Industry Update

Animal Health Institute

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Updates

- Categorical Exclusions
- Chemical Weapons Convention
- Rabies In-Vitro Potency Assay
- China Tariffs
- Extraneous Agent Testing
- Potency Specifications
- Regulatory Reform
- Pharmacovigilance

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Categorical Exclusions

- USDA published final rule in May
- Allows for exclusion of requirement to perform NEPA environmental assessment on recombinant/vector products
- Industry and APHIS both supportive of this decision
  - No word yet if CE has been requested/applied

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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

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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

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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

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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

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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

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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*

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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

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AHI 2019 Meetings

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

All meetings held at Gateway Hotel in Ames, Iowa

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Questions