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

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

110th 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”
11:20  AFWA-DAWG Tier Drug Status Updates – Alan Johnson (IA) / Kevin Kwak (CA)
  - Tier 1: 17-Methyltestosterone; Chloramine-T; Eugenol; Slice; LHRHa; Ovaplan 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