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AGENCIES

The Association of Fish and Wildlife Agencies—the organization that represents North America’s fish and wildlife agencies—promotes sound management and conservation, and speaks with a unified voice on important fish and wildlife issues..

DAWG MEETING NOTES
Association of Fish and Wildlife Agencies – Drug Approval Working Group
Saratoga Springs, New York
8 & 9 September 2008; 1300-1700 hr

Prepared by Thomas Bell on 1 October 2008
Final Revision: 12 November 2008

Monday Session, 8 September, 1300 to 1700 hr

Attendees: Doug Beard (USGS), Thomas Bell (FWS), Dave Erdahl (FWS), Mark Gaikowski (USGS), Laura MacLean (AFWA), Mike Mason (Iowa DNR), Don Prater (CVM), Roz Schnick (NCANADA), Steve Sharon (Chair; WY GFD), Dave Straus (USDA), Larry Riley (AZ G&F), Kelly Winningham (AR GFC)

- Introductions of attendees: Kelly W. is a new member representing Arkansas Game and Fish Commission, replacing Mike Gibson.
- Steve S. noted that the Post-DAWG will be used as an overflow for the DAWG meeting.
- Steve S. asked if there were comments or changes to the meeting minutes from the Phoenix meeting. No changes were suggested. Minutes were accepted as final.
- **Steve S. began a review of Actions Items from the previous meeting(s)**
 - Action Item #1 (*H₂O₂ Fact Sheets*): this is to be reinitiated for the next meeting. Roz S. will redistribute the draft to members for their review.
 - Action Item #2 (*New Fact Sheets*): this is to be tabled until AI#1 is completed.
 - Mark G. has an EA fact sheet for USGS that he will convert over once we have established our format.

- Dave S. asked whether meeting at Aquaculture America 2009 has been set-up yet. Steve S. stated that it has not, and he needs contacts to get this completed, as well as having to coordinate with Mark G., Dave S. and Jim Bowker relative to their research meeting at AA2009.
 - Mark G. requested a meeting room from John Cooksey for the DAWG meeting at Aquaculture America 2009 during the Sep 2008 DAWG meeting.
- Action Item #3 (*AFWA Website*): discussion deferred until Laura MacLean is able to join the meeting.
- Action Item #4 (*Letter of Commendation for Richloam Hatchery*): this has been completed (7 May 2008), signed by Matt Hogan and sent to the Director of the Florida Fish and Wildlife Conservation Commission.
- Action Item #5 (*Prioritization Issue*): Dave E. discussed the importance of AADAP meshing with AFWA priorities. Steve S. suggested that this topic be moved to the “transition discussion,” possibly on tomorrow’s agenda. Dave E. stated that FWS does not want the DAWG to go away, and wants to be sure AADAP activities are properly aligned with DAWG priorities. Roz S. noted that she directed, to AADAP, a phone call from a state resource agency regarding SLICE; Dave E. had no recollection of the call, but stated that it may have been received by Bonnie Johnson.
- Action Item #6 (*Revisions of the Aquaculture Drug Approval Process Brochure*): Steve S. suggested that we postpone discussion of this until tomorrow’s continuation of the DAWG meeting.
- Steve S. noted that there are a few Action Items carried over from previous meeting that have not been resolved nor forgotten.
 - Carried-over Action Item #1 - Carbonic acid and LRP status.
 - Don P. discussed potential changes to LRP status.
 - A phone conference call with CVM (including Fran Pell from SC), initiated by AADAP following the Phoenix DAWG to discuss the possible inclusion of CCP on the LRP-list, was discussed. It is important to note that discussion during the phone conference was not very favorable with respect to **any** additions to the current LRP-list.
 - Don P. discussed what was meant by LRP.
 - Don P. noted that CVM’s legal counsel has problems with CVM not taking action on the use of an unapproved drug.
 - Don P. noted that CVM has a new approach to regulatory discretion; exercising it less often and on a case-by-case basis.
 - Don P. noted that Randy MacMillan discussed LRP (particularly as it pertains to KMnO_4) with Don P. during the last Annual Drug Coordination Workshop.
 - National Aquaculture Association (NAA) sent a letter to Dr. Dunham presenting support & encouraging CVM to modify the LRP list over time.

