

Center for Veterinary Medicine: Enforcement Priorities and Actions

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CENTER FOR VETERINARY MEDICINE
OFFICE OF SURVEILLANCE AND COMPLIANCE

OSC 2018 Priorities

- Publish revised Section 105 report with sales and species data
- Withdrawn Compounding CPG
- Published new compounding CPG
- Improve data mining capabilities of our 700K+ ADE data base
- Make ADE data base data available via Open FDA



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OSC: 2018 Priorities

- Address post-approval safety concerns and shortages
- Support drug approval process by addressing competing unapproved and/or compounded products



OSC 2018 Priorities

- Implement Animal Preventive Controls rule in the animal food industry
- Develop multiple guidance documents supporting implementation of Animal PC
- Address anomalies in application of requirements



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Compliance Actions 2016

- **Compliance Regulatory Cases FY2016**
- 6 Injunctions
- 29 Warning Letters
 - 16 Tissue Residue
 - 7 Post Market Drugs
 - 6 Post Market Feed
- 6 Untitled Letters



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Unapproved Animal Drugs

Hot topics

- 1) Antimicrobial Resistance - Public Health Risk
 - Tylosin tartrate/tear stain remover

- 2) Health Fraud - Public Health Risk
 - Firms marketing products to cure/treat major disease (cancer)

- 3) Emerging Therapies - Public Health Risk
 - Pet products marketed with cannabis/cannabidiol (CBD)
 - Firms marketing cell-based products



Unapproved Animal Drugs-Warning Letter examples

- VetroGenics
 - One of several companies marketing an unapproved injectable cell-based products.
- Nature's Treasure
 - marketing laminil and cancer products
- Canna-Pet
 - marketing unapproved cannabinoid products with claims to treat disease.
- Ocubright
 - marketing tear stain product containing tylosin tartrate.
 - Antimicrobial resistance concerns.



Thank you

