
NATIONAL COORDINATOR FOR AQUACULTURE INADs/NADAs¹

Project *Termination Report* for the Period
July 15, 2004 to August 31, 2009

NCRAC FUNDING: \$89,000 (July 15, 2004 to August 31, 2009)

PARTICIPANT:

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REASON FOR TERMINATION

Funds terminated.

exemption requests and related submissions to CVM.

PROJECT OBJECTIVES

- (1) Ensure effective communications among groups involved with Investigational New Animal Drug/New Animal Drug Applications (INADs/NADAs), including Canada.
- (2) Serve as an information conduit between INAD/NADA applicants and the U.S. Food and Drug Administration's Center for Veterinary Medicine (CVM).
- (3) Identify and encourage prospective INAD participants to become involved in specific investigational studies and NADA approval-related research.
- (4) Seek the support and participation of pharmaceutical sponsors for INAD studies and NADAs and coordinate with INAD/NADA sponsors to achieve CVM approval more quickly.
- (5) Guide prospective and current INAD holders on the format for INAD

- (6) Identify existing data and remaining data requirements for NADA approvals.
- (7) Review, record, and provide information on the status of INADs and NADAs.
- (8) Encourage and seek opportunities for consolidating the INAD/NADA applications.
- (9) Coordinate educational efforts on aquaculture drugs as appropriate.
- (10) Identify potential funding sources for INAD/NADA activities.

PRINCIPAL ACCOMPLISHMENTS

The major objective of the National Coordinator for Aquaculture New Animal Drug Applications is to help obtain drug approvals for aquatic species through coordination of activities. These activities over the past five years have resulted in a number of NADA approvals and the

¹NCRAC has funded two National Coordinator projects. The termination report for the first project is contained in the 1999-00 Annual Progress Report. This Termination Report is for the second National Coordinator project. Ted R. Batterson served as the facilitator for this project interacting with a steering committee in overseeing the Coordinator's activities.

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potential for many more in the near future or that are under development. The major emphasis in the past five years of this position that began in 1995 is to work closely with the drug sponsor to ensure that all activities result in approvals. Following are those drugs and their label claims:²

ORIGINAL NADA APPROVALS

1. Florfenicol (Aquaflor®) for control of mortality in channel catfish due to enteric septicemia of catfish associated with *Edwardsiella ictaluri* (NADA #141-246; approved 10/24/05); sponsor: Intervet/Schering-Plough Animal Health (SPAH) ☼*
2. Hydrogen peroxide (35% PEROX-AID®) for control of mortality in (a) freshwater-reared finfish eggs due to saprolegniasis, (b) freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, and (c) freshwater-reared coolwater finfish and channel catfish due to external columnaris disease associated with *Flavobacterium columnare* (*Flexibacter columnaris*) (NADA #141-255; approved 1/11/07); sponsor: Eka Chemicals, Inc. ☼*

SUPPLEMENTAL NADA APPROVALS

1. Florfenicol (Aquaflor®) for control of mortality in freshwater-reared salmonids due to coldwater disease associated with

Flavobacterium psychrophilum (NADA #141-246; approved 3/19/07); sponsor: SPAH*

2. Florfenicol (Aquaflor®) for the control of mortality in all freshwater-reared salmonids due to furunculosis associated with *Aeromonas salmonicida* (NADA #141-246; approved 10/26/07); sponsor: SPAH*
3. Oxytetracycline dihydrate (Terramycin® 200 for Fish) to change formulation, oxytetracycline concentration, product name, and add approved lobster indication to the label for the control of Gaffkemia caused by *Aerococcus viridans* (NADA #038-439; approved 6/30/06); sponsor: Phibro Animal Health (PAH)
4. Oxytetracycline dihydrate (Terramycin® 200 for Fish) for control of mortality in (a) all freshwater-reared salmonids due to coldwater disease associated *Flavobacterium psychrophilum* and (b) *Oncorhynchus mykiss* due to columnaris disease associated with *Flavobacterium columnare*. To remove limitation on treating salmonids in water temperatures below 9°C. To add to the label of the previously approved indication for marking of skeletal tissue in Pacific salmon (NADA #038-439; approved 7/6/08); sponsor: PAH*
5. Oxytetracycline hydrochloride (Oxytetracycline HCL Soluble Powder-343®) for skeletal marking in finfish fry and fingerlings (NADA #200-247; approved 9/15/04); sponsor: IVX Animal Health, Inc., formerly Phoenix Scientific, Inc.
6. Oxytetracycline hydrochloride (Terramycin 343®) for skeletal marking in finfish fry and fingerlings (NADA

² ☼ Denotes a new drug that gained approval for an aquatic species;

* Denotes drug designations under the Minor Use and Minor Species (MUMS) Animal Health Act of 2004 that gives the sponsors of these drugs seven years of marketing exclusivity (as of October 27, 2009, the MUMS Office has granted 83 designations, 71 of those are to aquaculture drug sponsors, many of whom have received extensive help from the National Aquaculture NADA Coordinator); and

☼ Denotes a drug which is a candidate sedative (one of the drugs being considered by USDA for development; it is anticipated that there will be eight label claims for the selected sedative).

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#008-622; approved 6/13/05); sponsor:
Pfizer Animal Health

ABBREVIATED NADA APPROVALS

1. Formalin (Formacide-B®) for control of (a) external protozoa (*Chilodonella* spp., *Costia* spp., *Epistylis* spp., *Ichthyophthirius* spp. *Scyphidia* spp. and *Trichodina* spp.) on all finfish, (b) monogenetic trematode parasites (*Cleidodiscus* spp., *Dactylogyrus* spp., and *Gyrodactylus* spp.) on all finfish, (c) fungi of the family Saprolegniaceae on all finfish eggs, and (d) protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.) on penaeid shrimp (ANADA #200-414; approved July 17, 2007); sponsor: B.L. Mitchell, Inc.
2. Oxytetracycline hydrochloride (TETROXY AQUATIC®) for skeletal marking in finfish fry and fingerlings (ANADA #200-460; approved April 20, 2007); sponsor: Cross Vetpharm Group Ltd., Dublin, Ireland

CONDITIONAL APPROVAL

1. Florfenicol (Aquaflor®) for control of mortality in catfish due to columnaris disease associated with *Flavobacterium columnare* (NADA #141-246 CA1; approved April 18, 2007); sponsor: SPAH*

INDEXED DRUGS

1. Salmon gonadotropin Releasing Hormone analog and Domperidone (Ovaprim®) for use as a spawning aid in ornamental fish (Indexed 3/19/09); sponsor: Western Chemical, Inc.*
2. Metomidate (Aquacalm™) for the sedation and anesthesia of ornamental finfish (Indexed 6/3/09); Sponsor: Western Chemical, Inc.