- CVM will be talking about this internally.
- There will probably not be a response letter to the NAA letter; however Don P. stated that he would be an advocate for such.
- Don P. noted that this would probably be a good time to ask CVM to tweak the use-patterns for the drugs currently on the LRP list.
- Don P. said that CVM (at this time) is stating that the LRP list will not be going away.
- Don P. suggested that the AFWA-DAWG send a letter to CVM regarding a tweaking of the specifics for CO₂ on the LRP list.
- Steve S. stated that iodophore-disinfection of eggs during water-hardening is also a high priority for tweaking.
- Dave E. stated that our efforts should be to try to legitimize the claims for the drugs on the LRP list (i.e., make them fit the actual use-patterns).
- Dave E. suggested that the DAWG should also send in a letter to Dr. Dunham expressing AFWA's support of LRP and suggesting tweaks as examples of how the current LRP list could be improved upon, and to ask for a response letter.
- Roz S. asked if catfish pituitary (CP) should go on the list. At least some of the discussion focused on whether gross tissue extracts could be a vector for pathogen (e.g. Viral Hemorrhagic Septicemia) distribution.
- Steve S. suggested that everyone look at the current LRP list and suggest changes to the DAWG.
- Roz S. asked whether our letter should include removing some drugs from the list.
- Don P. stated that the DAWG's letter would be covering the public sector like NAA did for the private sector, with some examples (not an exhaustive list) of where it needs to be tweaked
- Steve S. will start the letter, and Halloween will be the drop-dead date to send it off to CVM. Steve S. will contact Randy MacMillan for a copy of NAA's letter.
 - Don P. stated that in our letter we can reference that letter is in partial reaction to "recent discussions at the DAWG meeting."
 - Don P. described what would happen if the LRP list went away.
- Carried-over Action Item #2 – H₂O₂ use as a pesticide.
 - Steve S. to do letter regarding H₂O₂ use as a water treatment as opposed to a drug.
 - Steve S. has yet to do this.
 - Don P. stated that this could be done as an email to Don, instead of a formal letter. Don P. would then forward to a CVM group which will decide and respond.

- Larry R. noted the steps required for a FIFRA (i.e., EPA) registration and the possibility of obtain “localized registration” for site-specific needs. He also noted that there are numerous FIFRA-labeled products currently on the market.
- Don P. noted that there may be acceptable/applicable data within the NADA that may be shared with EPA for a pesticide registration.
- Tom B. noted that even though CVM may respond back stating that the prescribed use for water treatment is not a “drug claim” and hence within the jurisdiction of EPA, the chemical company (i.e., Eka) may not be at all interested in pursuing a pesticide registration. Hence, a discussion early on with the sponsor may be prudent.
 - Steve S. suggested that we check with the sponsor first.
 - Roz S. will touch base with Dave Lovetro at Eka.
- Carried-over Action Item #3 – Letter to states participating in pivotal work.
 - Steve S. noted that this is not done, but we will try to discuss this in tomorrow continuation meeting.
 - Dave E. suggested that such action may not be all that value-added for those states which conducted the work did so more that 2-3 years ago, and that Roz has done a good job of recognizing those entities/agencies during her “new approval announcements.” Roz suggested that stroking the past deeds is a way to get more work from the same units and to possibly encourage others to participate.
 - Tom B. suggested that these acknowledgments could also be placed on the website for others to see.
- Carried-over Action Item #4 – Manuscript on successes and investments.
 - Roz S. stated that she has completed the draft intended for publication in AFS Fisheries magazine.
 - Roz S. will send, to Steve S., draft of letter to participants (USFWS, USGS, USDA, etc.) requesting an update of information.
 - Dave S. suggested that it should be a letter to Don Freeman (in the case of USDA-ARS).
 - Steve S. suggested that the letter should come from the DAWG
 - Roz S., at Dave E. request, will send back to Dave E. the earlier estimates that FWS provided to her.
- Carried-over Action Item #5 – letter regarding illegal use of drugs.
 - Roz S. asked about the status of the letter to go to fish chiefs reiterating the importance of not using drugs that are unapproved.
 - This letter was to come from the DAWG.
 - Will use the previous version as a starting point.

- Steve S. will initiate, but will have AADAP generate the first draft. It was suggested that mention of the recent AFS/AADAP poster should be included in the letter.
- Steve S. suggested that it would be best if the letter were to be sent out just before that next DAWG meeting being held at Aquaculture America 2009 in Seattle.
- **Discussions on the “zero-withdrawal” anesthetic issues**
 - Steve S. brought everyone up to speed on the Product Development Meeting held at CVM on 20 August. He noted that two sets of notes were passed out and were in need of review and feedback. Don P. noted that CVM will forward formal PDM notes to AADAP in the near future.
 - Steve S. acknowledged CVM for conducting an extremely informative meeting and for having gone out of their way to be of help.
 - Dave E. suggested that our discussions from this point forward regarding the anesthetics issue should be confined to the Human Food Safety technical section requirements.
 - Steve S. noted that the AFWA Grants Committee agreed (during the interim from the last DAWG meeting until now) to roll over the \$300+K for the 2 year project (note: Steve later determined that the \$300+K level was actually \$202K).
 - Steve S. also noted that he discussed, with Ron Regan and Virgil Moore (Fisheries and Water Resources Policy Committee or FWRPC) the potential of forwarding 2 drugs (preliminarily until we could narrow down to one) to the Committee.
 - Virgil agreed that this would be a good idea.
 - Ron suggested that the DAWG continue with very specific objectives, but not to the extent that we box ourselves in as we did in the past & that 2 drugs were OK.
 - Ron and Virgil also noted that we need to bring the concept of “immediate release” to the FWRPC during the September Committee meeting.
 - There was a discussion regarding the ADI (acceptable daily intake) vis-à-vis the concept of “immediate release” and that to get an actual “zero withdrawal” anesthetic approved may be problematic. CVM confirmed during the PDM that until the Acceptable Daily Intake (ADI) is determined based on completion of the required toxicology studies and a subsequent maximum residue limit (MRL) established, it is unknown whether fish would be considered safe for consumption immediately after treatment or if CVM would require information regarding the length of time fish would be unavailable for harvest. CVM did not rule out the possibility of zero-withdrawal, rather that the tissue levels were high immediately post-sedation but that a final ruling would not occur until the ADI and MRL is established.
 - Don Prater suggested that there needs to be a multi-factored approach for the “immediate release” material to go to CVM and a single argument may not work for all drugs, and that it is expected (by CVM) that the submitted material will not all come from the literature alone (i.e., some new data will need to be generated).
 - Don P. suggested that we could possibly follow the species-grouping approach that we used for efficacy and target animal safety.

