FROM THE PRESIDENT

Sanja Modric

Dear colleagues,

There has been a lot going on at AAVPT since the last Newsletter was issued in April. We successfully completed the first Pharmacology Teaching Workshop in College Station, TX in June 2012. Many thanks to Dr. Virginia Fajt and Texas A&M College of Veterinary Medicine & Biomedical Sciences for organizing and hosting this important event. For more information on the AAVPT Teaching Initiative, see the Education Committee Report.

In collaboration with the US Pharmacopeia (USP) we co-sponsored a 2-day workshop on Solubility Criteria for Veterinary Drugs, which was held at USP Headquarters in Rockville, MD on November 7-8, 2012. Based on the recommendations from the workshop, USP will develop a general chapter on determining solubility for canine and bovine drugs.

We finally got the new website up and running (through Affiniscape). Thanks to Ralph Claxton for starting the project and a huge THANKS to Carol Davis and Susan Longhofer for finally making it happen. The website link is still the same as before (http://www.aavpt.org/), but there are lots of changes and improvements. If you haven’t already visited it, take a look and see what’s new. The website finally allows us to manage our membership database online and it provides a secure and simple dues payment system. As a result, you don’t have an excuse for not paying your dues any longer, so – just do it! In addition, the new system allows us to have online registration for our meetings. This will make the registration and payment procedure for our meetings more efficient and will reduce the workload for our treasurer and secretary.

As always, let me know if you have any ideas for future meetings or workshops, or if you want to become more actively involved in the Academy. We always welcome new people and new ideas to make the Academy stronger!

I hope to see many of you at the next Biennial Symposium in May 2013. There will be several interesting sessions and focused discussions, and – as always – many opportunities to see old friends and meet some new ones.

As we’re entering another wonderful holiday season, I wish you all happy holidays and lots of joy, love, success and health in 2013.

ANNOUNCEMENTS

• 18th BIENNIAL AAVPT SYMPOSIUM WILL BE HELD MAY 20-22, 2013 AT THE BOLGER CENTER IN POTOMAC, MD

• CALL FOR AWARD NOMINATIONS (SEE PAGES 7 & 9)

• CALL FOR ABSTRACTS (SEE PAGES 11 & 12)

• REQUEST FOR HISTORICAL AAVPT INFORMATION (SEE PAGE 6)
The program will focus on three main themes
• latest requirements for bioanalytical method validation
• cutting edge utilization of pharmacokinetics
• improving veterinary drug labels

Additional topics include a discussion on veterinary-related activities at US Pharmacopeia, a follow-up from the AAVPT teaching workshop, as well as, student posters/oral presentations and AAVPT awards. The symposium will once again feature a general poster session for presenting the latest in veterinary pharmacology research.

We are also excited to announce that the AAVPT Biennial symposium will be immediately followed by a day-long workshop on regulatory requirements for approval of veterinary drugs in feeds.

The organizing committee members (Sanja Modric, Carol Davis, Lesley Rausch-Derra, Michele Sharkey, Ronette Gehring, Chantal Lainesse, Virginia Fajt and Anthony Lucas) hope to see you there.
FROM THE PRESIDENT-ELECT
Anthony Lucas

Things are really coming together for the 2013 Biennial Symposium.

We have signed a contract with the Bolger Center in Potomac, MD. For those of you who have not been there, we held the bioequivalence and Veterinary Drug Life Cycle courses there, and it is an excellent venue. We have secured the Stained Glass Hall which is particularly pretty, and we have always received positive reviews of the catering.

The program is nearly finalized. On Monday, May 20 we will have a keynote speaker, a review of USP activities that affect the animal health community and a lengthy discussion of the latest CVM perspective on bioanalytical method validation. The day will conclude with student presentations and wine and cheese. Tuesday will start with an update on the exciting progress coming out of the AAVPT Teaching workshop held in June 2012; the remainder of the day will focus on cutting edge utilization of pharmacokinetics, to be topped off with the traditional AAVPT Awards Dinner and Veterinary Pharmacology Research Foundation Silent Auction. Wednesday will concentrate on a hot topic from the last Biennial Symposium in Wisconsin--improving the understanding of animal drug labels.

Immediately following the closing of the Biennial Symposium, the workshop on regulatory requirements for approval of veterinary drugs in feeds will begin.

We are in the process of finalizing speakers and expect to get a full program schedule out soon.

