

# 110<sup>th</sup> Association of Fish & Wildlife Agencies VIRTUAL ANNUAL MEETING September 9-11 & 14-15, 2020



## DRUG APPROVAL WORKING GROUP Co-Chairs: Alan Johnson (IA), Kevin Kwak (CA)

Date: September 11, 2020  
Time: 9AM – 12PM CT

### 110<sup>th</sup> Association of Fish & Wildlife Agencies Annual Meeting Virtual

#### Agenda

- 9:00 Call to Order/Review Agenda/Announcements
- 9:05 Introductions
- 9:10 Approval of Minutes for the 2020 ADAC Aquaculture America Meeting
- 9:15 Federal-State Partnership MOA Status Update – *David Lind, AFWA*
- 9:20 INAD Indemnification Agreement Status Update – *Guppy Blair, FWS*
- 9:25 Aquatic Drug Approval Coalition Updates – *Alan Johnson (IA) / Kevin Kwak (CA) / All*
- Model Fish Group Development
  - Quarterly Call-in With FDA (July 27)
  - ADAC Meeting Briefs (July 29)
  - Next Quarterly Call Schedule
- 10:00 Discussion on Public Comments for GFI, DAWG Recommendations – *All*
- FDA GFI 61 (comments by 11/12/2020) “Special Considerations, Incentives and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.”
  - FDA GFI 265 (comments by 10/13/2020)- “Use of Data from Foreign Investigational Studies to Support Effectiveness of New Animal Drugs”
  - FDA GFI 266 (comments by 10/13/2020)- “Use of Real-World Data and Real-World Evidence to Support Effectiveness of New Animal Drugs”
  - FDA GFI 267 (comments by 10/13/2020)- “Biomarkers and Surrogate Endpoints in Clinical Studies to Support Effectiveness of New Animal Drugs”
  - FDA GFI 268 (comments by 10/13/2020)- “Adaptive and Other Innovative Designs for Effectiveness Studies of New Animal Drugs”

# 110<sup>th</sup> Association of Fish & Wildlife Agencies VIRTUAL ANNUAL MEETING September 9-11 & 14-15, 2020



- 11:20 AFWA-DAWG Tier Drug Status Updates – *Alan Johnson (IA) / Kevin Kwak (CA)*
- Tier 1: 17-Methyltestosterone; Chloramine-T; Eugenol; Slice; LHRHa; Ovaplant-L; Hydrogen Peroxide; Florfenicol;
  - Tier II: Diquat; Copper Sulfate; OxyTet Immersion; OxyTet Oral; Formalin; Erythromycin;
  - Tier III: Estradiol
- 11:45 Discussion on Future DAWG Meetings
- Virtual Pre-Meetings
  - Annual Drug Approval Meeting, Bozeman, MT
- 11:55 Wrap-up Discussion
- 12:00 Adjourn

DRAFT