Totals for NADAs and ANADAs (2004 to October 2009) = 11 NADAs and ANADAs for 5 drugs (2 new) and 14 different label claims

TOTALS for Indexed drugs (2008 to June 2009) = 2 Indexed drugs

NADA APPROVALS ANTICIPATED IN THE NEAR FUTURE

1. Chloramine-T (HALAMID® AQUA) for control of mortality in (a) freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum* and (b) walleye and possibly all warmwater finfish due to external columnaris disease associated with *Flavobacterium columnare* (original NADA); sponsor: Axcentive SARL, Bouc Bel Air, France*^{*}
2. Copper sulfate (Triangle Brand Copper Sulfate®) for control of mortality in channel catfish due to ichthyophthiriasis (original NADA); sponsor: Freeport-McMoRan Copper & Gold*^{*}
3. Emamectin benzoate (Slice®) for control of sea lice on saltwater-reared salmonids (original NADA); sponsor: SPAH*^{*}
4. Erythromycin thiocyanate (Aquamycin 100®) for control of mortality in salmonids due to bacterial kidney disease associated with *Renibacterium salmoninarum* (original NADA); sponsor: Bimeda, a Division of Cross Velpharm Group*^{*}
5. Florfenicol (Aquaflor®) for control of mortality in (a) freshwater-reared salmonids and warmwater finfish due to systemic columnaris disease associated with *Flavobacterium columnare* and (b) hybrid striped bass and tilapia due to streptococcosis associated with

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Streptococcus iniae (supplemental NADAs); sponsor: SPAH*

6. Formalin (Parasite-S®) for control of mortality in all freshwater-reared fish due to saprolegniasis (supplemental NADA); sponsor: Western Chemical, Inc.*
7. Hydrogen peroxide (35% PEROX-AID®) for control of mortality in (a) all warmwater fish due to saprolegniasis and (2) warmwater finfish due to external columnaris disease associated with *Flavobacterium columnare* (supplemental NADAs); sponsor: Eka Chemicals, Inc.*
8. 17 α -methyltestosterone (Masculinizing Feed for Tilapia®) for masculinization of female early life-stage tilapia (original NADA); sponsor: Rangen, Inc. * *
9. Oxytetracycline dihydrate (Terramycin® 200 for Fish) for skeletal marking in salmonids (supplemental NADA); sponsor: PAH*

Totals anticipated for NADAs (in the near future) = at least 9 NADAs for 9 drugs (5 new) and 12 different label claims

NADAS UNDER DEVELOPMENT FOR APPROVALS

1. Chloramine-T (HALAMID® AQUA) for control of mortality in coolwater finfish, except for walleye, due to external columnaris disease associated with *Flavobacterium columnare* (supplemental NADA); sponsor: Axcentive SARL, Bouc Bel Air, France*
2. Copper sulfate (Triangle Brand Copper Sulfate®) for control of mortality in channel catfish eggs due to saprolegniasis (supplemental NADA);

sponsor: Freeport-McMoRan Copper & Gold

3. Benzocaine for anesthesia, sedation during transport, short-term sedative for the purposes of handling for all freshwater-reared finfish (original NADA and supplemental NADAs); sponsor: Frontier Scientific, Inc. * * *
4. Benzocaine (BENZOAK®) to sedate to handleable condition all salt-water-reared salmonid finfish and to lightly sedate for transport purposes all salt-water-reared salmonid finfish (original NADA and supplemental NADAs); sponsor: ACD Pharmaceuticals AS, Ålesund, Norway * * *
5. Calcein (SE-MARK®) for skeletal marking in freshwater-reared finfish fry and fingerlings (original NADA); sponsor: Western Chemical, Inc. * *
6. Emamectin benzoate (Slice®) for control of external parasites on freshwater-reared finfish (supplemental NADA); sponsor: SPAH
7. Eugenol (AQUI-S E®) to sedate to handleable condition (a) all freshwater-reared salmonids, (b) all freshwater-reared coolwater finfish, (c) all freshwater-reared warmwater finfish, except freshwater-reared channel catfish, and (d) all salt-water-reared salmonid finfish and to lightly sedate for transport purposes (a) all freshwater-reared salmonids, (b) all freshwater-reared coolwater finfish, (c) all freshwater-reared warmwater finfish, except freshwater-reared channel catfish, and (d) all salt-water-reared salmonid finfish (original NADA and supplemental NADAs); sponsor: AQUI-S New Zealand Ltd., Lower Hutt, New Zealand * * *