Another exciting step into the future is that we are planning to use the new AAVPT website to make registrations to the event easier for you and for the organizing committee to track.

This will be an exciting event, and I look forward to seeing you there.

Special thanks to the organizing committee: Sanja Modric, Carol Davis, Lesley Rausch-Derra, Michele Sharkey, Ronette Gehring, Chantal Lainesse, Virginia Fajt, Ralph Claxton and Jay Donecker

FROM THE SECRETARY
Susan Longhofer

As Ralph Claxton reported in the Spring newsletter, we are moving to Affiniscape for our membership database and online dues collection. There has been a significant delay and the system will not go ‘live’ until end of October at the earliest. We’ll be sending out a notice via the Google Groups list serve, but also via snail mail. Please send any updates of your contact information to aavptsec@gmail.com.

In April 2012, we welcomed Steven Sutton as a new Fellow to the Academy.

We are always trying to reconnect with members, so if anyone has any information on location of Brian Lubbers, Nipattra Debaivalya, or William Salminen, please send it to aavptsec@gmail.com.

AAVPT FINANCE COMMITTEE REPORT
Jay Donecker

On Sept. 11, 2012 Dan Gingerich and I reviewed the 2010 and 2011 IRS returns for the AAVPT.

The fiscal year for us is April 30 through April 30 of the following year. This means our 2012 IRS return will be filed next spring in May. This will coincide with the three investment account reports and will be aligned with the AAVPT annual meeting report in June.

In addition, Dan updated the investment spreadsheet for the three accounts (LE Davis, Tom Powers and General Investment Accounts). All are performing as well as can be expected.
This has been a hectic summer as both co-editors of your Journal of Veterinary Pharmacology and Therapeutics (JVPT) have been pre-occupied: Dr. Johanna Fink-Gremmels with her successful hosting and chairing of the 12th International EAVPT Congress in the Netherlands this July; and myself with moving to Kansas State University in August after a 30 year career at North Carolina State University. It has been a busy summer, but things are now back on track for both of us.

A few key developments:
• 188 manuscript submissions this year which is perfectly in line with submissions over the last two years.
• We presently have a back-log of 4.5 issues of fully accepted articles, down one full issue from last quarter.
• A fully-reviewed Supplement was published in August entitled “A Novel Long-Acting Transdermal Fentanyl Solution for Dogs” supported by Elanco Animal Health and Nexcyon Pharmaceuticals, Inc.
• Our impact factor, although down from last year’s all-time high, remains in the top 1/3 of veterinary journals. As we try to publish more non-pharmacokinetic papers, they out of necessity cite papers not published in JVPT. Such diversification becomes a two-edged sword relative to this single metric. In order to get this elevated, it is essential that we strive to publish definitive review articles, have authors publish their best work in our journal, and cite papers published in our journal whenever possible.
• Wiley-Blackwell in September assigned a new production editor to JVPT necessitating a break with a very efficient professional who served us in this capacity for a number of years.

So as you can see from these points, the only constant with JVPT has been change, with a large dose of it this last quarter.

EDUCATION COMMITTEE REPORT

Virginia Fajt

The major work of the Education Committee this year was the development and hosting of the Pharmacology Teaching Workshop in College Station, TX, on June 11-12, 2012. One significant outcome of the Workshop was the creation of a listserv for pharmacologists and others interested in teaching veterinary pharmacology. AAVPT members and others are welcome to join the listserv and can be added by emailing me at vfajt@cvm.tamu.edu. The listserv continues to be active, and I hope it will be a good resource for sharing ideas and promoting discussion about teaching pharmacology.

Another outcome of the Pharmacology Teaching Workshop was a wiki, Veterinary Pharmacology Teaching and Learning, hosted on http://wikispaces.com. A wiki is a website that is collaboratively developed, with users able to add and edit content relatively easily. We hope this will become a platform for sharing (and potentially peer-reviewing) teaching resources and ideas. We also hope it will be a place to come to a consensus about the competencies needed by veterinary students and graduate veterinarians, a process which began at the Teaching Workshop in June. Send an email to vfajt@cvm.tamu.edu to request an invitation to the wiki; you will need a (free) account at wikispaces to log in and accept the invitation.

