

# Ultra-Comprehensive Regulation of Animal Products in the United States

**FDA & USDA Jurisdiction**

**Animal Drugs, Devices, and Biologics**

**Legal Framework, Strategy, Risk, and Enforcement**

**Todd A. Harrison**

Partner | 202.344.4724 | [taharrison@venable.com](mailto:taharrison@venable.com)

**Justin A. Coen**

Partner | 202.344.4639 | [jcoen@venable.com](mailto:jcoen@venable.com)

**VENABLE**  
LLP

# Executive Context

- Animal health products are regulated differently from human products
- Jurisdiction is fragmented across FDA and USDA
- Intended use and claims drive regulatory outcome
- Missteps create significant enforcement and commercial risk

# Meet Cyber, our FDA dog!



# Primary Statutory Authorities

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.)
- Virus-Serum-Toxin Act (21 U.S.C. §§ 151–159)
- Animal Welfare Act (7 U.S.C. § 2131 et seq.)
- USDA and FDA implementing regulations

# Why Statutory Authority Matters

- Determines agency jurisdiction
- Dictates approval or licensing pathways
- Defines enforcement tools and remedies
- Impacts speed to market

# Regulatory Philosophy: Animals vs. Humans

- Greater tolerance for animal health risk
- Zero tolerance for human food safety risk
- Post-market enforcement emphasized
- Claims policing is primary oversight mechanism

# FDA Organizational Structure (Animal Products)

- Center for Veterinary Medicine (CVM)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Cross-reference to Center for Devices and Radiological Health (CDRH) principles
- Office of Regulatory Affairs (ORA) inspections

# FDA-Regulated Animal Product Categories

- Animal drugs (Rx and OTC)
- Animal medical devices
- Medicated feeds
- Animal food and additives
- Drug residues in edible tissues

# USDA Organizational Structure

- Animal and Plant Health Inspection Service (APHIS)
- Center for Veterinary Biologics (CVB)
- Food Safety and Inspection Service (FSIS)
- Agricultural Marketing Service (AMS)

# USDA-Regulated Animal Products

- Veterinary biologics (vaccines, antisera)
- Disease surveillance and eradication
- Meat, poultry, and egg inspection
- Import/export certification

# FDA-USDA Jurisdictional Fault Lines

- Drug-delivery devices
- Software-driven diagnostics
- Products impacting the human food supply
- Devices vs. diagnostics using biological reagents

# TriPaw's New Products: Which Agency has Jurisdiction?

1. Canine steroid anti-inflammatory chewable tablet
2. Killed virus rabies vaccine for dogs, cats, horses
3. Serology kit (ELISA/IFA reagents to detect antibodies/antigens) with incorporated software to detect heartworm and Lyme disease in dogs
4. Monoclonal antibody
  1. Canine dermatitis immunomodulator
  2. Cat osteoarthritis pain control

# Animal Medical Devices: Legal Definition

- Instrument, apparatus, implement, machine, or implant
- Intended for diagnosis or treatment of disease
- Or to affect structure or function
- Primary mode of action is physical or mechanical

# Categories of Animal Medical Devices

- Surgical instruments
- Implantable orthopedic and dental devices
- Diagnostic imaging and monitoring systems
- Life-support equipment
- Software controlling physical outputs

# Animal vs. Human Medical Devices (Expanded)

- No statutory device classes for animals
- No 510(k), PMA, or de novo
- No mandatory QSR (21 CFR Part 820)
- Enforcement replaces premarket review

# Practical Consequences of No Premarket Review

- Manufacturer bears full safety burden
- Documentation becomes critical defense
- FDA engagement often reactive
- Recall risk managed privately

# Manufacturing Controls – FDA Expectations

- Controlled processes
- Supplier qualification
- Process validation for critical steps
- Complaint handling systems

# Recommended Quality System Architecture

- Risk-based design controls
- Change management
- CAPA processes
- Internal audits
- Training documentation

# Labeling: Legal Requirements

- Truthful and not misleading
- Adequate directions for use
- Species-specific instructions
- Warnings and limits

# Advertising and Promotion Risk

- Websites and brochures = labeling
- Disease claims escalate scrutiny
- Implied chemical or immune claims
- Off-label promotion concerns

# TriPaw's Website

**TriPaw™ (fictional)**

Product Safety Info Testimonials Talk to a Vet

## TriPaw™ SteroidSoft Chews

**Indication & Use (label-based)**

SteroidSoft Chews are indicated for the **management of inflammation** in dogs **when prescribed by a veterinarian**. Use is limited to the **approved labeling**; your veterinarian will determine whether this product is appropriate for your dog.