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8. Fish-eezzz™ for use as a sedative for all freshwater-reared finfish (original NADA); sponsor: Micro Technologies, Inc. *☼
9. Florfenicol (Aquaflor®) for control of mortality in (a) freshwater-reared coolwater finfish due to systemic columnaris disease associated with *Flavobacterium columnare* and (b) freshwater-reared coolwater and warmwater finfish due to motile *Aeromonas septicemia* associated with *Aeromonas* spp. (supplemental NADAs); sponsor: SPAH*
10. Hydrogen peroxide (35% PEROX-AID®) for control of *Ichthyophthirius multifiliis*, *Ichthyobodo necator*, and *Gyrodactylus* spp in freshwater-reared salmonids, coolwater, and warmwater finfish (supplemental NADA); sponsor: Eka Chemicals, Inc.*
11. 17 α -methyltestosterone (Masculinizing Feed for Tilapia®) for masculinization of swordtails and rainbow trout (supplemental NADA); sponsor: Rangen, Inc.*
12. Oxytetracycline dihydrate (Terramycin® 200 for Fish) for control of mortality in (a) freshwater-reared coolwater and warmwater finfish due to motile *Aeromonas septicemia* associated with *Aeromonas* spp., (b) freshwater-reared salmonids due to external columnaris disease associated with *Flavobacterium columnare*, and (c) penaeid shrimp due to necrotizing hepatopancreatitis (supplemental NADAs): sponsor: PAH*
13. Oxytetracycline hydrochloride (Terramycin 343®) for control of mortality in fry and fingerlings of all coolwater and warmwater species of freshwater-reared finfish due to (a) external columnaris disease associated with *Flavobacterium columnare*, (b) systemic columnaris disease associated with *Flavobacterium columnare*, and (c) bacterial gill disease associated with *Flavobacterium branchiophilum* (supplemental NADAs); sponsor: Pfizer Animal Health*
14. Porphyrins (AquaFrin®) for control of mortality in freshwater-reared salmonids due to saprolegniasis (original NADA); sponsor: Frontier Scientific, Inc. *☼
15. Potassium permanganate (Cairox®) for control of mortality in (a) freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium branchiophilum*, (b) freshwater-reared finfish due to external columnaris disease associated with *Flavobacterium columnare*, and (c) freshwater-reared salmonids due to coldwater disease associated *Flavobacterium psychrophilum* (original NADA and supplemental NADAs); sponsor: Carus Chemical Company*☼*
16. Salmon gonadotropin Releasing Hormone analog (OVAPLANT®) for the induction of spawning in mature salmonids (original NADA); sponsor: Aquatic Life Sciences, c/o Western Chemical, Inc. *☼*
17. Tricaine methanesulfonate (TRICAINE-S®) for the euthanasia of finfish not intended for food (supplemental NADA); sponsor: Western Chemical, Inc.*

Totals anticipated for NADAs under development = at least 12 drugs (+ 1 sedative; 5 new drugs) and 34 (+8 sedative) different label claims

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IMPACTS

Establishment of the National Aquaculture NADA Coordinator position in May 1995 has resulted in coordination, consolidation, and increased involvement in the INAD/NADA process on high priority drugs of interest to aquaculture. INAD/NADA sponsors and other entities have initiated new INADs and made progress toward unified efforts on existing and new INADs/NADAs or have renewed their commitment to the INAD/NADA process on their drug products.

Coordination and educational efforts directed toward potential INAD/NADA applicants saved time and effort for both the industry and CVM. The National Coordinator for Aquaculture New Animal Drug Applications served as a conduit between an INAD/NADA applicant and CVM. The National Aquaculture NADA Coordinator helped alleviate time demands on CVM staff, thus allowing more time to process a greater number of applications as well as increasing the breadth of research endeavors within the industry.

This enhanced coordination will help and has helped gain original, supplemental, and abbreviated NADAs (see the listing above for details).

These approvals aids the aquaculture industries to reduce mortalities associated with infectious and handling diseases and to increase their efficiency by using spawning aids, gender manipulation aids, and sedatives. The domestic aquaculture industry is now better able to compete with foreign producers because there are more legal drugs for producers to use.

RECOMMENDED FOLLOW-UP ACTIVITIES

- Ensure that 17 α -methyltestosterone gets approved for use as a gender manipulation aid for tilapia and that effort is made to extend the approval to other finfish species (e.g., rainbow trout) of interest to the North Central Region.
- Ensure that the efficacy studies on florfenicol and oxytetracycline dihydrate are completed so that an approval can be gained for control of mortality in freshwater-reared coolwater and warmwater finfish due to motile *Aeromonas* septicemia associated with *Aeromonas* species.
- Ensure that the private aquaculture sector needs in the North Central Region are met for a sedative or anesthetic that can be used for transport and handling with either a zero or short-term withdrawal period.
- Determine what spawning aids the private aquaculture industries need and provide that information to researchers for action so that those drugs can gain approvals.
- Determine what the remaining drug approval needs are in the North Central Region and ensure that this information is transferred to researchers for action.

PUBLICATIONS, MANUSCRIPTS, PAPERS PRESENTED, AND REPORTS

See the Appendix for a cumulative output for all NCRAC-funded National Coordinator for Aquaculture INADs/NADAs activities.

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SUPPORT

YEAR	NCRAC- USDA FUNDING	OTHER SUPPORT					TOTAL SUPPORT
		UNIVER- SITY	INDUSTRY	OTHER FEDERAL	OTHER	TOTAL	
2004-05	\$9,000		\$22,476	\$46,295	\$26,000	\$94,771	\$103,771
2005-06	\$15,000		\$17,500	\$58,527	\$21,500	\$97,527	\$112,527
2006-07	\$20,000		\$26,980	\$52,855	\$22,200	\$102,035	\$122,035
2007-08	\$20,000		\$32,980	\$57,400	\$22,200	\$112,580	\$132,580
2008-09	\$25,000		\$36,480	\$50,000	\$22,700	\$109,180	\$134,180
TOTAL	\$89,000		\$136,416	\$265,077	\$92,900	\$494,893	\$605,093

APPENDIX

NATIONAL COORDINATOR FOR AQUACULTURE INADs/NADAs

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Publications in Print

- Griffin, B.R., R.A. Schnick, and W.H. Gingerich. 2000. Update on the Federal-State Aquaculture Drug Approval Project. *Aquaculture Magazine* 26(3):56-58.
- MacMillan, J.R., R.A. Schnick, and G. Fornshell. 2006. Stakeholder position paper: aquaculture producer. *Preventive Veterinary Medicine* 73(2-3):197-202.
- Schnick, R.A. 1996. Chemicals and drugs. Pages 347-354 in R.C. Summerfelt, editor. *Walleye culture manual*. NCRAC Culture Series #101, North Central Regional Aquaculture Center Publications Office, Iowa State University, Ames.
- Schnick, R.A. 1996. Cooperative fish therapeutic funding initiative: States in partnership with federal agencies to ensure the future of public fish culture. *Transactions of the 61st North American Wildlife and Natural Resources Conference* 61:6-10.
- Schnick, R.A. 1997. International regulatory aspects of chemical and drug residues. Pages 186-194 in R.E. Martin, R.L. Collette, and J.W. Slavin, editors. *Fish inspection, quality control, and HACCP: a global focus*. Technomic Publishing Company, Inc., Lancaster, Pennsylvania.
- Schnick, R.A. 1998. Approval of drugs and chemicals for use by the aquaculture industry. *Veterinary and Human Toxicology* 40(Supplement):9-17.
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- Schnick, R.A., D.J. Alderman, R. Armstrong, R. Le Gouvello, S. Ishihara, E.D. Lacierda, S. Percival, and M. Roth. 1997. Worldwide aquaculture drugs and vaccine registration progress. *Bulletin of the European Association of Fish Pathologists* 17(6):251-260.
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- Schnick, R.A. 2007. News: Fisheries: major aquaculture drug approval for 35% PEROX-AID®. *Fisheries* 32(2):58.
- Schnick, R.A. 2007. News: Fisheries: major aquaculture drug approval (Aquaflor®). *Fisheries* 32(4):162, 190.
- Schnick, R.A. 2007. News: Fisheries: Aquaflor® approved for furunculosis in salmonids. *Fisheries* 32(12):578.
- Schnick, R.A. 2008. News: Fisheries: Aquaculture drug approval for Terramycin® for Fish. *Fisheries* 33(7):317.