Other notes from the Teaching Workshop:
• Number of attendees: 38
• Number of schools represented: 10 U.S., 3 Canadian, 3 Caribbean
• Number of posters presented: 6 (these were also posted on the wiki)
• Agenda items and handouts from the Workshop (available on the wiki)
AAVPT MEMBERSHIP/BYLAWS COMMITTEE REPORT

Jonathan Hare

Committee Members: Jonathan Hare (chair), Cynthia Cole, Carol Davis, Virginia Fajt, Jane Owens, and Kirby Pasloske

The Membership/Bylaws Committee’s focus on expanding the membership base continues. Virginia Fajt and Carol Davis are completing a database of AAVPT membership by vet school, and it is anticipated that the committee will start actively promoting AAVPT at the vet school level in early 2013.

The committee is continuing to work on revising the bylaws to allow qualified individuals to join AAVPT directly as Fellows. Furthermore, we are re-examining the various levels of membership, including Fellow, to bring the AAVPT more in line with peer societies and in a manner better reflective of our purpose and objective. We expect to have a draft document ready for review by the EC in early 2013.

Lastly, Carol Davis is working on a history of the AAVPT. This will provide valuable content for the website, as well as, provide new members with a sense of context when working on new initiatives.

If you wish to comment on our activities or (even better!) if you would like to become involved in the committee, please contact jhare@kingfisherint.com.

VETERINARY PHARMACOLOGY RESEARCH FOUNDATION (VPRF)

Jane Owens

The Foundation was formed in 2007 to provide grant funding to support research into new and currently approved medications for combating diseases of companion and food animals, projects that ensure the safety of food products from treated livestock, and training programs for veterinary pharmacologists. These areas have been unmet needs in veterinary medicine for over 30 years.

In 2009, VPRF formed a strategic partnership with the American College of Veterinary Internal Medicine Foundation (ACVIMF) to solicit, review, and administer the research grants. To date, this program has funded four veterinary pharmacology research projects. Any clinician or scientist with an interest in veterinary pharmacology is eligible to serve as Principal Investigator on the grant proposal. As this grant is a partnership between veterinary internists and VPRF, collaborations between pharmacologists and Diplomates of ACVIM are strongly encouraged.

In 2012, a total of 20 high quality veterinary pharmacology research proposals were received. Of these, two proposals were selected for funding. Drs. Chen Gilor and Christopher Adin of the Veterinary Clinical Sciences Department at the Ohio State University received approximately $16,000 in funding for evaluating exenatide extended release in cats. Approximately $4000 was awarded to Drs. Jennifer Myers, Janice Bright, Christopher Orton, Daniel Gustafson and Christine Swardson Olver from the College of Veterinary Medicine & Biomedical Sciences, Colorado State University for evaluation of the pharmacokinetics and pharmacodynamics of apibaxin in cats. These researchers also received additional funding from ACVIMF for this work.

VPRF greatly appreciates the support and generosity of AAVPT as we work toward our goal of advancing the field of veterinary pharmacology.

Donations may be sent to VPRF Secretary/Treasurer: Dr. Dan Gingerich, 2219 Wilmington Road, Lebanon OH 45036.

Donation forms are also available on the AAVPT web site: http://www.aavpt.org/documents/VPRFDonationForm.doc

President: Jane G. Owens owens_jane_g@lilly.com

Secretary-Treasurer: Dan Gingerich dgingerich@imulan.com

Board Members: Joe Gloyd, Anthony Lucas, Mark Papich
ATTENTION ALL AAVPT MEMBERS

We Need Your Help!

We would like to create a **history page** and have a place where we can archive information about AAVPT and its members.

We would like to build the site using pictures similar to the one above. It is one of a very few pictures we have that we can use to document our past. It was taken and appeared in the proceedings from the 1988 Biennial Symposium. But, as it stands now, we do not have any other pictures like this in our archives. We would like to begin to build an AAVPT scrapbook with your help!

To our long-standing members, we would like to make a specific appeal. We would love to get any pictures you have from any of our meetings. In addition to this we would like to obtain any pictures you might have showing you and your graduate students, you and your advisor when you were in school, pictures of your laboratory, pictures from any of our symposia, etc. It would be great to be able to populate the website with information from years gone by and show how our community has grown over the years.

