U.S. PHARMACOPEIA
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Veterinary Drugs Stakeholder Forum Meeting 1 - Summary

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Wrap Up Session
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Organization Overviews

- **FDA Center for Veterinary Medicine (CVM)**
  - Protects human and animal health; regulates animal drugs, animal feeds, veterinary devices; and protects human and animal health
- **Academy of Veterinary Pharmacology and Therapeutics (AAVPT)**
  - Promotes science of veterinary pharmacology and therapeutics through educational materials, meetings, and committees of experts
- **American Veterinary Medical Association (AVMA)**
  - Works to improve animal and human health and advance the veterinary medical profession
- **Animal Health Institute (AHI)**
  - Represents companies with an interest in veterinary health; members develop and produce medicines that help pets live longer, healthier lives
- **Generic Animal Drug Alliance (GADA)**
  - Represents, informs, and facilitates communications for the U.S. generic animal drug industry
- **The U.S. Pharmacopeial Convention (USP)**
  - Provides several routes for veterinary participation: Convention membership, Council of Experts, *PF* and public comment process, Workshops, and Stakeholder Forums

USP Veterinary Solubility Criteria Workshop

- **~80 attendees**
- **Workshop Outputs:**
  - Expert Panel will recommend concentrating on solubility, will handle other drug characteristics at a later date
  - Proposed General Chapter title: “Determination of Thermodynamic Solubility of Active Pharmaceutical Ingredient for Veterinary Species”
  - Dogs and Cattle: Solvent composition (pH, buffer, maybe surfactant for cattle); and Temperature
- **Next Steps**
  - Stimuli article with report from the workshop
  - Papers in some veterinary journals and trade magazines discussing workshop decisions and next steps
  - Stimuli article with rational for the new approaches
  - New USP General Chapter in *PF*
  - Broader promotion of all papers and activities
  - Next possible species: cats and pigs

USP General Chapters Impact on Industry

- **Industry Benefits of General Chapters**
  - Recognized standards for use (domestic and international)
  - Recognized by FDA
  - Agreement with FDA Guidance Documents
  - Pre-publication review and public comments
  - Applied uniformly to industry
- **Industry Concerns with General Chapters**
  - Uniqueness of animal drugs
  - Differences in data requirements between FDA divisions
  - Supply chain / vendor issues
  - Implementation costs
  - Requirements in the General Chapters sometimes not clear
  - Animal generics industry is not as well established as the human generics industry—routine channels for interact with USP are needed.
  - Small companies: limited resources and competition in small markets
  - Outsourced testing expenses to comply with USP requirements
  - Lack of awareness of upcoming changes in General Chapters—need to improve communication

Opportunities for Improvement – General Chapters

- **USP Areas for Refinement**
  - Clarify veterinary application of General Chapters
  - Involve veterinary drugs industry in roll-out and implementation of standards that impact them
  - Increase outreach and education with suppliers who may not be aware of revised standards
  - Reach out to animal generics industry to explain benefits of monograph submission and obtain updated tests

- **Industry and Regulatory: More Involvement with USP**
  - Provide public comments on Stimuli articles and *PF* proposals
  - Participate in public forums (i.e., Stakeholder Forums and Workshops)—comments are shared with USP Expert committee/Expert Panel
  - Submit draft monographs and revisions proposals

Unapproved Veterinary Drugs (UADs)

- **UAD Background & General Concerns**
  - Not approved by FDA and illegally marketed in the U.S.
  - Adulteration and misbranding
  - May fill an unmet need (medically necessary)
  - Promoted as equivalent or superior to an FDA approved drug product
  - Can mimic approved drugs
  - No assurance of quality, safety, purity, potency of the product
  - No assurance of effectiveness and safety
  - Suitability of manufacturing facility not assured
  - Products are promoted as equivalent or superior to an FDA approved drug
  - Products requiring prescription available without veterinary intervention

Unapproved Veterinary Drugs (UADs)

- **Recommendations for UADs**
  - Need for a legal home
  - Label claims in line with current and accepted industry practice
  - FDA published Federal Register Notice seeking comments on strategies for finding legal “homes” for unapproved products.
  - Indexed drugs
  - Health Canada model
  - Types of unapproved drugs:
    - Unapproved drugs for unmet need
    - Misbranded unapproved drugs (disguised)
  - Unapproved drugs with structure/function claim vs. disease claim
  - CFR Monograph System using the Expert Committee System

Compounding Perspectives

- **Regulatory Perspective**
  - Compounding of animal drugs by pharmacies raises same concerns as other unapproved animal drugs (i.e., safety, efficacy, manufacturing, labeling)
  - Compounded animal drugs can violate FDCA
- **AVMA Perspective**
  - Veterinarian-driven, not pharmacist-driven
  - Based on a Veterinarian-Client-Patient Relationship (VCPR)
  - Compliance with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Compliance Policy Guide
- **Industry Perspective**
  - Compounded preparations should not mimic FDA-approved drug products
  - Manufacturing under the guise of compounding raises concerns
  - Wholesale distribution of compounded preparations
  - Compounded drugs should be held to equivalent standards
- **USP Perspective**
  - Compounding need is great across veterinary medical practice
  - Interdisciplinary training/resources is lacking or absent

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Thank You