



Ultra-Comprehensive Regulation of Animal Products in the United States

FDA & USDA Jurisdiction

Animal Drugs, Devices, and Biologics

Legal Framework, Strategy, Risk, and Enforcement



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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)

ProductSafetyInfoTestimonialsTalk 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.

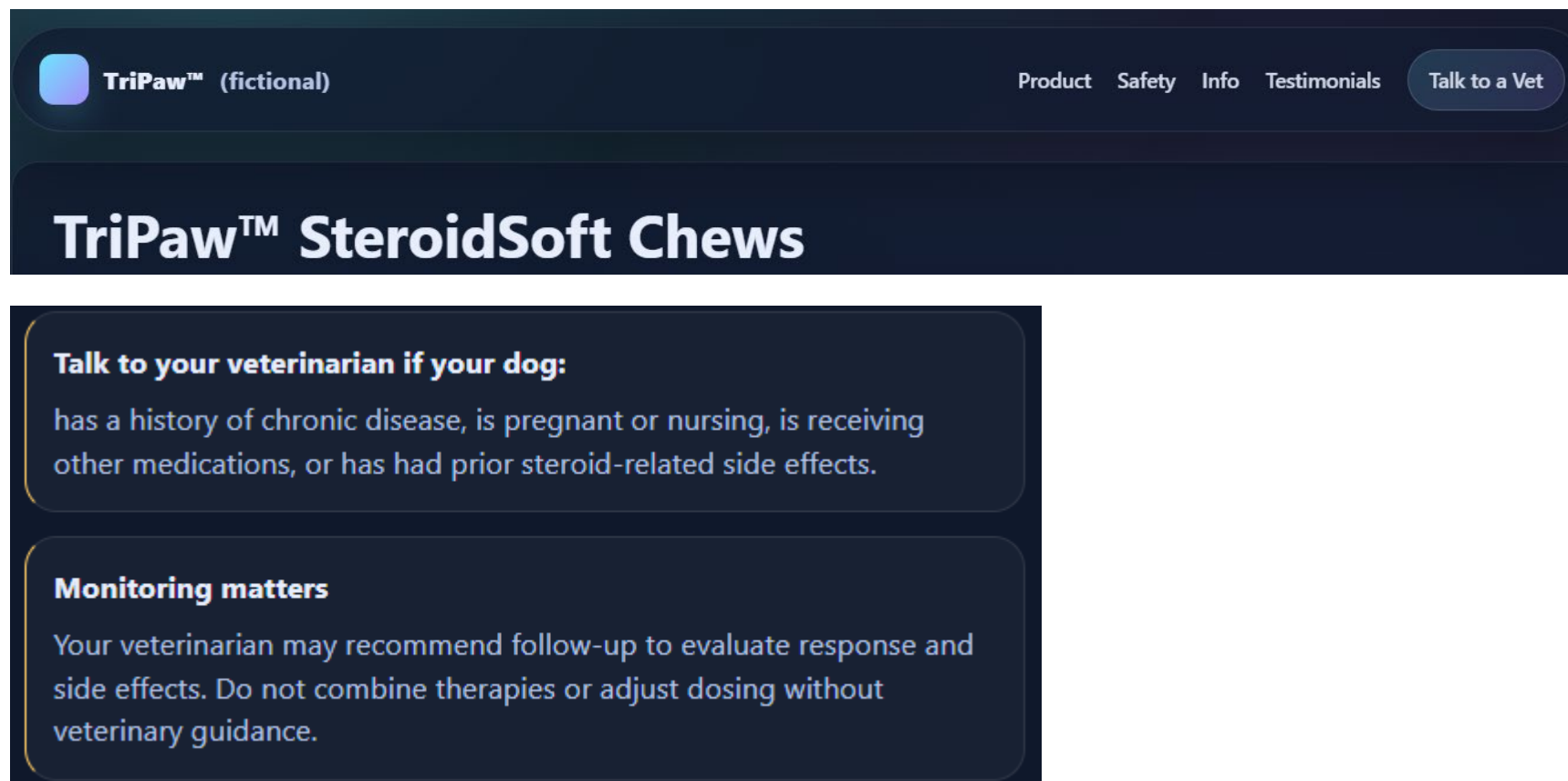
What we do (plain-language, no MOA)

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.