- Don P. further noted that we should check-in (informally with the CVM aquaculture team) periodically as we proceed to put together our strategy and begin to generate some data. The purpose being to make sure that we are on the right path.
- Don P. stated that the first step is to have a meeting (phone) with CVM to discuss our plan, specifically to see if it is wise to do it now relative to the other studies needed for approval of the specific drugs in question.
- **Discussion on AFWA's website for the DAWG**
 - Laura MacLean (AFWA Communications and Marketing Director) joined the meeting and explained what had been done over the past 6 months.
 - She stated that there is now a DAWG page (located under the Committee page).
 - Laura M. noted that the DAWG page has numerous links to AADAP's website
 - Laura M. stated that AFWA would be looking hard at how people get their information and will modify their site accordingly to maximize a user's ability to obtain the information they are seeking.
 - AFWA has already done some surveys on site-use.
 - Laura M. noted that she likes it when she is asked to help and reiterated her solicitation of our thoughts.
- **Resumed discussion on "zero-withdrawal" anesthetics issues**
 - Steve S. reiterated the DAWG's focus on field-use for public resource agencies with a primary goal of obtaining an anesthetic for short-term sedation to a handleable stage. Further, Steve S. stated that we needed to identify the "main" method of "capturing" fish for the "immediate release" submission.
 - Don P. noted that there is no response yet from the National Center for Toxicological Research (NCTR) regarding the methemoglobinemia issue and that a positive result (i.e., strong correlation) may be a "kiss of death" for benzocaine.
 - Dave E. asked that we morph the discussion onto that of MS-222. (i.e., based on what we learned from the PDM, is it still a viable immediate release anesthetic candidate or not?)
 - Don P. stated that there are no public data on MS-222 available.
 - Don P. discussed the genotoxicity data needed to be done for MS-222, which if positive would require carcinogenicity studies to be done. Essentially MS-222 would require a complete package, as would a totally new drug.
 - Steve S. asked whether a positive MS-222 genotox study might trigger a spotlight on MS-222, and possibly even result in its removal as currently labeled from the market.
 - Don P. stated that in his personal opinion there was a good probability.
 - Dave S. brought up the issue that NaCl is added to channel catfish ponds to eliminate chance of methemoglobinemia (brown blood disease) occurring.

- Roz S. stated that the NCTR studies are designed to assess the human food safety issue, not the target animal safety.
- Roz S. suggested that the rat reproduction study cost estimates are low; Schering-Plough Animal Health (SPAH) noted them to be \$500+K. Further she noted that there are 5-fold differences in cost estimates from CVM and her sources, therefore we should not pursue MS-222, as being the estimated most expensive (even more so than those estimates provided by CVM).
- Mark G. seconded the motion that MS-222 be removed based on a multiple number of issues, in particular the exceptionally large number of studies to be completed.
- Larry R. suggested that we should not use the potential of a positive genotox study results as a basis for eliminated MS-222 from further considerations.
- Dave E. responded by saying that he thought that potential positive genotox results should in fact be a consideration. If we generate data that results in the loss of MS-222, we're cooked.
- Dave S. asked why metomidate is not on the list of prospective anesthetics.
 - Roz S. stated that it was for the same reason as MS-222 that all studies would have to be done.
- Steve S. stated that the first thing we need to know is what is "immediate release" and that if hatchery (domesticated) reared rainbow trout were used in studies it would probably represent a worse case scenario (i.e. probably would show a positive feeding response following being anesthetized much quicker than wild fish, hence may be catchable before drug has been adequately eliminated from edible tissue).
- Mike M. stated that Iowa has walleye that are feed-trained and are about 8", and that can be used for catchability studies.
- Kelly W. has channel catfish on feed that are up to 1.0 pound.
- Roz S. suggested that there is an inherent recovery period that fish are kept following sedation and prior to actual release.
- Kelly W. noted that many times they will let their fish go immediately following sedation and they will watch them recover in their natural habitat (release into shallow/clear water).
- Dave E. stated that he felt how folks sedate/recover/release their fish is likely "all-over-the-board."
- Dave E. suggested that we have a phone conference to discuss a basic protocol for generating "time to catchable" data, including species of choice.
- Steve S. asked what is the time-frame to complete the "immediate release" submission.
- Roz S. recommended that the "worst-case due to habituation" (e.g., domesticated rainbow trout) should be the basis for our argument.

