RECOMMENDED NON-TEXTBOOK REGULATORY READINGS
FOR PREPARATION OF THE
AMERICAN COLLEGE OF VETERINARY CLINICAL PHARMACOLOGY EXAM

Regulatory Related Topics

FDA Regulation of Animal Drugs LINK

FDA Resources for Veterinarians LINK

A. Guidance for Industry (GFI)

Although links are provided below, these often change and it is the responsibility of the examinee to search and find the documents.

The general guidance search tool LINK

The specific guidance by number LINK

The CVM GFI website LINK

Both CVM and CDER GFIs may be used for veterinary drug approval, particularly for bioanalytical method validation, dissolution studies, and manufacturing. These are referred to as “Cross-cutting” guidelines. LINK

As of December 2020, there are several GFIs that are currently under revision or development LINK

VICH GL24 - Management of Adverse Event Reports (AER's) LINK

Antimicrobial Resistance

GFI # 152- Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern LINK

GFI # 209 - The Judicious Use of Medically Important Antimicrobial Drugs in Food- Producing Animals LINK

Additional non-guidance document: FDA’s Strategy on Antimicrobial Resistance – Questions and Answers LINK

CVM’s Five-Year Plan for Supporting Antimicrobial Stewardship in Veterinary Settings LINK

Chemistry Manufacturing and Controls (CMC) Bioanalytical Method Validation

The most recent (May 2018) CDER and CVM bioanalytical method validation GFI is the one that CVM uses to evaluate methods. LINK

Generics

GFI #35 Bioequivalence Guidance LINK

GFI #224 (VICH GL52) Bioequivalence : Blood level Bioequivalence Study LINK

The statistical supplement to GFI #224 LINK

GFI #171 – Waivers of *In Vivo* Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles. LINK

Human Food Safety

GFI #3 General Principles for Evaluating the Safety of Compounds Used in Food Producing Animals LINK

GFI # 152 – Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern. LINK

GFI #159 VICH GL36 - Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI. LINK

GFI #207 VICH GL48 - Marker Residue Depletion Studies to Establish Product Withdrawal Periods LINK

GFI # 120 Veterinary Feed Directive Regulation Questions and Answers (Revised) LINK

Minor Use Minor Species (MUMS)

GFI # 61 – Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species LINK

GFI # 261- Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs LINK

New Animal Drug Applications

GFI #132: Administrative Applications and the Phased review Process LINK

Target Animal: Effectiveness

GFI #56: Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials LINK

Target Animal : Safety

GFI #56: Protocol Development Guideline for Clinical Effectiveness and Target Animal Safety Trials LINK

GFI #185 VICH GL43 - Target Animal Safety for Veterinary Pharmaceutical Products LINK

VICH

GFI #85 VICH GL 9: Good Clinical Practice LINK

GFI #89 VICH GL 6: Environmental Impact assessments (EIA's) for veterinary Medicinal Products - Phase I LINK

GFI #166 VICH GL 38: Environmental Impact Assessments (EIA's_ for Veterinary medicinal Products (VMP's) – Phase II LINK

GFI: E10 Choice of Control Groups and Related Issues in Clinical Trials LINK

GFI: E9 Statistical Principles for Clinical Trials LINK

B. Compliance Policy Guidelines Chapter 6- Veterinary Medicine

Links to the following CPGs can be found at LINK

- CPG Sec 615.115 Extra-Label Use of Medicated Feeds for Minor Species
- CPG Sec. 625.200 Availability of Bulk Chemicals for Animal Drug Use
- CPG Sec. 645.100 Biological Drugs for Animal Use
- CPG Sec. 650.100 Animal Drugs for Euthanasia
- CPG Sec. 655.100 Devices for Use in Animals

C. Additional Regulations

Good Laboratory Practice 21 CFR Part 58 LINK

21 CFR Part 510: New Animal Drugs LINK

21 CFR Part 511: New Animal Drugs for Investigational Use LINK

21 CFR Part 514: New Animal Drug Applications LINK

21 CFR Part 516: New Animal Drugs for Minor Use and Minor Species LINK

21 CFR Part 530 Extralabel Drug Use in Animals LINK

21 CFR Part 201 Drug Labeling LINK

The Animal Medicinal Drug Use Clarification Act (AMDUCA; CFR Title 21) LINK

Animal Drug Availability Act of 1996 LINK

Generic Animal Drug and Patent Term Restoration Act (GADPTRA) LINK

Extralabel Drug Use, including Compounding LINK

GFI #256 Compounding Animal Drugs from Bulk Drug Substances LINK

Drugs Prohibited for Use in Food animals LINK

D. Other Regulatory Sources of Information

Drug Labels

Drug labels provide information on dosage and administration, warnings, contra-indications, pharmacokinetic/pharmacodynamic data, safety and effectiveness data, and withdrawal times for food animal drugs.

Freedom of Information Summaries

Each approved veterinary drug has a Freedom of Information (FOI) summary that lists the safety and effectiveness submitted by the drug sponsor to FDA to support the approval of a New Animal Drug Application (NADA) or an Abbreviated New Animal Drug Application (ANADA). The FOI is a public document that provides details on the following studies for each drug approval: dosage characterization, safety, effectiveness studies, and human food safety and environmental (food animals). LINK

Individual FOIs can be found by drug at animal drugs @ FDA or by NADA number at. LINK.

Recent Animal Drug Approvals LINK