Center for Veterinary Medicine (CVM)

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Rachel Cumberbach, Director, International and Regulatory Affairs, Animal Health Institute
Brian D. Eyink, Counsel, Hogan Lovells US LLP
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Moderated by Sean Lee, Of Counsel, Shook, Hardy & Bacon LLP
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FDLI Annual Conference
May 2, 2019

Steven M. Solomon, D.V.M., M.P.H.
Director, CVM
Guiding Principles

• Protecting public health
• Regulating based on the best evidence and science
• Leveraging and collaborating with domestic and international health and regulatory partners
• Operating transparently
• Encouraging continuous quality improvement
• Engaging stakeholders

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CVM Vision and Mission

Vision
“Excellence, Innovation, Leadership”

Mission
“Protecting Human and Animal Health”
CVM as a Microcosm of FDA

- **Center for Biologics Evaluation and Research**
  CVM: Genetically Altered Animals and Cell-based Products

- **Center for Drug Evaluation and Research**
  CVM: Animal Drugs

- **Center for Devices and Radiological Health**
  CVM: Animal Devices (post-market only)

- **Center for Food Safety and Applied Nutrition**
  CVM: Food Safety and Food Additive

- **Center for Tobacco Products**
  CVM: Second-hand Smoke and Pet Health

- **Office of Regulatory Affairs**
  CVM: Partner in Regulatory Oversight

- **International Activities**
  CVM: Strengthen animal drug and food regulatory infrastructures in other countries and harmonize product standards
CVM’s Core Values

We Serve
We are a mission-driven, public health, regulatory Center. Safeguarding human and animal health is what we do. We serve our stakeholders and hold their trust in the highest regard. Collaboration and communication, across all disciplines, are the tools we use to provide the greatest level of service.

We Lead
Everyone makes a difference. Each of us contributes our ideas and skills to influence CVM’s direction regardless of their title or position. New leaders emerge every day.

We Learn
We continuously learn, stretch, and grow. We provide opportunities for people to develop their skills and cultivate diverse talents. Our individual expertise is the expertise of the organization.

We Honor
CVM appreciates the exceptional people who work here. We encourage and support everyone to dream, inspire each other, and live our best lives, personally and professionally. We celebrate all life experiences, cultures, and backgrounds for the wealth of perspectives they bring to CVM.

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CVM Budget, FY 2015 – FY 2020

FY 2020 Budget Authority Increase Request:
$12,280,000

- New Medical Data Enterprise: $4,000,000
- Advancing FSMA: $3,000,000
- Outbreak Response: $280,000*
- Innovation & Emerging Tech: $5,000,000

* Companion to $5,600,000 ORA request

FY 2015 - FY 2019 Budget Authority and Increase Requests:

- **FY 2015**
  - BA: $87,846,000
  - UF: $25,809,000
  - Total Program Resources: $119,314,000
  - BA = 72%
  - UF = 22%

- **FY 2016**
  - BA: $93,505,000
  - UF: $28,503,000
  - Total Program Resources: $122,508,000
  - BA = 75%
  - UF = 25%

- **FY 2017**
  - BA: $94,005,000
  - UF: $30,671,000
  - Total Program Resources: $128,876,000
  - BA = 76%
  - UF = 24%

- **FY 2018**
  - BA: $98,205,000
  - UF: $24,270,000
  - Total Program Resources: $132,175,000
  - BA = 82%
  - UF = 18%

- **FY 2019**
  - BA: $108,919,000
  - UF: $43,617,000
  - Total Program Resources: $157,036,000
  - BA = 72%
  - UF = 28%
FDA’s Animal Health “Hoof” Print

CVM protects and promotes the health of humans and animals by ensuring the safety of the American food supply, the safety of animal food and devices, and the safety and effectiveness of animal drugs.

**Food-producing Animals**
- ~9.1 billion chickens
- ~68 million pigs
- ~89 million cows
- ~5 million sheep

**Companion Animals (Pets)**
- ~94 million cats
- ~89 million dogs
- ~7 million horses

**U.S. Animal Health & Related Industries**
- ~$11.4B in animal health products
- ~$560B total economic impact: food production, animal production, veterinary services, pet care, and animal health
- ~1.4M jobs in animal health and related industries