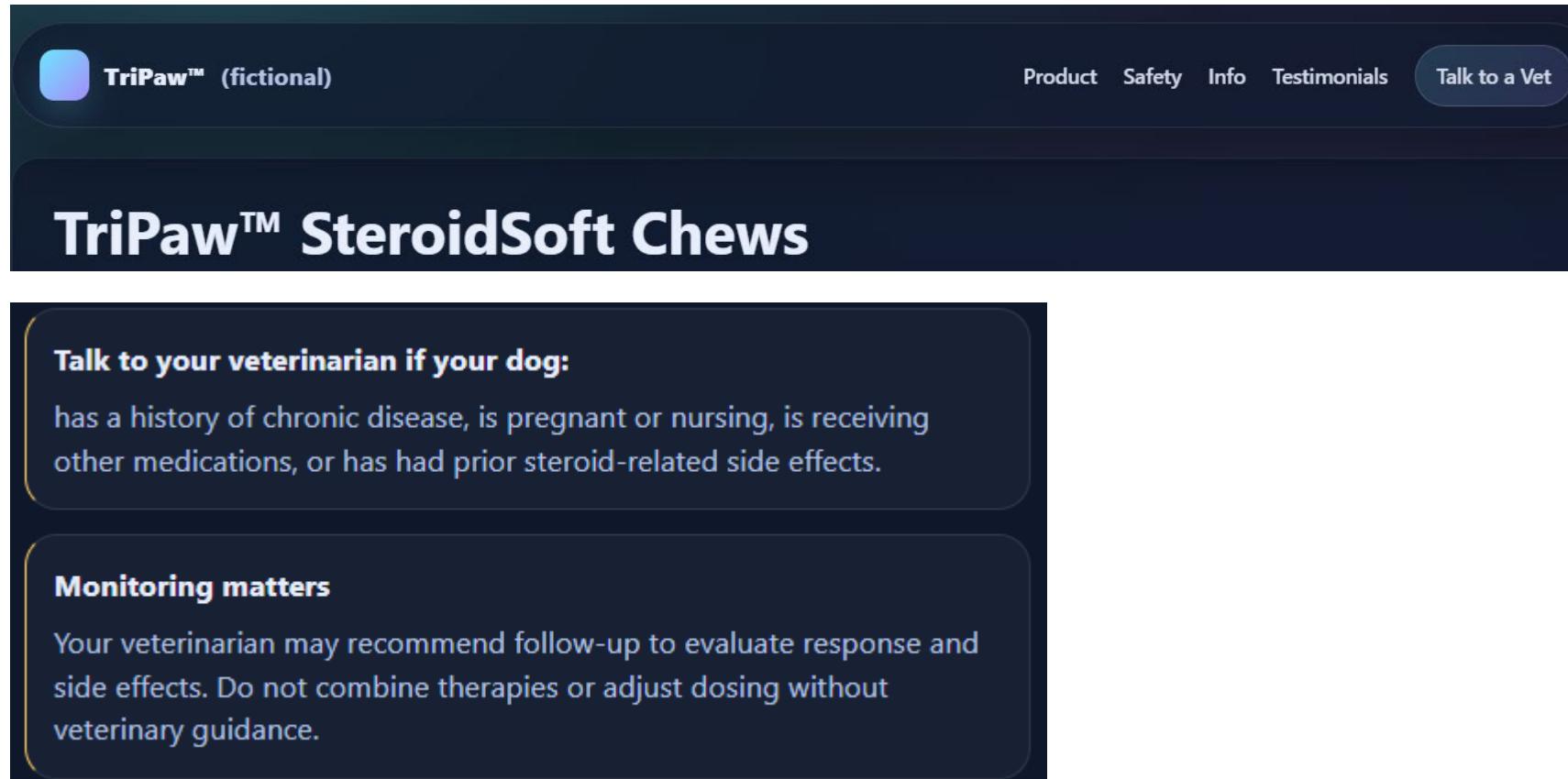
**What we do (plain-language, no MOA)**

SteroidSoft Chews are formulated to support **short-term** or **intermittent** anti-inflammatory therapy when clinically appropriate. We avoid technical pathway claims and focus on labeled use, monitoring, and safety.

**What's inside**

- **Active ingredient:** fictional corticosteroid API (see Prescribing Information)
- **Dosage form:** oral chewable tablet
- **Dispensing:** by veterinary prescription only
- **Use limitations:** not for human use; do not use outside labeled directions

# TriPaw's Website (cont.)



The screenshot shows a dark-themed website for "TriPaw™ (fictional)". The top navigation bar includes links for Product, Safety, Info, Testimonials, and a "Talk to a Vet" button. The main title "TriPaw™ SteroidSoft Chews" is displayed prominently. Below the title, two callout boxes provide information: one about consulting a veterinarian and another about monitoring for side effects.

**Talk to your veterinarian if your dog:**  
has a history of chronic disease, is pregnant or nursing, is receiving other medications, or has had prior steroid-related side effects.

**Monitoring matters**  
Your veterinarian may recommend follow-up to evaluate response and side effects. Do not combine therapies or adjust dosing without veterinary guidance.