**If you have any pictures or information you would like to submit, please contact Carol Davis** ([ca-davis@comcast.net](mailto:ca-davis@comcast.net)).
The American Academy of Veterinary Pharmacology and Therapeutics

Now Accepting Nominations for
The 2013 Lloyd E. Davis Award

The "Lloyd E. Davis Award" is presented to individuals for significant contributions over an entire career to the advancement and extension of knowledge in the fields of veterinary or comparative pharmacology. Previous Award Recipients include:

- Thomas E. Powers, 1990
- Folke Rasmussen, 1992
- Arthur L. Aronson, 1994
- Charles Short, 1998
- Carl Aronson, 2001
- Gary D. Koritz, 2003
- J. Desmond Baggot, 2005
- Peter Lees, 2007
- Pierre-Louis Toutain, 2009
- James Riviere, 2011

Nominations are accepted every two years and the award, if given, is presented at the AAVPT Biennial Symposium. The award consists of a commemorative plaque and a check for $750. The recipient is invited to attend our biennial as the guest of the AAVPT. All travel and meeting expenses are covered for the recipient. The award will be announced at the 18th Biennial Symposium (May 20-22, 2013). The recipient will be invited by the Academy to deliver a Lloyd E. Davis Lecture during the meeting.

Nominations should include at least two letters of support for the candidate from AAVPT members. The letters should describe the contributions and accomplishments of the nominee to the field of veterinary or comparative pharmacology, indicating why, in their judgment, the nominee should be recognized for their accomplishments. The letters should be submitted along with the nominee's complete curriculum vitae. Nominees need not be members of the AAVPT.

Nominations must be submitted to the Chair of the Awards Committee by November 30, 2012. Information can be sent via e-mail to ihrausch-derra@aratanarx or via mail to Lesley Rausch-Derra, 8085 N. Chariton Avenue, Parkville, MO 64152.
COUNCIL ON BIOLOGIC AND THERAPEUTIC AGENTS (COBTA)

Jane Owens

COBTA Meeting held at the AVMA Headquarters October 4-5, 2012

The Council on Biologic and Therapeutic Agents of the American Veterinary Medical Association consists of twelve AVMA members elected by the House of Delegates for terms of six years. Members represent the following areas of veterinary medical activity: microbiology, immunology, pharmacology, clinical pharmacology, private clinical practice (predominantly small animal), private clinical practice (predominantly food animal), private clinical practice (predominantly equine), epidemiology, and industry.

Typically, the pharmacology representative is recommended by the AAVPT and nominated by an AVMA Delegate. The clinical pharmacology representative is typically nominated by ACVCP and is also nominated by an AVMA Delegate.

The Council advises the AVMA Executive Board in the promotion of interest in the efficacy and proper use of biologic and therapeutic units in the practice of veterinary medicine; serves as an informational and advisory resource for the various agents of the Association on issues pertaining to biologic and therapeutic agents; advises the Executive Board in formulating positions concerning proposed or existing rules, regulations, and legislation; maintains awareness of activities and proposed actions by divisions of state and national governments concerned with veterinary biologic and therapeutic agents and advises the advertising manager of the journals as to the acceptability of advertising pertaining to biologic and therapeutic agents.

American Association of Swine Veterinarians, the American Association of Feline Practitioners, aquaculture and seafood medicine, and zoo and wildlife medicine.

Current CPAC members include:
- Dr. Scott Hurd, Chair, representing COBTA
- Dr. Thomas Cusick, representing the American Animal Hospital Association
- Dr. Patricia Gaunt, representing Aquaculture and Seafood Medicine
- Dr. K. Fred Gingrich II, representing the American Association of Bovine Practitioners
- Dr. Todd Hayden, representing the American Association of Feline Practitioners
- Dr. Justin B. Janssen, representing the American Association of Equine Practitioners
- Dr. Danny Magee, representing the American Association of Avian Pathologists
- Dr. Sarah Probst Miller, representing the American Association of Swine Veterinarians
- Dr. Jane Owens, Alternate Chair, representing COBTA
- Dr. K. Kurt K. Sladky, representing Zoo and/or Wildlife Medicine
- Dr. Andrea Mongini, American Association of Small Ruminant Practitioners

During the October meeting, updates were presented by representatives from FDA CVM, USDA-CVB, USP and AHI.

USDA Single-Tier Label. USDA overviewed their plans to implement the Single-Tier Labeling System on all veterinary biologics (2000 products) which is projected to be implemented over the next 3 years once rulemaking is proposed and finalized. Working closely with CVB and industry over many years, COBTA has advocated such label changes. A single label
Call for Nominations for the following awards to be presented at the AAVPT 18th Biennial Symposium
May 20-22, 2013 - Bolger Center, Potomac, MD

AAVPT Service Award

The AAVPT Service Award is presented to recognize significant service to the fields of veterinary or comparative pharmacology, or therapeutics. The award will consist of a commemorative plaque, meeting registration, hotel room, and a check for $500 to be presented at the Biennial Symposium. Nomination submission deadline is December 31, 2012.

