

Draft Minutes
National Aquaculture Drug Research Forum Meeting
Riviera Hotel and Casino
Rm 104
February 14, 3:15 – 4:30 pm

The meeting was moderated by Jim Bowker and Renate Reimschuessel. Attendees are listed in Table 1.

There was discussion on the following:

1. Use of the USFWS Aquatic Animal Drug Approval Partnership (AADAP) program website as a means to broadly disseminate information relative to the NADRF. Tom Bell, as the website guru, has agreed to establish and update this section of the AADAP website, which will be dedicated to exchange of NADRF information. The site will be updated as regularly as needed. NADRF Co-Chairs had previously agreed that, if there were no major objections, that the AADAP website would host this information

Action Required: None; Update site as needed

2. Use of another or additional website to disseminate information relative to NADRF. It was agreed upon, that if necessary, establishing another or additional website would be considered in the future.

Action Required: None

3. Subject Matter Expert Directory – following the August NADRF meeting, a SME Directory was drafted. After review and approval of all listed in the Directory, it was decided that the Directory was ready to be posted on the web. Recommendations for additions to the Directory can be made by anybody, including those interested in being included (and we will continue to solicit new additions). Updates to the Directory will be made by Jim Bowker.

Action Required: Add names, contact information, and area(s) of expertise to “new” members (e.g., Melissa Hobbs, USDA ARS SNARC); Add section for Sponsors and include new members in this category (e.g., Paul Duguette, Phibro Animal Health; Dick Endris, SPAH).

4. Posting efficacy and target animal safety research study protocols and associated Standard Operating Procedures on the NADRF website. Discussion focused on (1) whether there were Agency or University restrictions that might preclude posting such documents on a website for use by others, and (2) whether SOPs should remain in their current format or if they should be stripped down and made more generic. There appeared to be no issues for the following agencies that would preclude posting such information due to issues with respect to either a

higher level of peer-review or whether such documents are “intellectual property” of entities such as: USFWS, USGS, USDA, Miss. State Univ., and S. Ill. Univ. There may be issues with posting protocols and SOPs developed by CVM’s Office of Research. Jim Bowker will discuss this further with Renate R.

Note: There has been some follow-up discussion regarding posting Protocols and associated SOP’s on the AADAP website. As a result of these discussions, an additional action item or two were added to the list below that had not been discussed at the meeting.

Action Required: Jim will initiate further discussion to (1) determine if and how research protocols and associated SOP’s from other Technical Section subgroups (i.e., residue depletion, analytical methods development, environmental safety) will be utilized; and (2) create a situation where Protocols could “live” on the website of the author but could be accessed through the AADAP website. Dave Straus and Jim Bowker will work with the appropriate researchers in the NADRF to (1) reach agreement on what format SOPs should be in, and (2) to begin to assemble pertinent protocols and associated SOPs (in *.pdf format) to be posted on the NADRF or other website. Jim will also work with Susan Storey to see if there are protocols in Public Master files that might be suitable for posting. Jim Bowker will work with Jeff Meinertz to evaluate whether posting research protocols for Technical Section subgroups other than efficacy and TAS is feasible and/or practical, and how to set up a Protocol title that serves as a link to the authors home website.

Update of the activities from the Antimicrobial Resistance Group (Feb 14th, 2006, Las Vegas, NV)

AR Group Co-chairs
Drs. Christine Moffitt (U. Idaho) and S. Steve Yan (FDA)

Background: The antimicrobial resistance (AR) group was established in 2004. The group has met twice before. As a result of previous meetings, the group discussed the general data requirements for microbial food safety evaluation under FDA’s Guidance for Industry (GFI) #152 and identified the need for individual conferences with CVM for those seeking approvals for antimicrobial new animal drugs in food animals including aquaculture species. It was recognized by group participants that specific drug entities may have different drug-bacterium foci, and it may be best to present individual qualitative risk assessments.

Group’s Forum Summary

At this Forum meeting, the AR group provided updates on the following activities since the previous group meeting held in Bozeman, MT, on August 4th, 2005:

- 1) Dr. Moffitt suggested before the meeting that there is a need to clarify (at this Forum breakout session) the difference between FDA's GFIs #52 and #152, as there is some confusion on the scope of the these guidances;
- 2) Dr. Yan explained at this meeting that the two guidance address different aspects of human food safety. During the pre-approval process, GFI #152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern" (<http://www.fda.gov/cvm/Documents/fguide152.doc>), specifically addresses microbial food safety concerns (antimicrobial resistance) associated with the use of antimicrobial new animal drugs used in food animals including aquatic species. GFI #52 has been replaced with GFI #159, "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI" (<http://www.fda.gov/cvm/Documents/guide159.doc>). Although GFI #159 evaluates, as one of the endpoints, potential resistance development upon human exposure to antimicrobial drug residues contained in edible tissues derived from treated food animals, it is part of the toxicology component of human food safety evaluation. Work to address GFI #159 is reviewed by CVM's Toxicology Team (HFV-153) within the Human Food Safety Division, and Dr. Ana H. (Haydée) Fernandez should be contacted for any questions pertaining to GFI #159 assessments.
- 3) CVM's Microbial Food Safety Team (HFV-157) is charged with evaluating microbial food safety concerns (antimicrobial resistance) associated with the use of antimicrobial new animal drugs used in food animals including aquatic species, and can be contacted for clarification and explanation of the Agency's current policies on antimicrobial resistance during the pre-approval process. A poster on GFI #152 was presented by the team at this Aquaculture America 2006 meeting. HFV-157 representative(s) may attend the next group meeting in La Crosse, WI.
- 4) AR group participant Ms. Rosalie (Roz) Schnick reported that she has coordinated some drug sponsors to meet with HFV-157 to discuss resistance issues for specific products and will continue her role as an aquatic drug approval coordinator, assisting sponsors in their efforts to address microbial food safety.

February 2006 NADRF Meeting Participant List

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