Updates

- Categorical Exclusions
- Chemical Weapons Convention
- Rabies In-Vitro Potency Assay
- China Tariffs

- Extraneous Agent Testing
- Potency Specifications
- Regulatory Reform
- Pharmacovigilance
Categorical Exclusions

- USDA published final rule in May

- Allows for exclusion of requirement to perform NEPA environmental assessment on recombinant/vector products

- Industry andAPHIS both supportive of this decision
  - No word yet if CE has been requested/applied
Chemical Weapons Convention

- Recurring issue with push to have biologics producers’ (and others) facilities inspectable under the tenets of the CWC

- Would require no-notice, no-right-of-refusal inspections of US biologics production facilities by international cadre of inspectors

- AHI, BIO, and ACC successfully petitioned State Dept and Dept of Commerce to oppose this expansion of CWC
Rabies In-vitro Potency Assay

- Strong interest from three participating firms to develop for US

- Desired goal is firm-specific in-vitro potency assay to replace NIH mouse test
  - All assays would use same mAbs, but would be optimized for products
  - Discussions ongoing with CVB on potential of this plan

- Presentations delivered at NICEATM conference last week
China Tariffs

- Tariffs imposed on $50B+ of US & Chinese goods
  - Another $200B worth of products has been threatened w/tariffs

- Current tariff lists does not include line items identified that would greatly affect animal health industry

- Biologics manufacturers import little-to-no materials or products from China due to contamination/quality concerns
Extraneous Agent Testing

- USDA responding to concerns about potential contamination of biologic products and precursors

- Industry and USDA discussing what levels of additional testing are needed

- Final requirements should reflect risk levels and take into consideration the limits of PCR & other testing methods
Potency Specifications

- Continued debate on proper antigen content levels in biologics

- Industry meeting with CVB working group on Sept 21st
  - Very productive

- CVB reorganizing some sections of guidance document; industry awaiting publishing of this draft for comment
Regulatory Reform

- EO 13777 established mechanism for removal/updating of regulations seen as outdated or imposing costs greater than the benefits conferred

- AHI submitted two topics so far:
  - Sterilization (modernization of regs so as to eliminate routine exemptions)
  - Special Use and For-Export Only Labeling

- AHI plans to submit additional request for removal of requirement to perform Animal Batch Safety Testing
Pharmacovigilance in Biologics

- PV final rule published earlier this year: mandatory reporting of adverse events to CVB by manufacturers

- Will use PV Works 2 as reporting software platform

- AHI working group set up to provide input when requested
  - Potential face-to-face meeting with CVB early next year
AHI 2019 Meetings

- **Spring**: March 27th
- **Summer**: June 26th
- **Fall**: Oct 9th

All meetings held at Gateway Hotel in Ames, Iowa
Questions