- Don P. suggested running the master plan, with its rationale, by CVM first before protocol development.
 - This should be conceptual.
 - It would have a 30 day review turn-around.
 - If the master plan submitted for review is not complete, CVM will provide the missing pieces in its response letter.
- Dave E. stated that he felt that the completion of the “immediate release” submission is not time-sensitive.
- Mark G. stated that the determinative and confirmatory method development studies will be similar to those UMESC has previously completed and that some method development has already been completed for both eugenol and for benzocaine. Mark also stated that the total (eugenol) and marker (benzocaine or eugenol) residue depletion study designs are similar to what we have already done and we don’t expect any issues in completion of these studies. Mark stated that we need to know the expected MRL limit in order to develop the determinative method. Mark also stated that we need to establish the use pattern before conducting any marker residue depletion studies.
- Don P. noted that he recognizes that domesticated fish are probably the worst-case scenario.
- Steve S. recommended a new Action Item.
 - All members are to develop ideas as to how to test catchability of sedated fish.
 - Mark G. noted that several factors must be considered including 1) establishing the “at-risk” population (the total fish population available for angling); 2) gear (electrofishing, gill-netting, hoop-netting, etc.) selectivity and efficiency (to determine the proportion of the population that could be sedated); 3) time to first feeding post-capture, sedation, and handling; and 4) angler efficiency. These factors should be incorporated when developing estimates of the probability of capture of fish post-sedation. Many gear are relatively inefficient in capturing fish and often are species specific..
 - Need to get suggestions to Steve S. by the end of October (i.e., Halloween).
 - We should probably have one or two phone conferences in the interim.
 - Steve S. will send out a “Doodle” conference schedule for phone conference coordination.
- There was a discussion of the type of allocation of funds pertaining to the NCN grant; i.e., “no-cost” extension vs. rollover.
- Steve S. stated that he anticipated presenting a 2 drug scenario (short-term until one is eliminated with forthcoming information) to the FWRPC and it will be for a total of \$302K (with actual value of \$202K determined later to be the amount).
 - There was some discussion following this (as well as some prior and previous to this) regarding the amount of the remaining funds. Most seemed to think that this value

was probably around \$100K high. Mark G. provided the group with a summary of the original MSG funding allocation. Steve S. was to confirm this with Christina.

- Steve S. made the motion that we go forward to the FWRPC and the AFWA Grants Committee with the 2 drugs scenario (eugenol and benzocaine), until such time that we eliminate one drug, pending evaluation of incoming data.
 - Dave E. seconded the motion.
 - All voting members present voted in favor of the motion.
 - The following is the summary of the motion and the courses of action recorded by Mark G. for Steve S.
 - Motion to the FWRC Committee:
 - To go forward with eugenol and benzocaine as a sedative for short-term handling for **immediate release**, pending evaluation of incoming data until such time that one will be removed.
 - Sedative Objectives:
 - COA 1: MSCG will be spent immediately to complete residue chemistry studies to address unresolved issues related to total residue depletion of eugenol, and determinative/confirmatory methods for eugenol and benzocaine. Assumptions: no methemoglobinemia issues identified relative to benzocaine in the NCTR studies and MSG funds must be expended immediately.
 - COA 2: MSCG will be reserved to complete residue chemistry studies to address remaining HFS data requirements following the establishment of an ADI for either benzocaine or eugenol. Assumptions: MT data package is complete for either eugenol or benzocaine.
 - Action Items:
 - AADAP and UMESC develop a letter requesting FDA CVM to review the NTP carcinogenicity study for eugenol to determine which if any Mammalian Toxicology studies the NTP study may address or reduce data requirements.
- Dave E. asked Mark G. if UMESC was capable of conducting the genotox studies. Mark responded that they are not.
- Roz S. suggested that we wait until we get a clearer picture after the NTP (eugenol) & NCTR (benzocaine) studies have been reviewed before we start to invest money.
 - Roz S. posited 'what will the sponsor do in the interim,' and suggested that the sponsors might generate the genotox data and use it as proprietary data for purposes of exclusivity.
 - Dave E. responded that he believed the genotox should be done with AFWA funds (as opposed to a drug company doing the work and maintaining the data as proprietary), as this information is key to our decision-making process.
 - Mark G. disagreed, that the mammalian toxicology studies have historically been completed by the drug sponsors and that we should continue that paradigm.

- Don P. stated that for the NTP eugenol study to be reviewed by CVM relative to its acceptability and completeness, an INAD sponsor would have to request CVM to do so.
- The DAWG meeting was adjourned at 1700, with further discussion to be continued at tomorrow's "Post-DAWG" meeting.