Papers Presented

- Gingerich, W.H. and R.A. Schnick. 1997. Federal-state aquaculture drug approval partnership program. 28th Annual Meeting of the World Aquaculture Society, Seattle, Washington, February 19-23, 1997.
- Gingerich, W.H. and R.A. Schnick. 1997. Aquaculture drug registration study progress report. Meeting of the International Association of Fish and Wildlife Agencies, Inland Fisheries Committee, Washington, D.C. March 16, 1997.

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- Laurenson, J.P., B.L. Baxter, R.M. Kauffman, J.C. Cleland, and R.A. Schnick. 2005. Development and use of the Aquaculture Risk Information System (AQRIS) and Risk Ranking Tool (AQRRT) for prioritizing import sampling and other activities (poster). 2005 FDA Science Forum, Washington, D.C., April 27-29, 2005.
- MacMillan, R., and R.A. Schnick. 2005. MUMS update: Positive impact of MUMS legislation. 11th Annual Drug Approval Coordination Workshop, Bozeman, Montana, August 2-3, 2005.
- Ringer, R.K. 1993. Workshop on INADs, NADAs, and the IR-4 Project. California Aquaculture Association, Oakland, October 11, 1993.
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- Ringer, R.K. 1994. National INAD Coordinator's role in aquaculture. 25th Annual Meeting of the World Aquaculture Society, New Orleans, January 12-18, 1994.
- Ringer, R.K. 1994. State of current USDA regulations on drug, therapeutic, and chemical use. North Carolina Aquaculture Development Conference, New Bern, February 5, 1994.
- Ringer, R.K. 1994. Investigational New Animal Drugs Workshop. Tropical and Subtropical Regional Aquaculture Center Industry Advisory Council Meeting, Honolulu, Hawaii, March 14, 1994.
- Schnick, R.A. 1995. Idaho Aquaculture Association Annual Meeting, Twin Falls, Idaho, May 19-22, 1995.
- Schnick, R.A. 1995. Chemistry in Aquaculture Symposium. Convener and presenter, Cullowhee, North Carolina, May 31-June 2, 1995.
- Schnick, R.A. 1995. FWS/INAD Coordination Workshop. Presenter and coordinator, Bozeman, Montana, August 1-4, 1995.
- Schnick, R.A. 1995. Funding crisis for drugs/therapeutants and coordination of aquaculture INADs/NADAs. Annual meeting of the U.S. Trout Farmers Association, Twin Falls, Idaho, September 27-30, 1995.
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- Schnick, R.A. 1995. INAD/NADA Coordinators workshop under the sponsorship of CVM. Organizer and presenter, Rockville, Maryland, November 1-2, 1995.
- Schnick, R.A. 1996. Status of aquaculture INADs and NADAs. Presenter and coordinator, Midcontinent Warmwater Fish Culture Workshop and INAD/NADA Coordination Meetings, Council Bluffs, Iowa, February 6-8, 1996.
- Schnick, R.A. 1996. INAD/NADA update. Western Regional Aquaculture Expo '96, Sacramento, California, February 7-9, 1996.
- Schnick, R.A. 1996. National Aquaculture NADA Coordinator update. Working Group on Quality Assurance in Aquaculture Production, Arlington, Texas, February 14, 1996.
- Schnick, R.A. 1996. Proper use of fish therapeutants based on legal requirements—gill lice, bacterial gill disease, furunculosis, etc. Annual Meeting of the Michigan Aquaculture Association, East Lansing, Michigan, February 23, 1996.
- Schnick, R.A. 1996. Status of aquaculture drug development. Great Lakes Fish Disease Workshop, La Crosse, Wisconsin, February 28, 1996.
- Schnick, R.A. 1996. Advances in therapeutants. Southeastern Fish Diagnosticians' Workshop, Mississippi State, Mississippi, March 13-14, 1996.
- Schnick, R.A. 1996. Report on progress and research study objectives of the Federal-State Drug Registration Partnership. Meeting of the International Association of Fish and Wildlife Agencies, *ad hoc* Committee on Aquaculture, Tulsa, Oklahoma, March 24, 1996.
- Schnick, R.A. 1996. Cooperative fish therapeutic funding initiative—States in partnership with Federal agencies to ensure the future of public