# TriPaw's Website (cont.)

The image shows a screenshot of a website for 'TriPaw™ (fictional)'. The top navigation bar includes links for Product, Safety, Info, Testimonials, and a 'Talk to a Vet' button. The main content area features two large sections: 'Get Started' on the left and 'Order / Subscribe' on the right. The 'Get Started' section contains text about veterinary assessment and steroid therapy, along with buttons for 'Find a veterinarian', 'Download Prescribing Info (PDF)', and 'Clinic portal'. The 'Order / Subscribe' section contains buttons for 'Add to Cart' and 'Start Subscription'. A 'Vs.' label is positioned between the two sections.

TriPaw™ (fictional)

Product Safety Info Testimonials Talk to a Vet

## TriPaw™ SteroidSoft Chews

**Get Started**

The best first step is a veterinary assessment. Steroid therapy should be individualized based on your dog's health history and the labeled indications.

[Find a veterinarian](#) [Download Prescribing Info \(PDF\)](#)

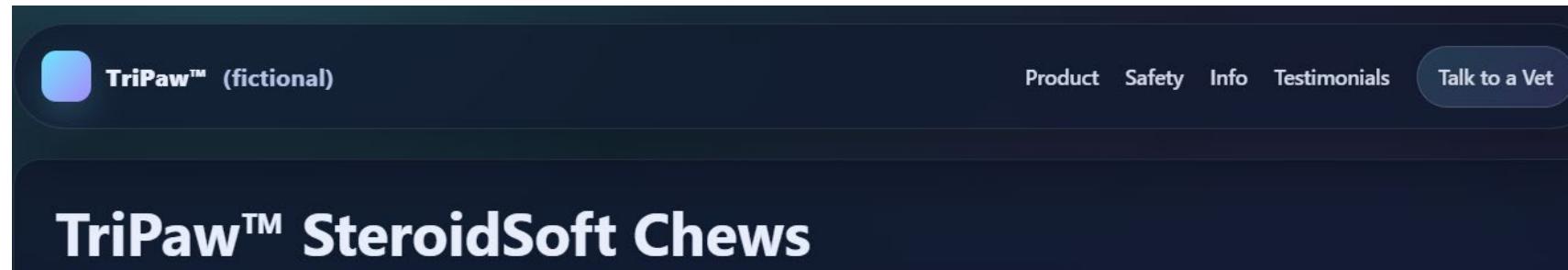
[Clinic portal](#)

**Order / Subscribe**

[Add to Cart](#) [Start Subscription](#)

Vs.

# TriPaw's Website (cont.)



The screenshot shows the TriPaw website with a dark header. On the left is a blue square icon with a white paw print, labeled "TriPaw™ (fictional)". On the right are navigation links: Product, Safety, Info, Testimonials, and a "Talk to a Vet" button. The main title "TriPaw™ SteroidSoft Chews" is displayed in large white text on a dark background.

### Testimonials (Moderated)

**Palatability / administration**  
"Easy to give and my dog takes it without a struggle."

**Support experience**  
"Our clinic got quick answers on storage and handling."

VS.

### Testimonials

**Owner review (implied disease outcome)**  
"After 3 days, my dog's [DISEASE OUTCOME REDACTED] disappeared."

**Off-label dosing testimonial**  
"We doubled the chew on flare days and it [OUTCOME REDACTED]."

# Post-Market Responsibilities

- Monitor complaints and failures
- Investigate adverse outcomes
- Implement corrections
- Maintain recall readiness

# FDA Enforcement Mechanisms

- Inspections
- Untitled and warning letters
- Seizure and injunction
- Criminal liability (rare but possible)

# Food-Producing Animal Overlay

- Human food safety is paramount
- Residue and tissue migration risk
- Milk, meat, egg implications
- Export market impacts

# Animal Drugs (Expanded)

- Chemical action or metabolism
- Premarket approval required
- GMP compliance mandatory
- Withdrawal periods enforced

# Veterinary Biologics (Expanded)

- Immune-based mechanism
- Licensed by USDA APHIS CVB
- Batch release oversight
- Field safety monitoring

# Combination Products (Expanded)

- Device + drug or biologic
- Primary Mode of Action analysis
- Multi-agency coordination
- Longest timelines and highest cost

# Regulatory Decision Tree (Detailed)

- Intended animal use?
- Chemical or metabolic action?
- Immune system involvement?
- Physical or mechanical action?
- Combination product?
- Food-producing animal?
- Claims consistency check

# Primary Compliance Risks

- Product misclassification
- Overly aggressive claims
- Inadequate quality controls
- Poor post-market documentation
- Food safety exposure

# Strategic Risk Mitigation

- Conservative labeling strategy
- Robust internal documentation
- Quality systems scaled to risk
- Early legal and regulatory review

# Executive Takeaways

- Regulatory burden depends on classification
- Animal devices offer speed but not immunity
- Food-animal use dramatically raises risk
- Claims discipline is the strongest compliance tool

© 2026 Venable LLP.

This document is published by the law firm Venable LLP. It is not intended to provide legal advice or opinion. Such advice may only be given when related to specific fact situations that Venable has accepted an engagement as counsel to address.

VENABLE LLP