

# ANIMAL HEALTH INSTITUTE

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# UPDATE ON AHI

- New staff members
- Current issues/recent developments
  - Regulatory Reform
  - Single-Tier Labeling
  - Categorical Exclusions
  - Rabies In-Vitro Assay Development
- Future topics
  - Potency Specifications for Biologics
  - VICH
  - FMD Vaccine Bank
- Questions

# NEW AHI STAFF

- **Will McCauley**

- Undergrad, MBA, and DVM at Texas A&M
- Practitioner in Dallas for 4 years
- Stepped into Kent McClure's role at AHI in June

- **Rachel Cumberbatch**

- DVM & BS at Purdue University
- Completed two D.C. fellowships (AVMA and AAAS)
- Manager of Regulatory Affairs at AHI (VBS & ADS)

- **Ginny Siller**

- Director of Public Affairs at AHI
- Registered lobbyist



# CURRENT ISSUES/RECENT DEVELOPMENTS

- **Regulatory Reform**

- Initiated by EO 13777
- Seeks to remove outdated and burdensome regulation
- USDA: four “batches” of submissions to be considered
- AHI’s submissions:
  - 1<sup>st</sup> batch- Outdated steam/heat sterilization requirements
  - 2<sup>nd</sup> batch- Elimination of Animal Batch Safety Testing requirements
  - 3<sup>rd</sup> & 4<sup>th</sup> batch- TBD

# CURRENT ISSUES/RECENT DEVELOPMENTS

- **Single-Tier Labeling**
  - *9 CFR 112: Packaging and Labeling* (May 2011)
  - Seeks to streamline review & approval process as well as standardize labeling to improve practitioner usage experience
  - CVB & AHI member firms reached agreement on implementation
  - Final discussions to be held at AHI's fall meeting next week

# CURRENT ISSUES/RECENT DEVELOPMENTS

- **Categorical Exclusions**

- Broad-based support of this issue among industry and regulators
- Process currently bogged down on legislative side
- AHI's Public Affairs Section routinely monitoring progress of this issue and will advise on any actions needed by VBS

# CURRENT ISSUES/RECENT DEVELOPMENTS

- **Rabies In-Vitro Assay Development**
  - Represents co-operative effort by industry & regulatory researchers to implement 3 R's into a globally demanded process
  - Scientific vs Legal
    - Scientific: new discoveries and developments tempered with changes in key personnel at CVB
    - Legal: Freedom-to-Operate agreement in the works; currently awaiting one AHI member firm to sign-on

# FUTURE TOPICS

- **Potency Specifications for Biologics**
  - Disagreement on what is the “proper” antigen level in veterinary biologics
  - Goal is to have acceptable potency that achieves population immunity while avoiding the risk of an increase in adverse events due to an “excessive” antigen content
  - Topic will be discussed at AHI’s fall meeting next week



# FUTURE TOPICS

- **Veterinary International Conference on Harmonization**
  - Partnership by EU, US, & Japanese regulators
  - Goal is to harmonize technical requirements for veterinary product registration on the international market
  - Upcoming meeting in Tokyo
  - CVB has requested a US industry representative attend
  - AHI will identify an industry rep by next VICH meeting in Brussels

# FUTURE TOPICS

- **FMD Vaccine Bank**

- “Hot topic” in D.C. over the summer
- Risk of FMD outbreak and benefits of vaccine bank are clear
- Issues to be decided:
  - On-shore vs Off-shore (tied to Select Agent status vs novel vaccine)
  - Funding (likely tied to Farm Bill)
  - Requirements to ensure security and quality of banked vaccine supply
- Disagreements among AHI member firms to be addressed next week

# QUESTIONS