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- Schnick, R.A. 1996. International regulatory aspects of chemical and drug residues. International Conference on Fish Inspection and Quality, Arlington, Virginia, May 19-24, 1996.
- Schnick, R.A. 1996. Aquaculture drug approval progress in the United States. Aquaculture Canada '96, 13th Annual Meeting of the Aquaculture Association of Canada, Ottawa, Ontario, June 2-5, 1996.
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- Schnick, R.A. 1996. Overview of pivotal study protocol requirements. Chloramine-T Pivotal Efficacy Protocol Development Workshop, Kansas City, Missouri, November 7-8, 1996.
- Schnick, R.A. 1997. INAD and drug clearance update. Midcontinent Warmwater Fish Culture Workshop, Springfield, Missouri, February 3-5, 1997.
- Schnick, R.A. 1997. Overview of partnerships for aquaculture drug approvals. Partnerships for Aquaculture Drug Approvals: Models for Success. Chair of Special Session at 28th Annual Meeting of the World Aquaculture Society, Seattle, Washington, February 19-23, 1997.
- Schnick, R.A. 1997. Current status and future needs for drugs in aquaculture: regional needs. Workshop on International Harmonization for Drugs and Biologics, Seattle, Washington, February 24, 1997.
- Schnick, R.A. 1997. Aquaculture drug approval progress for the catfish industry. Catfish Farmers of America 1997 National Convention, Nashville, Tennessee, February 27-March 1, 1997.
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- Schnick, R.A. 1997. Review of the November 1996 chloramine-T data requirements; Data call-in. Chloramine-T INAD Coordination Workshop, Bozeman, Montana, August 5, 1997.
- Schnick, R.A. 1997. Overview of NADA Coordinator activities. FWS-INAD Coordination Workshop, Bozeman, Montana, August 7, 1997.
- Schnick, R.A. 1997. NADA Coordinator update. JSA Working Group on Quality Assurance in Aquaculture Production, Washington, D.C., August 21-22, 1997.
- Schnick, R.A. 1997. Worldwide aquaculture drug approvals through partnerships in the United States. Seminar to Schering-Plough Animal Health, Union, New Jersey, August 26, 1997.
- Schnick, R.A. 1997. Progress with registration of drugs and vaccines for aquaculture: introduction and the United States. Chair and presenter at Workshop on "Models of Partnership for Registration of Drugs and Vaccines" and "Round Table on Progress with Registration of Drugs and Vaccines for Aquaculture," EAFP Eighth International Conference on Diseases of Fish and Shellfish, Edinburgh, Scotland, September 14-19, 1997.
- Schnick, R.A. 1997. Role of the national NADA office in aquaculture drug approval activities. Aquaculture Drugs and Chemicals Approval Update, Arlington, Virginia, September 30, 1997.
- Schnick, R.A. 1997. Partial support for National Coordinator for Aquaculture New Animal Drug

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- Applications. WRAC IAC/TC Meeting, Reno, Nevada, October 20-21, 1997.
- Schnick, R.A. 1998. Priorities subcommittee report. Workshop on International Harmonization of Aquaculture Drugs and Biologics, Las Vegas, Nevada, February 15, 1998.
- Schnick, R.A. 1998. Upcoming successes for aquaculture drug approvals in the United States through unique partnerships. Special Session, "Aquaculture drug approvals—a success story about to happen," 29th Annual Meeting of the World Aquaculture Society, Las Vegas, Nevada, February 15-19, 1998.
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- Schnick, R.A. 1998. Progress on aquaculture drug approvals. Fisheries Management and Habitat Protection Statewide Training Conference, Green Bay, Wisconsin, March 10-12, 1998.
- Schnick, R.A. 1998. IAFWA Project status and progress. Meeting of the Inland Fisheries Committee, North American Natural Resources Conference, Orlando, Florida, March 20-24, 1998.
- Schnick, R.A. 1998. Use of chemicals in fish management and fish culture: past and future. Symposium, "Xenobiotic metabolism in fish," American Chemical Society, Dallas, Texas, March 29-April 2, 1998.
- Schnick, R.A. 1998. Drug approval partnership. American Fisheries Society, Fisheries Administrator's Section, Phoenix, Arizona, April 17-19, 1998.
- Schnick, R.A. 1998. Overview of NADA Coordinator activities. FWS-INAD Coordination Workshop, Bozeman, Montana, August 4-5, 1998.
- Schnick, R.A. 1998. NADA Coordinator update. Meeting of the JSA Working Group on Quality Assurance in Aquaculture Production, Washington, D.C., September 4, 1998.
- Schnick, R.A. 1998. Overview of the activities of the National Coordinator for Aquaculture New Animal Drug Applications and suggestions for enhancing dialogue with the Minor Use Animal Drug Program. Meeting of the Minor Use Animal Drug Program Technical Committee for NRSP-7, Rockville, Maryland, September 22, 1998.
- Schnick, R.A. 1998. The effect of the Animal Drug Availability Act of 1996 and the FDA Modernization Act of 1997 on approvals of animal health products for minor species/minor uses. 1998 Animal Health Institute Joint Meeting, San Diego, California, November 9, 1998.
- Schnick, R.A. 1998. Overview of IAFWA Project Status. Coordination meeting for IAFWA Aquaculture Drug Approval Project, La Crosse, Wisconsin, November 19-20, 1998.
- Schnick, R.A. 1998. Overview of the international aspects of antimicrobial sensitivity determination and the need for harmonization in aquaculture drugs. Workshop on MIC Methodology (EU Concerted Action - Fair-CT97-3760), Weymouth, England, November 24-27, 1998.
- Schnick, R.A. 1999. National NADA Office aquaculture drug approval activities. Aquaculture Drugs and Chemicals Approval Update—1999, Arlington, Virginia, January 11, 1999.
- Schnick, R.A. 1999. Introduction and discussion of INADs and new NADAs. "Aquaculture drug approvals through producer INADs,"