AAVPT Teaching Award

The AAVPT Teaching Award is presented to recognize significant teaching activities in the fields of veterinary or comparative pharmacology, or therapeutics. The award will consist of a commemorative plaque, meeting registration, hotel room, and a check for $500 to be presented at the Biennial Symposium. Nomination submission deadline is December 31, 2012.

AAVPT Research Award

The AAVPT Research Award is presented to recognize significant research contributions to the fields of veterinary or comparative pharmacology, or therapeutics. The award will consist of a commemorative plaque, meeting registration, hotel room, and a check for $500 to be presented at the Biennial Symposium. Nomination submission deadline is December 31, 2012.

Lloyd E. Davis Award

The "Lloyd E. Davis Award" is presented for significant contributions over an entire career to the advancement and extension of knowledge in the fields of veterinary or comparative pharmacology. The award will consist of a commemorative medallion/plaque, round-trip transportation, meeting registration, hotel room, and a check for $750 to be presented at the Biennial Symposium. Nomination submission deadline is November 30, 2012.

Nominations shall consist of a curriculum vitae and no fewer than two letters of recommendation/support describing the contributions that make the candidate eligible. Nominations must be submitted to the Chair of the Awards Committee via e-mail, lrausch-derra@aratanarx.com, or via mail to Lesley Rausch-Derra, 8085 N. Chariton Avenue, Parkville, MO 64152

See the AAVPT website (aavpt.org) for more details.

There were several contentious issues. For example, one was related to Risk Management Recommendations for Veterinary Drugs for which no ADI and/or MRL has been recommended by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) due to specific health concerns (Agenda Item 10)\(^17\).

The following are excerpts from this discussion: “The EU Delegation informed the Committee that, in developing its recommendations, the Working Group had taken into account the principle that veterinary drugs that are both genotoxic and carcinogenic would in general not be considered acceptable for use in food-producing animals. In taking into account this principle, some members of the Working Group were of the opinion that genotoxic and carcinogenic veterinary drugs should not be allowed for use in food-producing animals, while other members were of the opinion that such a decision was too restrictive and could create trade barriers and rule out other effective options for risk management. The Delegation of the United States of America objected to this discussion: ”

The 20th Session of the CCRVDF agreed to establish the following five electronic Working Groups to work between sessions, four physical working groups to meet prior to the 21st Session, and distributed additional work through circular letters:

**Electronic Working Groups**
- EWG on the Proposed “Concern Form” for CCRVDF (format and policy procedure for its use. REP12/RVDF para. 80. Host: Brazil and Australia
- EWG on Discussion Paper on Guidelines on the Establishment of MRLs or Other Limits on Honey (REP12/RVDF para. 147) Host: United Kingdom

**Circular letters**
- CL 2012/23-RVDF
  2. Part B (7) Risk analysis policy on extrapolation of MRLs of veterinary drugs to additional species and tissues (see REP12/RVDF para. 158 and Appendix XI). Due 30May2012

**Physical Working Groups**
- Physical WG extrapolation
- Physical WG on Priorities. Host: Australia

Participating countries and observer organizations are invited to identify experts to assist in this work and forward their names and e-mail addresses to the Codex Contact Point of the European Union (Codex@ec.europa.eu) with a copy to Mr. Risto Holma (Risto.Holma@ec.europa.eu) by 15 November 2012.

The next CCRVDF meeting, the 21st Session, will be held August 26-30, 2013, at a location still to be determined.

The next US CCRVDF Delegation meeting is scheduled for 25 October 2012, 1:00 - 3:00 pm EST. FDA-CVM. The agenda will be focused on debriefing of the 20th CCRVDF meeting held in Puerto Rico 7-11 May 2012, debrief of 35th Codex Alimentarius Commission held in Rome, Italy, 2-7 July 2012, overview of strategy to address the above tasks and anticipated controversies.
Call for Abstracts for the
ACVCP/AAVPT Resident/Graduate Student Award
AAVPT 18th Biennial Symposium
May 20-22, 2013 – Bolger Center, Potomac, MD

Award Objective: The purpose of the Resident/Graduate Student Pharmacology Research Award is to recognize research excellence in clinical and/or basic pharmacology for residents and graduate students. A winning research presentation (includes oral presentation followed with poster presentation) will be identified during the AAVPT Biennial Symposium.

