

# FSMA Implementation Update 2018

**Summer 2019 Pet Food Alliance Meeting  
June 27, 2019**

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# Outline

- Major FDA/CVM Personnel Changes
- FSMA Updates
  - 2018 data
  - 2019 data (to date)
- Key/Emerging Hazards and Research Gaps
- Need for Collaborative Approach



# Major FDA/CVM Personnel Changes

# CVM Organization Chart

## Office of the Center Director

### *Director*

Steven M. Solomon, D.V.M., M.P.H.

### *Deputy Director*

Tracey Forfa, J.D.

### *Deputy Director, Science Policy*

William Flynn, D.V.M., M.S.

## Office of Management

### *Director*

Roxanne Schweitzer

### *Deputy Director*

Lynnette Riggio

## Office of New Animal Drug Evaluation

### *Director*

Matt Lucia, D.V.M.

### *Deputy Director*

Elizabeth A. Luddy, D.V.M.

## Office of Surveillance and Compliance

### *Director*

Tim Schell, Ph.D.

### *Deputy Director*

Martine Hartogensis, D.V.M.

## Office of Research

### *Director*

Vacant

### *Deputy Director*

Mary Allen, Ph.D.

## Office of Minor Use Minor Species Animal Drug Development

### *Director*

Margaret Oeller, D.V.M.



# FSMA Updates



# FSMA Implementation Update

## *CGMP Inspections (FY18): General Findings*

- Approximately 400 CGMP inspections conducted in FY18
- 60% by FDA, 40% by State agencies
- Approximately 6% of inspections resulted in observations documented on an FDA Form 483
- 1 FDA Warning Letter issued for CGMP violations

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## *CGMP Inspections (FY18): General Findings*

- General Feedback from Investigators
  - Pest Management
  - House Keeping
- Most Frequent FDA Form 483 Findings
  - Plant Management (21 CFR 507.25(a) and (b)(1))
  - Pest Management (21 CFR 507.19(e))

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## *Inspections (FY19): What to Expect*

- CGMP inspections are being conducted at all business sizes
- Routine PC inspections started in October 2018 for “large” businesses
- Routine PC inspections at “small” businesses will begin in fall 2019; however are conducting some “for cause” inspections in FY 19
- Inspections will consider the various regulations that may apply at a facility





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*Inspections (FY19): Numbers to Date*

Type of Inspection	Number of Inspections	Percent of 483's issued
CGMP	156	14%
PC (by FDA)	75	27%
PC (by State)	14	Unknown
Sanitary Transportation	25	5%
FSVP	2	0%

\*Data reported up to mid-June, 2019



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*Inspections (FY19): General Findings for PC inspections*

- Continue to “Educate Before and During” regulation
- Significant public health concerns result in advisory or enforcement action
- Findings to date:
  - Not enough data yet to draw conclusions
  - Pre-requisite program implementation

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*Inspections (FY19): General Findings for PC inspections*

- Common inspection citations:
  - Failure to identify/implement a preventive control
  - Hazard analysis
  - No written food safety plan
  - Food safety plan not done/overseen by PCQI
  - Failure to establish/implement corrective action procedures
  - Failure to validate preventive control
  - Failure to conduct a reanalysis



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*Inspections (FY19): General Findings on PC inspections*

- Perspectives from Investigators:
  - Hazard analysis
  - Pre-requisite programs
  - Corporate plans vs. facility specific plans

# Key/Emerging Hazards and Research Gaps

# Pathogens in Pet Food

- Key pathogens of concern:
  - *Salmonella spp.*
  - *Listeria monocytogenes*
  - *E. Coli*
- Concern for all pet food
- Data trends

# Pathogens in Pet Food

- Research gaps:
  - Adequate controls in raw pet food
  - Post kill step contamination issues (ingredients and final product)
  - Transportation best practices (primarily unpackaged ingredients)

# Pentobarbital

- FDA withdrawal of CPGs
- FDA method available for detection in tallow
- FDA developing method for detection in:
  - Meat
  - Finished product



# Pentobarbital

- Research Gaps
  - Widespread vs. local problem
  - Appropriate control
    - Supply chain?
    - Process?
  - Humane euthanasia alternatives

# Dilated Cardiomyopathy

- FDA updated released 6-27-19
  - Update on number of cases/reports
  - “Case” definition
  - Current data and findings including data from VetLIRN labs
  - Released raw case data as received

# Dilated Cardiomyopathy

- Research Gaps:
  - Is there a causal link between diet and DCM?
  - Formulation data
  - Medical data (cardiac, bloodwork) from animals that meet the case definition

# African Swine Fever Virus

- Highly virulent virus that impacts pigs
- Rapid spread through Asian continent in past year
- Foreign animal disease
- Catastrophic impact if reaches U.S. swine herd

# African Swine Fever Virus

- Research Gaps:
  - Natural contamination
  - What does a “positive” test mean in feed
  - Appropriate control

# Need for Collaborative Approach to Research

**Center for Veterinary Medicine  
Protecting Human and Animal Health**

**Thank you!**



**U.S. FOOD & DRUG  
ADMINISTRATION**