Agenda

- Modernizing Human and Animal Food Safety
- Recall and Response Activities
- Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
- Antimicrobial Resistance
- Pre-market Animal Drug Review
- Emerging Technologies and Innovation
- Innovation and Flexibility
- Regulatory Reform
- Unapproved Animal Drugs Compounded from Bulk Drug Substances
- Post-market Drug Safety, Effectiveness, and Quality
- Lifecycle Approach
- International Activities
- Outreach to Consumers and Stakeholders
Modernizing Human and Animal Food Safety

- FSMA: Training, education, and outreach
- Modernized inspections for
  - Current good manufacturing practices (CGMPs)
  - Preventive controls for animal food
- Human food by-products
- New Era of Smarter Food Safety
Recall and Response Activities

- Pet food safety
- Recalls and outbreak response activities
- Natural disaster response activities

Hurricanes Harvey, Irma, Maria, Florence, Michael; California wildfires; Midwest flooding
Veterinary Laboratory Investigation and Response Network (Vet-LIRN)

To promote human and animal health by collaborating with veterinary diagnostic laboratories to provide scientific information, build lab capacity, and investigate issues with CVM-regulated products

- Network includes 43 laboratories
- Develops mechanisms for conducting investigations
  - Confidentiality agreements
  - Grants/contracts
  - Collaborate with other networks
- Activities
  - Proficiency and product testing
  - Fanconi testing
  - Necropsy examinations
  - Emergency response exercises
  - Investigate consumer complaint cases

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Antimicrobial Resistance

• Supporting Antimicrobial Stewardship in Veterinary Settings (5-Year Plan)
  www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM620420.pdf

• National Antimicrobial Resistance Monitoring System (NARMS)
  www.fda.gov/animalveterinary/safetyhealth/antimicrobialresistance/nationalantimicrobialResistanceMonitoringSystem/default.htm
Pre-market Animal Drug Review

- Animal Drug User Fee Act (ADUFA)
- Animal Generic Drug User Fee Act (AGDUFA)
- Minor Use/Minor Species (MUMS)
Emerging Technologies & Innovation

Animal Biotechnology
• Intentional Genomic Alteration (IGA) technology continues to advance (e.g., CRISPR, CAS9, TALENs)
• Stem cells and cell-based therapeutics

Pre-Market Animal Food
• Food additives
• GRAS (generally recognized as safe)
• New animal food ingredients
• “GE” or “BE” plants

Plant and Animal Biotechnology Innovation Action Plan
• Flexible regulatory approach based on risk
• Ensure safety, quality, and consumer confidence
• Includes Veterinary Innovation Program (VIP)

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Innovation and Flexibility

• Public webinar about genome editing in animals
• Public meeting on alternative approaches in clinical investigations
• Research programs to address certain challenges of drug development
• Initiatives to develop predictable pathways for novel products
• We heard you
• We’re considering opportunities for animal drug development and public health
• We’re developing appropriate responses
Unapproved Animal Drugs
Compounded from Bulk Drug Substances

• CVM is concerned about the number of animal drug products being sold to animal owners and veterinarians that are compounded from bulk drug substances

• Compounded copies of approved animal drugs have not demonstrated safety or efficacy

• Compounded copies undermine the legal drug approval process
Post-market Drug Safety, Effectiveness, and Quality

Number of Adverse Drug Event Reports

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Lifecycle Approach

• Looking more holistically at pre- and post-market drug review
• Similar to the approach taken by FDA’s other medical product centers
• Allows CVM to leverage great expertise and anticipate and address post-market concerns for target animal safety and human user safety
International Activities

- **VICH** (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) – Trilateral (EU-Japan-USA)
- **CODEX Alimentarius** (UN Food and Agriculture Organization / World Health Organization)
  - Codex Committee on Residues of Veterinary Drugs in Foods
  - Task Force on Antimicrobial Resistance
- **US-EU MRA** (Mutual Recognition Agreement) – Veterinary Drugs (EU)
- **ICCF** (International Cooperation for the Convergence of Technical Requirements for the Assessment of Feed Ingredients) – Trilateral (EU-Canada-USA + industry)
- **OIE** (World Organisation for Animal Health)
- **VDD** (Veterinary Drugs Directorate – Canada)
- **EMA** (European Medicines Agency)
- **Systems Recognition**

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Outreach to Consumers & Stakeholders

• Proactively engaging with diverse and disparate stakeholders on a wide variety of public health priorities

Logos are the intellectual property of their respective association owners.
Keep Up To Date

http://www.fda.gov/AnimalVeterinary

Reference the CVM Website for the most current information

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FDA – Center for Veterinary Medicine
Protecting both Human and Animal Health
Thank you!
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