Tuesday Session, 9 September, 1300 to 1700 hr

Attendees: Doug Beard (USGS), Thomas Bell (FWS), Dave Erdahl (FWS), Gary Frazer (FWS), Mark Gaikowski (USGS), Mike Mason (Iowa DNR), Don Prater (CVM), Roz Schnick (NCANADA), Steve Sharon (Chair; WY GFD), Dave Straus (USDA)

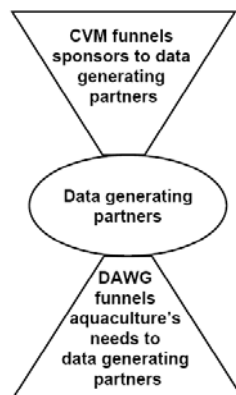
- Steve S. noted that the motion proposed during yesterday's meeting (i.e., the DAWG proceed with the 2 drugs scenario (eugenol and benzocaine), until such time that we eliminate one drug, pending evaluation of incoming data) was presented at this morning's Fisheries and Water Resource Policy Committee and the FWRPC unanimously accepted our motion.
- Steve S. stated that he has discussed our budget with Christina of the AFWA Grants Committee and was informed of the following:
 - rollover amount from 2007 = \$196,256.50
 - new amount for 2008 = \$106,321.00
 - total = \$302,577.50
- Steve S. thinks that we should assume that we have \$178K as our base and he will reconfirm actual amount with Christina. **Update: 10 September – original communiqué was in error, the correct total is \$202,577.50.**
- Roz S. passed out a status update of AFWA-project drugs and proceeded to go over the details.
- **Discussions on chloramine-T**
 - Steve S. asked, relative to chloramine-T, whether there was a discharge limit listed in the environmental section of the label.
 - Don P. stated that there was not a discharge limit, but instead there is a benchmark level such as found on the H₂O₂ label. Mark G. confirmed that a benchmark level had been established for Cl-T at 0.13 mg/L and described the implications of establishing a water quality benchmark.
 - Roz S. noted that Wisconsin would not allow any use of any chlorine-based drug.
 - Steve S. asked Don P. is he could comment on the CMC status.
 - Don P. said "no."
 - Roz S. stated that there are no "red flags."
 - Roz S. stated that she had altered claim #3 to include LMB or all warm-water fish

- Dave E. asked Don P. if the present number of efficacy studies completed or nearly completed (by AADAP and others) would be adequate to complete an all cool- and warmwater fish claim for use to control external columnaris (Dave E. was referencing a question that Jim Bowker had posed to Don in a recent voice-mail message).
 - Don P. stated that basically CVM will stick to requirements as delineated in a letter to AADAP describing the number of species from each temperature group, which is in fact the bare minimum
- Roz S. said that bacterial gill disease (BGD) was the #1 need with respect to un-met label claims
 - Dave E. stated that if this is indeed so, then these people need to engage in the data generating process
- Don P. stated that the current claim does not include channel catfish in earthen ponds with no outflow, and this restriction will somehow need to be included on the label. The label may include a statement that drug cannot be used for exposures exceeding 60 min (which would exclude use in ponds with no discharge). Mark G. discussed the current label exposure durations for hydrogen peroxide and how those label restrictions could be applied to chloramine-T.
- Don P. noted that now is the time to tweak the label
- Don P. stated that the label could include “not to be used in recirculating systems.” Steve S. asked if the DAWG could see the current draft label to help tweak it now
 - Roz S. stated that she would look into this.
- Roz S. noted that we are still looking at a 2009 approval date for chloramine-T
- Roz S. said in reference to Item #1 (under Claims #1 & 2) of her handout that CVM is on-target to review the Axcentive’s CMC submission in November.
- Roz S. stated in reference to Item #2 (under Claims #1 & 2) of her handout (request by Axcentive that CVM consider the Environmental Technical Section complete) that there is no timetable for this to happen.
- Roz S. stated in reference to Item #3 (under Claims #1 & 2) of her handout that a phone conference is being scheduled with Jeff Gilbert to discuss this issue
 - Mark G. stated that UMESC was currently in discussions with FDA regarding the p-TSA determinative method’s quantitation limit. Mark stated that UMESC would complete the additional method development work to reduce the method quantitation limit to <20 ppb. The original method had been developed when the MRL for p-TSA was thought to be 1 ppm, presently the MRL will likely be at 20 ppb. Roz stated that if option #1 were accomplished it could also result in something less than an 11 day withdrawal period.
- **Discussions on copper sulfate**