Candidate Qualification: To be eligible for the Resident/Graduate Student Pharmacology Research Award, candidates must have completed their research under one of the following conditions: 1) while in training for qualification to sit the ACVCP exam; 2) as a resident/graduate student while being mentored by an ACVCP diplomate; or 3) as student member of AAVPT while in a graduate program under the guidance of an AAVPT Fellow. The abstract must be submitted BEFORE the candidate has become certified as a Diplomate of ACVCP, or in the case of a graduate student, before the graduate degree is awarded. An Oral presentation and a poster of the research must be presented at the AAVPT Biennial Symposium.

Submission: Abstracts must be forwarded to the Chair of the AAVPT Awards Committee with a letter from the nominee’s mentor confirming eligibility by April 1, 2013. Electronic or hardcopy submissions will be accepted. Acceptance of abstracts not meeting the submission deadline will be subject to the discretion of the Chair of the AAVPT Awards Committee, who will make a judgment regarding the existence of compelling extenuating circumstances.

See the AAVPT website (aavpt.org) for abstract format.

Award Amount: The award will be in the amount of $1,000 (US) and accompanied by a certificate signed by the officers of the ACVCP and AAVPT.

Send submissions and questions to:
Lesley Rausch-Derra
AAVPT Awards Committee Chair
lrausch-derra@aratanarx.com
816-951-2131
Call for Abstracts for the Poster Session at the AAVPT 18th Biennial Symposium
May 20-22, 2013 – Bolger Center, Potomac, MD

The AAVPT 18th Biennial Symposium Program Committee invites the submission of abstracts for poster presentations at the Symposium. The Symposium is organized around scientific, teaching and regulatory themes and all abstracts that address some aspect of veterinary pharmacology and therapeutics will be considered. Abstracts may be included as a part of the Symposium Proceedings. Abstracts for the ACVCP/AAVPT Resident/Graduate Student Award will also fall under the following guidelines. (See the AAVPT website for eligibility requirements)

Guidelines for submission:

Abstracts must be submitted by the 1st April 2013 to Lesley Rausch-Derra

Abstracts must be submitted as a single document that is compatible with Microsoft Word® (any version for Windows). File names must be in the format of:
AAVPT 18 BS Abstract <space> first initial <space> surname <space> abbreviated title
i.e. AAVPT 18 BS Abstract C Smith PK of diazepam

The total length of the abstract must be equal to, or less than, 250 words. This word limit excludes the title, author names, degrees, board certifications, addresses, telephone numbers, email addresses and key words, all of which must be included. The presenting Author’s name must be underlined. Authors should include up to five key words. Abstracts should include only text i.e., may not contain diagrams, figures, pictures, tables or charts. If references are required, they must be listed at the end of the abstract in the following format:

Abstracts not conforming to the AAVPT guidelines by the deadline will be returned to the author for correction before consideration for presentation at the Symposium.

Edits: Abstracts will be copy proofed by the AAVPT 18th Biennial Symposium Program Committee. The AAVPT will communicate with the author to ensure that editing will not change content or meaning. Keywords are subject to approval, and revision, by the editors. If more extensive editing is deemed necessary, the abstract will be returned for appropriate changes. If changes are made, a proof will be sent to you and you will have a short period of time to confirm that the formatting is correct; however, please note that content revision will not be allowed.

Copyright agreement: The author grants unlimited and nonexclusive copyright ownership of the materials contained in the submitted abstract to the AAVPT. Unlimited means that the author agrees that the AAVPT may use various modes of distribution, including online and CD-ROM electronic distribution formats. “Nonexclusive” means that the AAVPT grants to the author an unlimited right to subsequently reuse the submitted materials.

Please direct questions to:
Lesley Rausch-Derra e-mail: lrausch-derra@aratanarx.com
COUNCIL ON BIOLOGIC AND THERAPEUTIC AGENTS (COBTA) (CONTINUED)

Jane Owens

claim (single uniform indication statement) is being proposed to replace the current 4-tier label claim system described in VS Memorandum 800.202. The 4-tier label claim system is often poorly understood in the market place, and in some cases it has been used for inappropriate comparisons between products. This system will provide publicly available efficacy and safety data for all products. This information will not include confidential business information. For example, the specific organism used in the supporting studies will be disclosed but the strain will not be delineated. The proposed single label claim will not change the manner efficacy studies are evaluated, and no new data will be required from manufacturers of existing products. Information that is envisioned to be made public includes: number, age, and serological status of animals; age at first vaccination; interval between vaccinations if appropriate; interval between vaccination and challenge; challenge organism (not strain) and dose (including numbers of organisms/ml). The proposed rule is expected to be published next year at which time there will be a sixty day public comment period.

