Implications for Registration and Approval of Innovative Technologies

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Four Critical Standards for Evaluating Veterinary Drugs

• Safety
  – Human Food
  – Target Animal
  – Environmental
  – User Safety

• Effectiveness

• Quality Manufactured Product

• Properly Labeled Product
Core Mission

Our public health mission succeeds when we put in the hands of the user:

- an approved,
- safe and effective,
- quality manufactured,
- properly labeled

new animal drug to meet therapeutic and production needs of animals
Core Mission

Meeting the Therapeutic and Production Needs of Animals

- For companion animals:
  - increase the level of high quality medical care for companion animals
  - increase in quality of life through medical interventions for companion animals
  - impact of animal health on the Human-Animal Bond
Core Mission
Meeting the Therapeutic and Production Needs of Animals

• For food-producing animals:
  – improve animal welfare and health
  – improve animal health and production toward increasing the availability of an affordable, abundant and wholesome food supply to meet the needs of a growing human population
The Challenge – Feeding People

• Ensuring an Affordable and Adequate Food Supply to Prevent Hunger is a Public Health Mission

• This is both a domestic and an international challenge
Status of Veterinary Drug Development

• Concern over antimicrobial resistance
  – Limited development of new antimicrobials
  – Increase in novel alternatives to antimicrobials

• Concern over antiparasitic drug resistance
Status of Veterinary Drug Development

• Change in Pharmaceutical Company Portfolios
  – Increase in non-traditional entities
    • Biotechnology, nanotechnology, immunological drugs
  – For food animals more production enhancing indications and indications for environmental sustainability
  – For non-food producing animals more non-traditional indications
    • Chronic disease treatments, cancer therapy, life quality enhancements
Future Animal Health Environment

• New products will more likely come from acquisitions than discovery. CVM will work with more venture capital companies.

• Further consolidation/tighter financial accountability is highly likely.

• The future animal health industry will consist of a few large animal health companies, numerous small venture firms and coalitions of individual public and private organizations.

• More sponsors will be global firms and many will be from outside of the U.S.
Our Challenge

• To engage in the development and evaluation of new animal drugs, especially new innovative technologies, to meet the demand for increased safe, affordable and abundant food production
Future Animal Health Environment

- The products of the future may not fit the current paradigm.

- Products of the future will deploy new technologies for which we are just beginning to consider the critical safety and effectiveness standards for evaluation.
New Model for Success

• As the industry changes so must we

• Challenge to efficiently adapt our policies and review approaches to meet new technologies

• Employ new scientific approaches to proving safety and effectiveness

• Provide predictability in regulatory decisions

• Avoid the lure of increasing scientific rigor beyond that which is necessary

• Address ambiguity
CVM’s Innovation Initiative Is

• An attempt to position CVM where it needs to be in the future
• An attempt to work smarter at engaging new technology
• An attempt to move forward when the status quo is not meeting our needs
• Based on trust that people have good intentions and talent to make this happen
Innovation Initiative

• CVM created and is implementing processes to enable global availability of safe, effective, quality manufactured, properly labeled new animal drugs.

• Working with international partners, CVM is addressing challenges in a global animal health environment to meet our public health mission.

• CVM re-designed its drug evaluation process for new technologies to enable new technologies to reach the market to impact these public health challenges on a global basis.

• Overcome obstacles to ensure access to veterinary drugs and their proper use in food-producing animals.
What’s the Win?

• Develop new approaches and engagement to enable a new technology to be met with the same predictability and seamless regulatory process that a traditional animal drug meets at CVM

• Remove barriers that prevent a pharmaceutical company from filling their pipeline with new innovative products
Current Review Process

Discovery/Proof of Concept

Development

Regulatory Submission

Launch Marketing

Sponsor Decision To Develop Product

Presubmission Conference

NADA Approval

Knowledge Acquisition

Formulation of Risk Questions

Review Process

Conditional Approval (Phase IV)

Data Collection

Continued Evaluation of Safety and Effectiveness

Extensive Scientific Interaction between Sponsor and CVM

Agree on Specific Risk Questions and Plan for Answers

Predictable/Seamless Reviews

NADA Approval

Presubmission Conference

Sponsor Decision To Develop Product

TECH TEAM

Risk Analysts

TECH TEAM

Risk Analysts
Global Animal Health - Current Activities

- OIE Collaborating Center in International Cooperation to Strengthen Veterinary Drug Regulatory Infrastructure
- Codex Alimentarius Commission
- VICH
- Inter-governmental Coordination
- Outreach
  - World Organization for Animal Health (OIE)
  - Food and Agriculture Organization (FAO)
  - National and Regional Capacity Building Efforts
Global Animal Health - The Future

• What challenges in a global animal health environment have to be addressed to meet our public health mission?

• Are we adequately addressing the challenges of the future?

• What steps need to be taken to enable new technologies to reach the market to impact these public health challenges?

• What obstacles need to be overcome to ensure access to veterinary drugs and their proper use in food-producing animals?
Global Animal Health - The Future

• What regulatory structures/approaches need to be developed and enhanced to enable the expansion of food production?

• What has to be initiated and what needs to be changed to meet the needs of the future?

• What is/are the necessary venues for us to intentionally and aggressively meet these new challenges internationally?
Questions???