- Dave S. stated that the 3rd version of the label is to be submitted soon to the sponsor and then to CVM. The revision is based on the CVM's review of, and response to, the previously submitted 2nd version.
- Don P. stated that the label will be for ictalurids only, not "catfish"
- Dave S. noted the Guidance Document 152 related submission is not complete yet and the contractor has not been responding to Dave's correspondence.
- Dave S. said that the Environmental Assessment for fungus on eggs is to be farmed out.
- Don P. noted that CVM has suggested that the label can be streamlined via a limitation of no water to be released in 4 days. This label is for Ich in ictalurid ponds.
- Roz S. asked if fungus is approved for eggs, could it be extended to catfish in raceways.
 - Don P. stated that it is "possible."
 - Mark Gaikowski said that it has already been done for another chemical
 - Dave E. asked if Mark G. would consider doing an EA for flow-thru for ictalurids.
 - Mark G. stated "yes", UMESC would consider collaborating to complete the EA.
- Dave S. stated that the hazard characterization has been submitted and Don P. said that the completion of the review is 180 days out.
- Dave S. said that the AOI is being worked on and Don P. noted that once submitted it will only be good for 90 days.
- Dave S. noted that the in-life phase of the target animal safety studies are completed and that he will be starting to write it up, compile components for the final study report (FSR), get the stats completed, write associated manuscripts and submit the FSR to CVM.
 - Dave S. said that they ended up with only 3 replicates, given that one was lost due to a power switch being inadvertently turned off in the middle of the study.
 - Tom B. questioned the order in which the various tasks were to be completed, in particular completing manuscripts first before the FSR.
 - Dave S. stated the order of completion was based on programmatic responsibilities.
 - Don P. suggested that it might be easier to write manuscripts after the FSR has been completed.
- **Discussions on florfenicol**
 - Dave E. stated that the hybrid striped bass/streptococcus efficacy study has been accepted by CVM as being complete.
 - Dave E. said that the systemic columnaris study on rainbow trout was completed at Bellingham SFH and AADAP is confident it will be adequate to complete the efficacy for systemic columnaris for all freshwater-reared salmonids.

- Dave E. stated that in discussions with the sponsor and CVM it was established that target animal safety-wise to get a label for use at 15 mg/kg for all fish, AADAP (or others) would need to complete only two additional target animal safety studies. One study should be conducted on yellow perch, and the other study on hybrid striped bass. AADAP has been proceeding with developing plans and study protocols to get this completed. However AADAP has just learned that Vaughn Ostland at Kent SeaTech (site for HSB study) will no longer be at Kent after the end of October, and a new HSB study site will need to be found.
- Steve S. noted that Wyoming is seeing the need to treat twice at 10 mg/Kg for cold water disease. They are finding it difficult to get adequate amount of medicated feed into the fish.
- Dave E. said that if all went well AADAP would be able to complete the yellow perch TAS study this spring.
- Dave E. made the motion that the DAWG make it a priority to pursue 15 mg/Kg as an alternative dose for all fish (i.e., not 10 to 15 mg/Kg but 10 or 15 mg/Kg).
 - The motion was seconded and the motion was unanimously approved.
- Roz S. asked Mark G. if his efficacy studies in tilapia would support both a 10 and 15 mg/Kg dose for all fish.
 - Mark G. responded “yes”
- **Discussion on hydrogen peroxide**
 - With respect to Item #2 under “Remaining requirements” Mark G. stated that once the RBT/saprolegniasis pivotal protocol is accepted by CVM, UMESC will then submit a walleye protocol to CVM (that is identical to the RBT protocol) and will proceed to conduct the study without waiting for the protocol approval from CVM.
- **Discussion on the transition from “with” to “without” the National Coordinator for Aquaculture New Animal Drug Applications (i.e., Roz Schnick)**
 - Steve S. provided some introductory comments on the transition that will take place before and after Roz S.’s retirement in April 2010.
 - Doug B. stated that the current contract to provide Roz S. funds will not be renewed after this year for USGS does not have the money for new funding.
 - Doug B. further stated that we need to define the critical things that Roz S. is doing and that we need to pick these up.
 - Doug B. also said that we need to figure out what we could do with the 2010 budget, and now is the time to make that determination.
 - Steve S. said that we currently have an MOA, which includes the NCANADA position, and we thus need to think about what we are going to do about the MOA (i.e., we probably need to modify it to reflect post-transition responsibilities and signatories).
 - Roz S. stated that she gave a seminar to CVM about her transition and included in her seminar were several items suggesting that the transition should be relatively easy:

1. CVM has put a lot of processes in place that can take over what Roz has been doing
 2. The aquaculture community has now got an arsenal of drugs approved and hence there may not be as much work to do.
 3. There has been a maturation of the generating partners relative to interaction with sponsors and CVM and hence CVM will not monetarily support a NCANADA after 2010.
- Don P. noted the following relative to the transition:
 1. CVM has seen the need for the NCANADA since the early 90's, as well as the need to support the position at the level of up to \$50K per year.
 2. CVM has recently reassessed the situation and has concluded that there are enough infrastructures in place within the "aquaculture drug approval consortium" to sustain same level of efforts exerted by the NCANADA in the past.
 3. CVM sees two functions or traits of the public data generating system that will allow it continue the efforts of the NCANADA when Roz retires:
 - a) Show sponsors what to do to complete an NADA; at the beginning CVM had only one person and could not be of much assistance to new sponsors, whereas now they can assist the sponsor directly or indirectly via expertise within the public data generating system.
 - b) The DAWG is now in place to develop accurate and timely lists of industry needs, and to efficiently direct/prioritize the work of the research partners. Don P. envisions the future process as CVM funneling sponsors to the data generating partners, and the DAWG funneling the needs of the aquaculture community to the data generating partners.



