Regulatory Challenges to Approval of Non-Surgical Animal Sterilants

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Regulatory Challenges to Approval

- Points to Consider
  - Products for use in animals require pre-market approval
  - Federal jurisdiction is determined by mode of action in the USA
  - Labeling is a key factor
  - Cornerstones of approval are safety, efficacy, and quality

Regulatory Challenges to Approval

- Products for use in animals require pre-market approval
  - Premarket review of animal health products dates to 1913 with the Virus, Serum, and Toxin Act
  - Sweeping legislation in 1938 (Food, Drug, and Cosmetic Act) and in 1962 (Amendments) set standards for scientific review of data to prove products safe and effective prior to sale
  - Animal drugs are subject to many of the same requirements as human pharmaceuticals

Regulatory Challenges to Approval

- Federal jurisdiction is determined by mode of action in the USA
  - USDA
    - Virus, Serum, Toxin Act
    - Animal Plant Health Inspection Service (“APHIS”)
    - Center for Biologics (“CVB”)
    - Conventional and recombinant production
    - Quality, Safety, Efficacy
    - Associated with a disease

Regulatory Challenges to Approval

- Federal jurisdiction is determined by mode of action in the USA (cont.)
  - FDA
    - Food, Drug, and Cosmetic Act
    - Center for Veterinary Medicine (“CVM”)
    - All New Animal Drugs as defined by the Act
    - Safety, Efficacy, Quality (cGMP)

Regulatory Challenges to Approval

- Outside of the USA
  - EU
    - “Veterinary Medicinal Product”
    - EMEA and CVMP
  - Australia
    - Stronger focus on Food Animal Products
  - Japan
    - Accepting of EU dossier
  - Latin America
    - Emerging regulatory environment

Regulatory Challenges to Approval

- Labeling is a key factor
  - Must define what the product will do
    - Claim of activity
  - Dose
    - Sufficient to achieve desired effect
    - Adequate margin of safety
  - Route of administration
    - Oral
    - Injectable
  - Safety of the administrator
  - Likely to be followed
    - Will the directions for use be followed in practice

Regulatory Challenges to Approval

- Cornerstones of approval are safety, efficacy, and quality
  - Safety
    - To the Target Animal
      - GLP Safety Study
      - 1,3,5 X design standard
      - Sacrifice study with histopathology
    - To the User
      - Production safety
      - End User and risk assessment
    - To the Environment
      - Either categorical exclusion
      - Environmental Assessment

Regulatory Challenges to Approval

- Cornerstones of approval are safety, efficacy, and quality (cont.)
  - Efficacy
    - Mandate to prove effectiveness for the claim made
    - Laboratory
    - Field Study(ies)
    - GCP standard
    - “Substantial Evidence of Efficacy”

Regulatory Challenges to Approval

- Cornerstones of approval are safety, efficacy, and quality (cont.)
  - Quality
    - Good Manufacturing Practice (“GMP”) is a requirement in the EU for all VMPs - Drugs and Biologics
    - GMP is required for New Animal Drugs
    - USDA has separate Quality Guidelines

Regulatory Challenges to Approval

- Summary
  - Scientific and Legal Standard to be Met
  - Pre-Market Review and Approval Required
  - Agencies with Various Jurisdictions
    - USDA
    - FDA
    - Fish and Wildlife Service (Feral Dogs and Cats)
    - Environmental Protection Agency
  - Regulatory Discretion
    - Emergency Use
    - MUMS

Regulatory Challenges to Approval

- Summary (cont.)
  - Definitional Questions
    - Status of Feral Cats and Dogs
    - Pregnancy not a disease, a condition
    - Food, Drug, and Cosmetic Act
    - Federal Insecticide, Fungicide, and Rodenticide Act
    - Memoranda of Understandings
      - USDA & FDA
      - FDA & EPA