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- Schnick, R.A. 1999. Update on the IAFWA drug approval process. 1999 Mid-Continent Fish Culture Workshop, North Kansas City, Missouri, February 2-3, 1999.
- Schnick, R.A. 1999. Aquaculture drug approval progress for the catfish industry. Annual Meeting of the Catfish Farmers of America, New Orleans, Louisiana, February 18-20, 1999.
- Schnick, R.A. 1999. Advances in fishery chemicals. 1999 Colorado/Wyoming AFS Meeting, "Reeling in the next millennium," Cheyenne, Wyoming, March 1-3, 1999.
- Schnick, R.A. 1999. Overview of florfenicol approval process. Coordination meeting for florfenicol efficacy studies, La Crosse, Wisconsin, March 17-18, 1999.
- Schnick, R.A. 1999. Progress and issues related to the federal-state aquaculture drug approval partnership. Meeting of the IAFWA Drug Approval Oversight Subcommittee, San Francisco, California, March 25-28, 1999.
- Schnick, R.A. 1999. International cooperation toward aquaculture drug approvals. 30th Annual Meeting of the World Aquaculture Society, Sydney, Australia, April 26-May 2, 1999. (Keynote address)
- Schnick, R.A. 1999. USA programs related to aquaculture drug approval development and issues. Australian Department of Agriculture, Fisheries and Forestry, Canberra, Australia, May 3, 1999.
- Schnick, R.A. 1999. Overview of NADA Coordinator activities. USFWS - INAD Coordination Workshop, Bozeman, Montana, August 4-5, 1999.
- Schnick, R.A. 1999. Aquaculture NADA Coordinator update. Meeting of the JSA Working Group on Quality Assurance in Aquaculture Production, Washington, D.C., September 9, 1999.
- Schnick, R.A. 1999. International harmonisation of antibacterial agent approvals and susceptibility testing. Chaired Workshop at European Association of Fish Pathologists 9th International Conference, "Diseases of Fish and Shellfish," Rhodes, Greece, September 19-24, 1999.
- Schnick, R.A. 2000. National Coordinator for Aquaculture New Animal Drug Applications update. Working Group on Quality Assurance in Aquaculture Production at Aquaculture America 2000, New Orleans, Louisiana, February 2, 2000.
- Schnick, R.A. 2000. Introduction and background to the MUMS legislation. Special Session "Future drug approval process: MUMS opportunities," Aquaculture America 2000, New Orleans, Louisiana, February 2-5, 2000.
- Schnick, R.A. 2000. You can make a difference. Special Session "Future drug approval process: MUMS opportunities." Aquaculture America 2000, New Orleans, Louisiana, February 2-5, 2000.
- Schnick, R.A. 2000. Drug approvals. Mid-Continent Warmwater Fish Culture Workshop, Council Bluffs, Iowa, February 7-8, 2000.
- Schnick, R.A. 2000. New drug approval progress. Missouri Aquaculture Association Annual Meeting, Cape Girardeau, Missouri, February 22-23, 2000.
- Schnick, R.A. 2000. Update on the Federal-State Aquaculture Drug Approval Project. International Association for Fish and Wildlife Agencies, Drug Approval Working Group Meeting, Chicago, Illinois, March 26, 2000.
- Schnick, R.A. 2004. Brief overview—Recent developments and highlights on drug approval progress. Drug Approval Working Group Meeting, Atlantic City, New Jersey, September 27, 2004.
- Schnick, R.A. 2004. Review and Policy Guidance #5—Strategic plan for end point to IAFWA Project. Drug Approval Working Group Meeting, Atlantic City, New Jersey, September 27, 2004.

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- Schnick, R.A. 2004. IAFWA Project Work Plan—National Coordinator for Aquaculture New Animal Drug Applications. Post-Drug Approval Working Group Meeting, Atlantic City, New Jersey, September 27, 2004.
- Schnick, R.A. 2004. Aquaculture outside of NRSP-7. NRSP-7 Fall 2004 Meeting, Rockville, Maryland, October 6, 2004.
- Schnick, R.A. 2004. Drug issue and needs for Southern U.S. Marine Aquaculture. Workshop on Marine Aquaculture Drug and Chemotherapeutant Issues and Needs on Southern United States, Sarasota, Florida, November 16, 2004. PowerPoint presentation distributed to interested entities and placed on the National Aquaculture NADA Coordinator Web site.
- Schnick, R.A. 2005. An update on the approval of therapeutants for use in aquaculture. Coolwater Fish Culture Workshop, Cherry Valley Lodge, Ohio, January 9-11, 2005.
- Schnick, R.A. 2005. Need for a zero withdrawal anesthetic for coolwater fish culture. Coolwater Fish Culture Workshop, Cherry Valley Lodge, Ohio, January 9-11, 2005.
- Schnick, R.A. 2005. Drug Matrix Database. JSA Working Group on Quality Assurance in Aquaculture Production, Aquaculture America 2005, New Orleans, Louisiana, January 17, 2005.
- Schnick, R.A. 2005. INAD/NADA Overview—17 α -methyltestosterone. 17-MT Mini-Session, Aquaculture America 2005, New Orleans, Louisiana, January 18, 2005.
- Schnick, R.A. 2005. Responsible use of therapeutants drugs in aquaculture. Environmental and Ethical Issues in Aquaculture, Aquaculture America 2005, New Orleans, Louisiana, January 19, 2005.
- Schnick, R.A. 2005. Update on product approvals for fish health. Striped Bass Industry Forum, Aquaculture America 2005, New Orleans, Louisiana, January 19, 2005.
- Schnick, R.A. 2005. Highlights and progress toward aquaculture drug approvals. Producer Session “Successes in Drug Approvals,” Aquaculture America 2005, New Orleans, Louisiana, January 20, 2005.
- Schnick, R.A. 2005. Highlights on IAFWA Project drug approval progress. Drug Approval Working Group Meeting, Arlington, Virginia, March 16, 2005.
- Schnick, R.A. 2005. Questions in Strategic Plan for End Point to the IAFWA Project. Drug Approval Working Group Meeting, Arlington, Virginia, March 16, 2005.
- Schnick, R.A. 2005. IAFWA Project Work Plan—National Coordinator for Aquaculture New Animal Drug Applications. Drug Approval Working Group Meeting, Arlington, Virginia, March 16, 2005.
- Schnick, R.A. 2005. Aquaculture drug approval progress. NRSP-7 Meeting, Rockville, Maryland, May 19, 2005.
- Schnick, R.A. 2005. Upcoming aquaculture drug approvals. American Fisheries Society Fish Health Section Meeting, Bloomington, Minnesota, July 27-29, 2005.
- Schnick, R.A. 2005. Matrices for tracking major aquaculture drug approval development. 11th Annual Drug Approval Coordination Workshop, Bozeman, Montana, August 2-3, 2005.
- Schnick, R.A. 2005. Brief overview—recent developments and highlights on drug approval progress. Drug Approval Working Group Meeting, Nashville, Tennessee, September 15, 2005.
- Schnick, R.A. 2005. Overview of the status of (1) Expansion and extension of the oxytetracycline (OTC) label claims, (2) Initial label claims for chloramine-T, (3) Microbial Food Safety submissions on these and other aquaculture drugs, and (4) Information on public and private aquaculture production statistics. Meeting on Microbial Food Safety Data Requirements for Oral Oxytetracycline and Chloramine-T for Approval in U.S. Commercial and Public Freshwater Aquaculture, Rockville, Maryland, October 5, 2005.
- Schnick, R.A. 2006. Internet-based drug matrix database and application. Working Group on Quality Assurance in Aquaculture Production

