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  – Seeks to remove outdated and burdensome regulation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:
    • 1st batch- Outdated steam/heat sterilization requirements
    • 2nd batch- Elimination of Animal Batch Safety Testing requirements
    • 3rd & 4th 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