USP. Updates from USP included a report from Dr. Donald Sawyer who serves as AVMA’s representative to the 2010-2015 USP Council of Convention (former COBTA member, representing pharmacology). The Council of Convention meets twice a year and has 15 members and currently includes three veterinarians.

Steven Paul from USP relayed that the USP Compounding guide was released electronically in June. This publication is geared toward the compounding pharmacy with all data derived from USP NF. It is available as a yearly subscription that has 3 publications all of which have extensive links to compounding information. The guide is currently updated for USP 35 (second supplement) and will be updated for USP 36 when it releases.

Compounding. COBTA was updated on several items related to veterinary compounding restrictions by several states. The Arizona State Veterinary Medical Examining Board has recently clarified that veterinarians cannot compound drugs themselves or dispense compounded drugs to patients. In this state, only pharmacists may compound or dispense compounded medications. Veterinarians must write a prescription for compounded drugs.

The Texas State Board of Veterinary Examiners has ruled to prohibit compounding from bulk drug by veterinarians. Idaho is also considering other restrictions on veterinary compounding. In other news related to compounding, FDA’s case for injunction against Franck’s has been dropped due to Franck’s cessation to own and operate the facilities at issue.

FTC Workshop on Pet Medication Issues. AVMA Staff and AHI representatives updated COBTA on the recent workshop to examine competition and consumer protection issues in the pet medications industry. This workshop examined many of the issues associated with HR 1406: Fairness to Pet Owners Act of 2011 which would require veterinarians to provide pet owners with written prescriptions for all medications they prescribe (currently referred to House Energy and Commerce, Subcommittee on Health). This workshop also examined the extent to which recent changes to restricted distribution and prescription practices in the contact lens industry might yield lessons applicable to the pet medications industry. The FTC will issue a report from this workshop in the coming months. The AVMA has opposed HR 1406 which would require mandatory prescription writing for veterinarians.

VFD Process. The AVMA Steering Committee for FDA Policy on Veterinary Oversight of Antimicrobials gave an update on their activities. The purpose of this group is to promote the involvement of veterinarians in the decision making process on the use of antimicrobials in animals and to increase veterinary oversight in the use of antimicrobials in food animals. This group made several recommendations to FDA on the VFD process. They recommended a 6 month expiration be established for VFDs and veterinarians must be licensed in the state where the animals reside. The group also made recommendations to the AVMA on the model practice act which was updated in 2012 to state that the veterinarian may only issue a VFD if they are licensed in the state where the animals reside and have a VCPR.

COBTA also reviewed several drug, stem cell and vaccine related draft policies and made recommendations on those policies to the AVMA Executive Board and other AVMA councils.
ACVCP/AAVPT LIAISON REPORT

Jane Owens

AAVPT and ACVCP co-sponsored seven hours of pharmacology sessions at the American College of Veterinary Internal Medicine (ACVIM) Annual Forum which was held in New Orleans in late May. The theme for 2012 was antimicrobial therapy in companion animals and immune-modulation.

In 2013, the ACVIM Forum will be held from June 12 to 15 in Seattle. AAVPT and ACVCP will again co-sponsor 7 hours of pharmacology sessions at this meeting. The selected theme for 2013 is: Nutraceuticals: a Critical Evaluation of Their Use. Speakers include Drs B. KuKanich, D. Boothe, K. Viviano, L. Freeman, S. Budsberg, K. Simpson, and K. KuKanich.

JOB LISTINGS (as received on the AAVPT Google Group; please address all inquiries to contact provided in listing)

Research Scientist
Elanco, Greenfield

Elanco has a Research Scientist position available. Please contact Rob Hunter (rphunter64@gmail.com) if you have questions. You can proceed to the www.elanco.com website which will lead you to careers and then connect you to the Eli Lilly career website where you can search and apply using position number 00917149.

Position Brand Description: Contribute leadership and technical expertise in planning, developing and analyzing non-pivotal and pivotal ADME and human food safety studies to develop and deliver novel animal health products for global use in intensive beef. The scientist will coordinate and leverage external partner capabilities; develop relevant sections of study protocols; ensure compliance with regulatory requirements; interpret data; and co-author technical reports for submission to regulatory authorities. Some travel required (25%), including international.

