Animal Drug Compounding

Federal-State Intergovernmental Working Meeting on Drug Compounding
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CVM Priorities

- Implementing the Food Safety Modernization Act of 2010 (FSMA)
- Compounding / Unapproved Animal Drugs
- Antimicrobial Resistance (includes the National Antimicrobial Resistance Monitoring System [NARMS])

Why we are concerned about animal drug compounding

- Animals are harmed by substandard compounded drugs
  - Death of 21 polo ponies - Franck's Pharmacy
  - Death of race horses - Wickliffe Pharmacy
    - Sampling showed sub- and super-potent drugs
- Copies directly compete with approved products creating disincentives to obtaining approval

FDA's Regulatory Framework – Animal Drugs

- Animal drugs compounded from bulk are "new animal drugs" under the Federal Food, Drug, and Cosmetic Act (FD&C Act)
  - Medical Center Pharmacy *(536 F. 3d 383 (5th Cir. 2008)*
- Unless a statutory exemption applies, new animal drugs must meet all applicable statutory requirements

FDA's Regulatory Framework – Animal Drugs (cont'd)

- FDA's framework for regulating compounded animal drugs is different than its framework for regulating compounded human drugs
- Sections 503A and 503B of the FD&C Act do not apply to compounded animal drugs

FDA's Regulatory Framework – Animal Drugs (cont'd)

- Nothing in the FD&C Act exempts animal drugs that are compounded from bulk drug substances from having to meet all requirements for new animal drugs

Pathways to Legally Market Animal Drugs

Animal drugs must be:

- Approved
- Conditionally approved, or
- Listed on the index of legally marketed unapproved drugs

FDA's Regulatory Framework – Animal Drugs (cont'd)

- Limited exemption for compounding from approved animal or human drugs
  - This activity falls under a 1994 amendment to the FD&C Act - Animal Medicinal Drug Use Clarification Act or "AMDUCA"
  - Drugs compounded from approved animal or human drugs are exempt from the approval requirements and requirements for adequate directions for use

AMDUCA (cont'd)

- AMDUCA allows extralabel use of animal drugs, under certain conditions:
  - Within context of veterinarian-client-patient relationship
  - In compliance with extralabel use regulations at 21 CFR 530

Extralabel Use Regulations

- Extralabel use regulations - compounding
  - Only applies to extralabel use from compounding of approved new animal and approved human drugs
    - Must be by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine
  - "Nothing in this part shall be construed as permitting compounding from bulk drugs" *(21 CFR 530.13(a))*

Extralabel Use - Compounding

- No approved new animal or approved new human drug available to appropriately treat the condition diagnosed
- Certain restrictions on compounding for food animals
- Adequate procedures and processes are followed that ensure the safety and effectiveness of the compounded product
- All relevant State laws relating to the compounding of drugs for use in animals are followed

CVM Rethinking Policy

- Agency announced intent to revise guidance on Compounding of Drug for Animals
- Stakeholders:
  - Veterinarians
  - Pharmacies
  - Outsourcing facilities registered under 503B
  - Animal owners
  - Pharmaceutical companies

CVM's Concerns

- Compounding for food producing animals
- Drug quality
- Copies of approved drugs
- Compliance with State pharmacy laws
- Compounding for resale
- Office stock

Summary

- Unapproved drugs are a high priority for CVM
  - Including compounded drugs
- Legal framework for animal drug compounding is different from human compounding framework
- Safe animal drugs benefit everyone
- FDA and States should work together
  - Identify inventory of animal drug compounders
  - Joint response to problems
    - Red Cross Pharmacy, Oklahoma
    - Wickliffe Pharmacy, Kentucky

Thank You!

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