



## Center for Veterinary Medicine (CVM)

### Public Meeting: Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs

Johns Hopkins University – Montgomery County  
9601 Medical Center Drive, Rockville, MD 20850

July 16, 2019

#### AGENDA

Meeting Website: [www.fda.gov/animal-veterinary/workshops-conferences-meetings/public-meeting-incorporating-alternative-approaches-clinical-investigations-new-animal-drugs](http://www.fda.gov/animal-veterinary/workshops-conferences-meetings/public-meeting-incorporating-alternative-approaches-clinical-investigations-new-animal-drugs)

Docket No. **FDA-2019-N-2281**

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#### 8:30 a.m. Welcome and Opening Remarks

Dr. Steven Solomon, Director, Center for Veterinary Medicine, FDA CVM  
Dr. Norman E. "Ned" Sharpless, Acting Commissioner, FDA

#### 9:00 a.m. Session 1: Complex adaptive and other novel investigation designs

**Speakers:** Robert Temple, FDA CDER  
Aloka Chakravarty, FDA CDER

**Panel:** Speakers and  
Margie Bell, Animal Clinical Investigations, LLC  
Dorothy Brown, Elanco Animal Health  
John Scott, FDA CBER

**Moderator:** Virginia Recta, FDA CVM

**Public Comment**

#### 10:30 a.m. Break

#### 10:45 a.m. Session 2: Real world evidence

**Speakers/Panel:** Elizabeth Lund, DataDogs, LLC  
Laura Hungerford, Virginia-Maryland College of Veterinary Medicine

**Moderator:** Emily Smith, FDA CVM

**Public Comment**

#### 12:00 noon Lunch break

#### 1:30 p.m. Session 3: Biomarkers and surrogate endpoints

**Speakers:** Johann Coetzee, Kansas State University  
Lisa McShane, National Institutes of Health  
Chad Ray, Zoetis

**Panel:** Speakers and Terry Katz, Merck Animal Health

**Moderator:** Phillip Turfle, FDA CVM

**Public Comment**

#### 3:00 p.m. Break

**3:15 p.m. Session 4: Data from foreign countries**

**Speakers:** Mary Jane Ireland, Health Canada Veterinary Drugs Directorate  
Sharon Chase, Schafer Veterinary Consultants, LLC  
Rick Clemence, Dechra Pharmaceuticals PLC  
Kristi Smedley, CFR Services, Inc.

**Public Comments**

**4:30 p.m. Public Comments**

**4:45 p.m. Closing Remarks**

Dr. Matthew Lucia, Director, Office of New Animal Drug Evaluation, FDA CVM