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- meeting at Aquaculture America 2006, Las Vegas, Nevada, February 13, 2006.
- Schnick, R.A. 2006. 2005 Survey to determine unmet label claims for the IAFWA Project drugs. Working Group on Quality Assurance in Aquaculture Production meeting at Aquaculture America 2006, Las Vegas, Nevada, February 13, 2006.
- Schnick, R.A. 2006. Drug approvals for salmonids: success soon. US Trout Farmers Association Industry Update at Aquaculture America 2006, Las Vegas, Nevada, February 14, 2006.
- Schnick, R.A. 2006. 17alpha-methyltestosterone activities timeline. 17alpha-methyltestosterone: Approval status and activities overview at Aquaculture America 2006, Las Vegas, Nevada, February 14, 2006.
- Schnick, R.A. 2006. Update on product approvals for fish health. Striped Bass Growers Association Industry Update at Aquaculture America 2006, Las Vegas, Nevada, February 15, 2006.
- Schnick, R.A. 2006. Partnerships toward the approval of 17-MT. American Tilapia Association Industry Update at Aquaculture America 2006, Las Vegas, Nevada, February 15, 2006.
- Schnick, R.A. 2006. Recent aquaculture drug approval successes. Producer Session “Aquaculture Drug Approval Successes” at Aquaculture America 2006, Las Vegas, Nevada, February 16, 2006.
- Schnick, R.A. 2006. Special funding for aquaculture drug approvals. Producer Session “Aquaculture Drug Approval Successes” at Aquaculture America 2006, Las Vegas, Nevada, February 16, 2006.
- Schnick, R.A. 2006. Update and status of IAFWA Project drugs. Drug Approval Working Group, Columbus, Ohio, March 21, 2006.
- Schnick, R.A. 2006. Brief highlights of the last six months for IAFWA Project drugs. Drug Approval Working Group, Columbus, Ohio, March 21, 2006.
- Schnick, R.A. 2006. Drug approval status: Then and now. 31st Eastern Fish Health Workshop, Charleston, South Carolina, March 27-31, 2006.
- Schnick, R.A. 2006. Drug approval status: Why we are where we are and not where you thought we should be. 31st Eastern Fish Health Workshop, Charleston, South Carolina, March 27-31, 2006.
- Schnick, R.A. 2006. Presentation to NRSP-7. NRSP-7 Spring Meeting 2006, Rockville, Maryland, May 11, 2006.
- Schnick, R.A. 2006. Private aquaculture sector survey needed to complete the exciting progress toward drug approvals. National Association of State Aquaculture Coordinators, Little Rock, Arkansas, May 23-26, 2006.
- Schnick, R.A. 2006. History of efforts toward aquaculture drug approvals. Center for Veterinary Medicine, Rockville, Maryland, June 5, 2006.
- Schnick, R.A. 2006. Overview of Public Aquaculture Sector Survey to determine unmet label claims for IAWFA Project drugs. 12th Annual Aquaculture Drug Approval Coordination Workshop, La Crosse, Wisconsin, August 1-2, 2006.
- Schnick, R.A. 2006. Introduction to non-IAFWA projects for aquaculture drug approvals. 12th Annual Aquaculture Drug Approval Coordination Workshop, La Crosse, Wisconsin, August 1-2, 2006.
- Schnick, R.A. 2006. Aquaculture NADA Coordinator’s perspective on non-IAFWA Project drugs. 12th Annual Aquaculture Drug Approval Coordination Workshop, La Crosse, Wisconsin, August 1-2, 2006.
- Schnick, R.A. 2006. Update on AFWA Project Drugs. AFWA Drug Approval Working Group, Aspen, Colorado, September 18, 2006.
- Schnick, R.A. 2006. Advances toward drug approvals for farmed fish. Penn Aqua 2006, Harrisburg, Pennsylvania, September 20-23, 2006.
- Schnick, R.A. 2006. Advances in aquaculture drug approvals. NRSP-7, La Crosse, Wisconsin, October 10, 2006.
- Schnick, R.A. 2006. Actual and anticipated NADA approvals for 2006-2009. JSA Working Group on Aquaculture Drugs, Biologics, and Pesticides Meeting, Washington, D.C., October 25, 2006.