- Don P. stated that he envisions the DAWG will do the project management, with the partners stepping up. Don further noted that CVM will be writing a new guidance document for how to start a Public Master File.
- Steve S. said that it is important for an entity (the DAWG?) to manage the partners, and if a "master manager" is from one of the agencies it probably would not work.
- Steve S. further stated that the DAWG and the "consortium" should work to share the responsibility

- Dave S. stated that he would not want to see a single coordinator.
- Doug B. stated that he supports the notion that the DAWG **not** go away.
- Steve S. asked whether the MOA should go away.
- Doug B. followed by saying that there might possibly be a different way to cover the DAWG's potential responsibilities of coordination.
- Steve S. suggested that an individual within each agency be designated as a spokesperson to the DAWG.
- Don P. noted that the DAWG may be even more important due to the demise of the JSA's Working Group on Aquaculture Drugs, Biologics.
- Roz S. noted that there are managers at CVM that are "project managers" that could do some of Roz's jobs.
 - Don P. responded that these CVM managers would have to work with the pharmaceutical sponsor's project managers.
- Steve S. stated that we don't know what ARS's position in the future will be and that the Department of Commerce's National Marine Fisheries Service (NMFS) has also expressed some interest in re-engaging in the drug approval process and the DAWG.
- Don P. said that we need to keep all federal agencies engaged in this process and that CVM has explained the process to the NMFS and their need to have approved drugs.
- Doug B. noted that we need to talk further with NMFS and that unless NMFS engages we (i.e., the U.S. aquaculture community) could end up in a similar situation in 2010 as we were in the early 90's relative to no drugs for a growing segment of the community.
- Doug B. asked "if we get all the drugs [on our current list] will we have all we need?"
 - Don P. responded by saying that there will continue to be needs in spite of the new drugs that we get approved.
 - Don P. also stated that we are becoming, or have become, like the terrestrial animal industry in that we now have a model to apply to any new drug/need that comes along.
- Doug B. suggested that we:
 - Revisit the MOA
 - Restructure the DAWG as needed
 - Steve S. stated that the efforts to gain a new anesthetic will probably take 3-4 years under the new "process"
 - We need to look at project management needs that could fall between the cracks with a new system.
- Mark G. stated that the DAWG is a high-functioning group and that he doesn't see that the needs will be any different than in the past.

- Dave E. said that the DAWG is essential to AADAP & FWS, and that our partners have benefitted tremendously by our actions. Dave went on further to say that AADAP is going to have to step-up when Roz leaves and that we can do it with our current personnel. Dave also stated that we need to keep the DAWG functioning.
- Doug B. suggested that we need to make sure that the FWRPC understands the [new] function of the DAWG.
- Gary F. stated that, as a member of the AFWA's Fish & Wildlife Health Committee, he will try to get fish elevated to a higher priority on the committee's agenda.
- Don P. mentioned the potential role of CVM's Minor Use and Minor Species (MUMS) Office in presenting at the Grants Committee meeting.
- Roz S. stated that the "plan" is doable and that she has confidence in the partners' (including CVM) ability to do the job. She further stated that there has been "...astronomical changes and progress made..."
- **Further discussions on anesthetics**
 - Don P. stated that he would get back to the DAWG with a timeline for the completion of the NCTR methemoglobinemia study.
 - Don P. further noted that any [eugenol] sponsor could ask CVM to review the National Toxicological Program's (NTP) eugenol studies.
 - Dave E. asked to confirm whether the request by the INAD sponsor should be for CVM to review the NTP eugenol study as to its acceptability and completeness as it relates to the entire toxicology portion of the human food safety technical section.
 - Mark G. suggested that UMESC and AADAP work with Tom Goodrich (Aqui-S NZ's U.S. representative) to be sure that if Aqui-S NZ has other data that it could be included in the request for CVM review.
 - Dave E. disagreed with the suggestion of working with Tom Goodrich and Aqui-S NZ at this point in time as the inclusion of potentially proprietary data "in-the-mix" would/could hinder the DAWG's ability to make important decisions. Dave noted that Tom Goodrich could ask for review under Aqui-S NZ's own INAD
 - Dave E. stated that AADAP would work with UMESC to submit a request for CVM to conduct a review on the NTP eugenol study.
 - Plan to submit the request within 2 weeks
 - Don P. suggested that we talk with Karen Ekelman first to determine how best to make the request, i.e., should it be addressed to her?
 - Mark G. stated that relative to eugenol, the residue depletion study would be the first priority, and that it would cost approximately \$80K for the uniformly radio-labeled drug alone.
 - Roz S. brought up the issue of the complexity of the contracting process when using public funds to generate mammalian toxicology studies and the inherent time involved in the administrative portion of it.