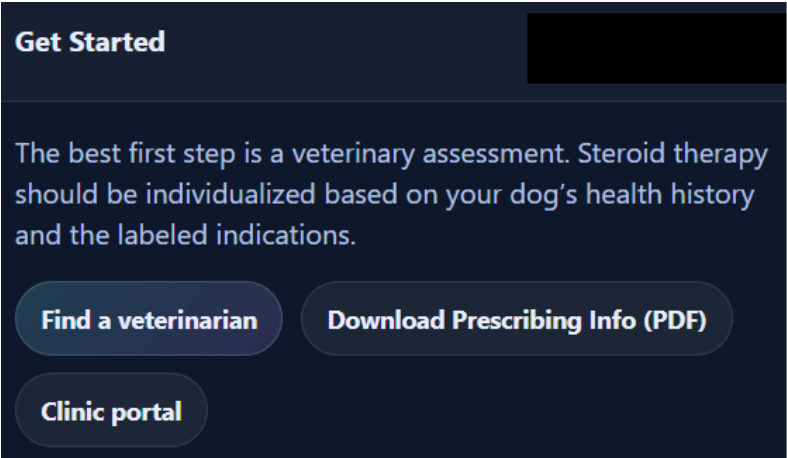
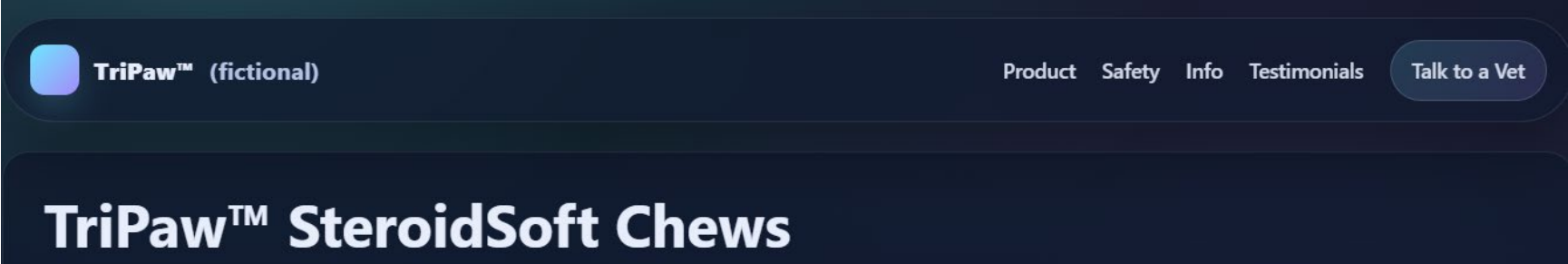
What's inside

- **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

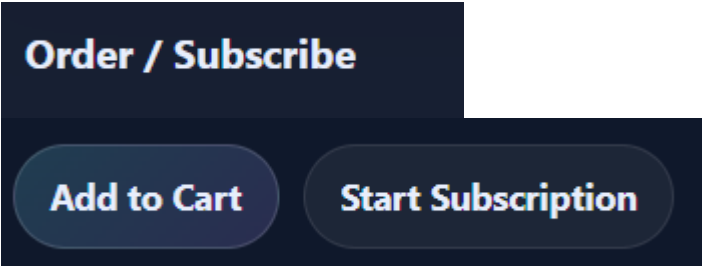
TriPaw's Website (cont.)




TriPaw's Website (cont.)



Vs.



TriPaw's Website (cont.)

 **TriPaw™** (fictional)

[Product](#) [Safety](#) [Info](#) [Testimonials](#) [Talk to a Vet](#)

TriPaw™ SteroidSoft Chews

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



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