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- Schnick, R.A. 2006. Effect of MUMS designations on sponsor participation. JSA Working Group on Aquaculture Drugs, Biologics, and Pesticides Meeting, Washington, D.C., October 25, 2006.
- Schnick, R.A. 2006. Proposed actions to meet unmet label claims from the Public Aquaculture Sector Survey. JSA Working Group on Aquaculture Drugs, Biologics, and Pesticides Meeting, Washington, D.C., October 25, 2006.
- Schnick, R.A. 2007. Update on aquaculture drug approvals. North Central Regional Aquaculture Center Annual Meeting, Columbus, Ohio, February 9-11, 2007.
- Schnick, R.A. 2007. Update on new drug approvals for catfish. Catfish Farmers of America Annual Meeting, Orange Beach, Alabama, February 15-18, 2007.
- Schnick, R.A. 2007. Recent aquaculture drug approval successes. Aquaculture 2007, Producer Session "Aquaculture drug approval successes," San Antonio, Texas, February 28, 2007.
- Schnick, R.A. 2007. Progress on drug approvals. Aquaculture 2007, Striped Bass Growers Association Annual Meeting, San Antonio, Texas, February 28, 2007.
- Schnick, R.A. 2007. Progress on drug approvals for salmonids. Aquaculture 2007, US Trout Farmers Association Forum, San Antonio, Texas, February 27, 2007.
- Schnick, R.A. 2007. Progress on drug approvals for tilapia. Aquaculture 2007, American Tilapia Association Session, San Antonio, Texas, March 1, 2007.
- Schnick, R.A. 2007. Status of aquaculture drug approvals. NRSP-7 Spring Meeting, Rockville, Maryland, March 5-7, 2007.
- Schnick, R.A. 2007. AFWA Project Drugs: Remaining requirements and progress September 2006 to March 2007, Drug Approval Working Group Meeting, Portland, Oregon, March 22, 2007.
- Schnick, R.A. 2007. Thoughts on administrative NADA process, Drug Approval Working Group Meeting, Portland, Oregon, March 22, 2007.
- Schnick, R.A. 2007. How Extension Specialists can help in the aquaculture drug approval process. 4th National Aquaculture Extension Conference, Cincinnati, Ohio, April 30 to May 4, 2007.
- Schnick, R.A. 2007. Dialog with Upper Midwest Environmental Sciences Center on Fisheries Management Chemicals and Drugs Program. Upper Midwest Environmental Sciences Center Partner Meetings, La Crosse, Wisconsin, May 10-11, 2007.
- Schnick, R.A. 2007. Progress towards aquaculture drug approvals. 144th AVMA Annual Convention, Washington, D.C., July 14-18, 2007.
- Schnick, R.A. 2007. Possibilities for expediting Canadian aquaculture drug approval processes. Veterinary Drugs Directorate, Ottawa, Ontario, Canada, July 18, 2007.
- Schnick, R.A. 2007. Historical background to this fabulous partnership. 13th Annual Drug Approval Coordination Workshop, Bozeman, Montana, July 31-August 1, 2007.
- Schnick, R.A. 2007. The future of this fabulous partnership. 13th Annual Drug Approval Coordination Workshop, Bozeman, Montana, July 31-August 1, 2007.
- Schnick, R.A. 2007. The AFWA Project: NADA approvals, label claims under development for initial and/or expanded NADA approvals, and status of technical section completions. 13th Annual Drug Approval Coordination Workshop, Bozeman, Montana, July 31-August 1, 2007.
- Schnick, R.A. 2007. Progress on new aquaculture drug approvals for disease management. Disease Management Strategies for the Aquatic Environment: Alternatives & Innovations. AFS Annual Meeting, San Francisco, California, September 5, 2007.
- Schnick, R.A. 2007. Strategic review of UMESC's Fish Management and Drug Research Program. La Crosse, Wisconsin, September 13, 2007.
- Schnick, R.A. 2007. Update discussion of AFWA Project Drugs. Drug Approval Working Group.

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- AFWA Annual Meeting, Louisville, Kentucky, September 17-18, 2007.
- Schnick, R.A. 2007. Major efforts and accomplishments: National Coordinator for Aquaculture New Animal Drug Applications. Center for Veterinary Medicine, Rockville, Maryland, December 5, 2007.
- Schnick, R.A. 2007. Efforts to gain aquaculture drug approvals. Center for Veterinary Medicine, Rockville, Maryland, December 5, 2007.
- Schnick, R.A. 2008. Update on product approvals for fish health. Striped Bass Growers Association Industry Forum, Aquaculture America 2008, Orlando, Florida, February 10, 2008.
- Schnick, R.A. 2008. Overall progress toward aquaculture drug approvals. Aquaculture Drug Approval Successes, Aquaculture America 2008, Orlando, Florida, February 12, 2008.
- Schnick, R.A. 2008. Status report on aquaculture drug approvals. North Central Regional Aquaculture Center Annual Program Planning Meeting, Indianapolis, Indiana, February 22-24, 2008.
- Schnick, R.A. 2008. Isoeugenol (AQUI-S®) and sedative issue. Drug Approval Working Group, 73rd North American Wildlife and Natural Resources Conference, Phoenix, Arizona, March 26-28, 2008.
- Schnick, R.A. 2008. Update discussion on AFWA Project drugs. Drug Approval Working Group, 73rd North American Wildlife and Natural Resources Conference, Phoenix, Arizona, March 26-28, 2008.
- Schnick, R.A. 2008. Partnerships: The key to AFWA Project successes. 14th Annual Drug Approval Coordination Workshop, Bozeman, Montana, July 29-31, 2008.
- Schnick, R.A. 2008. Zero withdrawal sedative dilemma and solutions. 14th Annual Drug Approval Coordination Workshop, Bozeman, Montana, July 29-31, 2008.
- Schnick, R.A. 2008. Aquaculture drug approvals: successes and challenges. U.S. Trout Farmers Association Annual Meeting, Milwaukee, Wisconsin, September 19, 2008.
- Schnick, R.A. 2008. It's been a wonderful life. Onalaska Rotary Club, Onalaska, Wisconsin, December 10, 2008.
- Schnick, R.A. 2009. Aquaculture drug approvals: successes and challenges. NRSP-7 Spring Meeting, Washington, D.C., January 26, 2009.
- Schnick, R.A. 2009. Introduction and brief overall progress toward aquaculture drug approvals, Part I. Aquaculture Drug Approval Successes, Aquaculture America 2009, Seattle, Washington, February 18, 2009.
- Schnick, R.A. 2009. Overall progress toward aquaculture drug approvals, Part II. Aquaculture Drug Approval Successes, Aquaculture America 2009, Seattle, Washington, February 18, 2009.
- Schnick, R.A. 2009. Update on product approvals for fish health. Striped Bass Growers Association, Aquaculture America 2009, Seattle, Washington, February 18, 2009.
- Schnick, R.A. 2009. Aquaculture drugs—Status report. North Central Regional Aquaculture Center Board of Directors and 2009 Program Planning Meeting, Kansas City, Missouri, February 28, 2009.
- Schnick, R.A. 2009. 45 years of efforts toward aquaculture drug approvals: a perspective. 15th Annual Drug Approval Coordination Workshop, Little Rock, Arkansas, June 9, 2009.
- Schnick, R.A. 2009. National Aquaculture NADA Coordinator perspective on all aquaculture drug approvals. 15th Annual Drug Approval Coordination Workshop, Little Rock, Arkansas, June 9, 2009.
- Schnick, R.A. 2009. Update on all sedative needs & what we need to do to meet those needs. 15th Annual Drug Approval Coordination Workshop, Little Rock, Arkansas, June 10, 2009.
- Schnick, R.A. 2009. Humble reflections on the aquaculture drug approval process and progress: a 40-year perspective. 14th European Association of Fish Pathologists Conference on Diseases of Fish and Shellfish, Prague, Czech Republic, September 14-19, 2009.
- Schnick, R.A. 2009. Transition October 2009–April 2010: The National Coordinator for Aquaculture New Animal Drug Applications, Center for

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