- Mark G. stated that we know now that CVM does not consider eugenol to be a carcinogen and that the remaining toxicology studies are will be used to establish the ADI and MRL but will not stop its approval. Benzocaine, however, still has unresolved issues regarding MHGB and its carcinogenicity status is not presently known. Given the information at hand, eugenol seems to be the best choice now given what we know.
- Roz S. noted that there is another negative related to benzocaine, that being that it does not yet have a formulation.
- Dave E. and Mark G. discussed the value of paying for the genotoxicity studies for benzocaine using MSG funds. Dave E. was in favor of paying for the studies whereas Mark opposed it. Mark noted that the DAWG and the public-data generating partners have established a data development paradigm in which no public funds have been used to generate mammalian toxicology data packages. Mark also noted that we have always expected sponsors to complete the mammalian toxicology technical section as well as the CMC to ensure that the sponsors have some financial commitment to the drug development process. Mark noted that if a sponsor isn't willing to pay for a genotox battery, what will they do?
- Steve S. brought up the lack of residue depletion [for eugenol] and how such information must be factored into the "immediate release" document.
 - Don P. noted that it is best to establish that window [between the time to deplete the drug to an acceptable level and the time it takes before the anesthetized fish is catchable].
 - Don P. suggested that it might be possible to use isoeugenol to extrapolate to eugenol for the purpose of establishing eugenol's residue depletion boundary of the window.
- Steve S. stated that the strategy is to provide the Grants Committee with a plan based on contingencies related to the NCTR and NTP studies, and to inform them of the our plans to conduct the "immediate release" studies partly with base-funds.
 - Steve S. stated that he will go to the Grants Committee with the following:
 1. Grant funds will be spent on residue chemistry studies; in particular to complete the determinative method development if the funds have to be spent in a short timeframe.
 2. Coordination efforts will also be requested under the funding packet.
 3. Final decision on one drug will be based on the outcome of the review of the NTP study, the NCTR study and the "immediate release" document.
- **Discussion on the AFWA Drug Approval Process brochure**
 - Dave E. will provide edits to Steve S. who will forward to all DAWG members by the end of September.
 - Steve S. stated that the intent is to have it placed on everyone's website for their own use and for distribution.
 - Dave S. noted that he would like to distribute it at the World Aquaculture Conference sessions.

- Tom B. is to check, if possible, on the number of hits that the brochure is currently receiving.
- **Continuation of discussions on drug status**
 - Formalin
 - Roz S. stated that all that is left is Renate's saprolegniasis in channel catfish study to be written up and submitted.
 - H₂O₂
 - Roz S. referred the members to her handout
 - Dave E. stated that the columnaris/largemouth bass study has been completed and that the columnaris/bluegill study is just beginning, both of which are at Florida's Richloam facility.
 - Mark G. noted that he has been talking to hatcheries to do a coaster brook trout/gyrodactylus study this winter.
 - Dave E. said that AADAP is looking into conducting a rainbow trout/saprolegniasis study at the DC Booth NFH in SD.
 - OTC feed and 343
 - See Roz's handout
 - Florfenicol and TM-200
 - Roz S. noted that UMESC just received the North Central Regional Aquaculture Center's contract for identification of the etiological agent for motile aeromonas septicemia, which is part of an efficacy study
 - Mark G. stated that the contract was for \$75K/year for 2 years
 - Potassium permanganate
 - Dave E. stated that the DAWG needs to provide some guidance relative to John Boll's statement at this year's Workshop relative to Carus being very close to totally pulling the plug on their sponsorship.
 - Dave S. said he will contact Randy MacMillan regarding if/when they will get involved in data generation.
 - Mike M. stated he will do an informal survey as to what others [states?] feel about the DAWG potentially dropping KMnO₄ from our list of priority drugs.
 - Steve S. will ask Randy MacMillan the same question.
- The meeting was adjourned at 1700 hr.
- Attachment: Roz S.'s handout
- September 2008 DAWG Action Items
 1. **H₂O₂ Fact Sheets:** review draft at February meeting at AA2009, finalize, and determine distribution plan.

2. **New Fact Sheets:** set time line for remaining fact sheet.
3. **Carbonic Acid LRP Letter to CVM:** Steve S. will initiate letter to Dr. Dunham in support of the LRP list (sister the NAA letter). Reference DAWG meeting discussion, NAA letter, and identify drugs on the list needing adjustment. Deadline for sending the letter, All Hallows Eve.
4. **Letters to states participating in pivotal work:** Deferred to February AA2009 DAWG meeting for developmental discussion.
5. **Illegal Drug Use Letter:** DAWG will send letter to state and federal agencies reinforcing using approved drugs. AADAP will generate draft referencing recent AFS/AADAP poster. Letter to be sent by the chair prior to AA2009 meeting.
6. **Immediate Release Catchability of Sedated Fish Project:** Need suggestions from DAWG members on studies assessing catchability of sedated fish by All Hallows Eve to Steve S. This will require a teleconference call or calls prior to fully developing a project for initial discussion with CVM. A Doodle conference schedule will be forwarded by Steve S. by 9/24/08.
7. **AFWA Drug Approval Process Brochure:** Edits of brochure will be forwarded to Steve S. by the end of September. Updated brochure will be forwarded for final review before AA2009.