Balancing Access and Safety

Animal Drug Compounding

Challenge

FDA-Approved PRODUCTS

Pre-Market Review

- Demonstrated Safety and Efficacy
- Label Approval
- Properly manufactured

Post-Market Reporting

- Adverse Event Reports
- Reports on Manufacturing Quality

Unapproved Animal Drugs

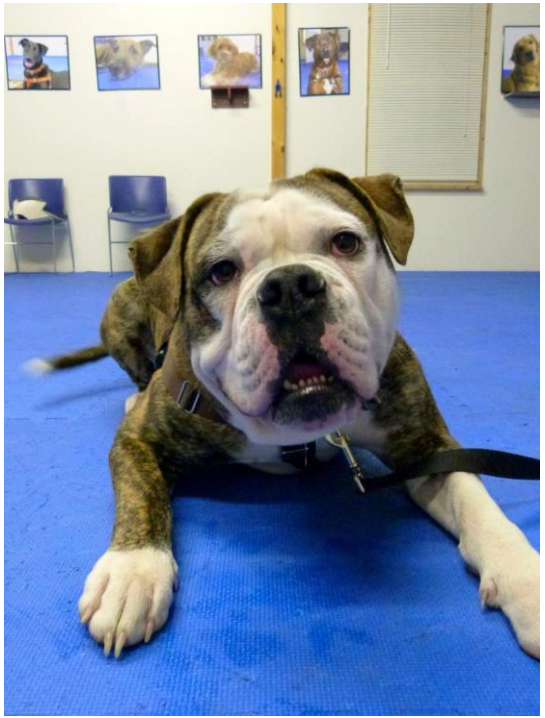
http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UnapprovedAnimalDrugs/default.htm#Unapproved_Animal_Drugs

- New animal drugs that don't have legal marketing status, as defined by section 201(v) of the FD&C Act [21 U.S.C. §321(v)].

- May not meet the agency's strict standards for safety and effectiveness and may also be improperly manufactured and labeled.

- To be legally marketed in the U.S., an animal drug must be the subject of the following:
  - an approved new animal drug application (NADA),
  - an approved generic application [abbreviated new animal drug application (ANADA)],
  - a conditional drug approval,
  - or index listing

Brando



Zeke

Moxie

Thank You!!

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