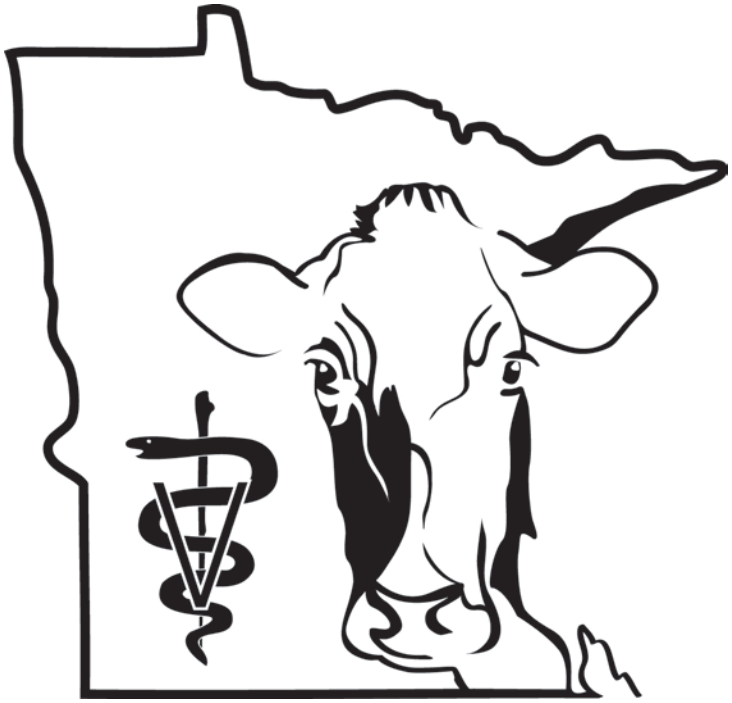
THIS ARTICLE IS SPONSORED BY THE
MINNESOTA DAIRY HEALTH CONFERENCE.

UNIVERSITY OF MINNESOTA

College of Veterinary Medicine

VETERINARY CONTINUING EDUCATION



ST. PAUL, MINNESOTA
UNITED STATES OF MINNESOTA

Overview of the Center for Veterinary Medicine, Animal Drug Legislation Update, and the Animal Drug Approval Process

Chellie L. Stull, DVM (mstull@cvm.fda.gov)
Veterinary Medical Officer, Office of New Animal Drug Evaluation
Center for Veterinary Medicine, Food and Drug Administration

OVERVIEW OF THE CENTER FOR VETERINARY MEDICINE

The Center for Veterinary Medicine (CVM) is one of the six centers in the Food and Drug Administration (FDA). CVM's role in the regulation of animal health products is to assure that animal drugs are safe and effective and that food from treated animals is safe to eat. CVM's responsibilities are handled by six offices, including the Office of New Animal Drug Evaluation, which reviews information submitted by sponsors who want to obtain approval to manufacture and market animal drugs, and the Office of Surveillance and Compliance, which conducts post-marketing monitoring of animal drugs, food additives, and veterinary devices.

The CVM web page (http://www.fda.gov/cvm) can be a valuable information resource for veterinarians. The web page contains access to guidance documents, animal drug regulations, the "Green Book" database of approved animal drugs, Freedom of Information (FOI) Summaries, and information about a variety of issues, including extralabel drug use, compounding, and bovine spongiform encephalopathy (BSE). The web page also includes adverse event reporting instructions. CVM encourages veterinarians to call 1-888-FDA-VETS to report adverse drug reactions, lack of effectiveness, and product defects.

ANIMAL DRUG LEGISLATION UPDATE

The Animal Drug User Fee Act (ADUFA) and the Minor Use and Minor Species (MUMS) Animal Health Act are two recent amendments to the Federal Food, Drug, and Cosmetic Act. The ADUFA legislation authorizes FDA to collect fees for certain animal drug applications, and for the establishments, products, and sponsors associated with these and previously approved animal drug applications. The fees are being used to support animal drug review activities, including hiring additional review staff, which will result in shorter, more predictable review times and substantial savings to the animal drug industry. The MUMS Animal Health Act will provide incentives for developing and marketing drugs for minor uses and minor species, as well as make some existing drugs legally available for MUMS uses. CVM is currently developing the implementing MUMS regulations. Veterinarians are encouraged to check CVM's web page for further developments and take the opportunity to comment when proposed regulations are published.

OVERVIEW OF THE ANIMAL DRUG APPROVAL PROCESS

An approved new animal drug application (NADA) means that the product is safe and effective for its intended use, and that the methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity. The approval process begins when a sponsor submits a letter to CVM requesting the establishment of an investigational new animal drug (INAD) file. The INAD file provides an exemption from certain requirements while the drug is in the investigational stage, allows shipment of the drug for use in studies, and may authorize the use of edible tissues from animals treated with the investigational drug in human food or rendering.

Once the INAD file is established, the sponsor plans and conducts the studies needed to support approval. The main requirements for approval are divided into seven "technical sections" – target animal safety; effectiveness; human food safety; chemistry, manufacturing, and controls; environmental; labeling; and "all other information". As the sponsor completes each section, they submit the data to CVM for review. Once the requirements have been met for a particular section, CVM issues a "technical section complete" letter. CVM also assembles the FOI Summary, which contains a summary of the safety and effectiveness studies used to support approval.

After all technical sections are complete, the sponsor submits copies of the technical section complete letters, the final facsimile product labeling, and a completed FDA Form 356V (New Animal Drug Application) for an administrative NADA review. Alternatively, the sponsor may submit all of the information needed for approval in a single application. CVM prepares an "approval package" for the Office or Center Director's signature. If all requirements have been met, the new animal drug application is approved, and the product may be legally marketed for its intended use. New animal drug approvals are announced by a FEDERAL REGISTER notice and added to the Code of Federal Regulations and the Green Book.