Basic Requirements: Ph.D. (or equivalent experience) in Pharmacology, Biochemistry, Analytical Chemistry or related field.

Additional Preferences: Experience with GLP regulatory requirements; Bioanalytical experience with LC/MS, radiotracer methodology, and pharmacokinetic data analysis software.

Manager, Development Projects
Dechra

Dechra has a Manager, Development Projects position available. Please contact Susan Longhofer (susan.longhofer@dechra.com) if you are interested.

Broad Function: Project Team Leader for pharmaceutical compounds in pre-clinical and clinical development.

Essential Functions: Design of registration and product development operating plans; Manage all clinical development aspects of pharmaceutical compounds including design of protocols for product registration studies in the EU and US; Preliminary safety, metabolism, pharmacokinetics, and dose titration studies; First efficacy studies in laboratory conditions and pharmacokinetics studies with the final formulation; Efficacy studies, safety studies and field trials; Responsible for negotiations on the clinical program with relevant regulatory agencies; Prepare Parts III and IV (Safety and Efficacy Technical Sections) of new drug submissions for Veterinary Medicinal Products/New Animal Drugs.

Knowledge, Skills, and Abilities: Experience in research and regulatory veterinary medicine including interaction with governmental agencies; Understanding of product development, protocols, Good Clinical Practice guidelines, research reports, and dossier preparation

Specifications: Graduate veterinarian (D.V.M., V.M.D., B.V.Sc., or equivalent) with a minimum of five years of experience in veterinary practice, with a large component of companion animal medicine; Advanced degree or specialty board certification a plus but not essential; State licensure or eligibility for licensure a plus but not essential; Industry experience in similar position preferred

Post Doctoral Fellow
Kansas State University

Opportunity 1

A Post Doctoral Fellow position is opening immediately to conduct research within the new Institute of Computational Comparative Medicine under the direction of Professor Jim Riviere (http://www.vet.k-state.edu/depts/ap/faculty/Riviere.htm) at Kansas State University housed within the College of Veterinary Medicine. A PhD in pharmacokinetics, pharmacoanalytics or biostatistics along with experience doing population-based mixed effect pharmacokinetic modeling is required.

The individual in this position will develop and apply pharmacokinetic models to aid in the prediction of chemical and drug tissue withdrawal times in food producing animals for the aim of insuring safe foods for human consumption. This work is primarily involved in making interspecies extrapolations based on data collected in the USDA-supported national Food Animal Residue Avoidance Databank (FARAD), as well as, designing experiments and analyzing data obtained in new animal trials.

Please send your letter of interest, curriculum vitae and list of three references to:
Barbara Lutjemeier, Department of Anatomy & Physiology, College of Veterinary Medicine, Kansas State University. Email: blutjeme@vet.k-state.edu.

Screening of applicants begins November 30, 2012 and continues until the position is filled. KSU is an equal opportunity employer and actively seeks diversity among its employees. Background check is required.
FROM THE EDITOR

Maya M. Scott-Garrard

I would like to thank all of the AAVPT members who contributed reports and information for this newsletter. The newsletter is provided for the members of AAVPT, and I am always looking for interesting articles to include. Please let me know if you have any news or information to share with the organization.

JOB LISTINGS (CONTINUED) (AS RECEIVED ON THE AAVPT GOOGLE GROUP; PLEASE ADDRESS ALL INQUIRIES TO CONTACT PROVIDED IN LISTING)

Post Doctoral Fellow
Kansas State University
Opportunity 2

A Post Doctoral Fellow position is opening immediately to conduct research within the new Institute of Computational Comparative Medicine under the direction of Professor Jim Riviere (http://www.vet.k-state.edu/depts/ap/faculty/Riviere.htm) at Kansas State University housed within the College of Veterinary Medicine. A PhD in pharmacokinetics, pharmacometrics or biostatistics along with experience doing physiological-based pharmacokinetic modeling in animals is required.

The individual in this position would develop and apply physiological based pharmacokinetic (PBPK) models and other pharmacometric approaches to describe the disposition of drugs and dietary supplements in dogs and other veterinary species. The focus is on developing general frameworks that could easily incorporate in vitro and QSAR data into canine PBPK models.

Please send your letter of interest, curriculum vitae and list of three references to: Barbara Lutjemeier, Department of Anatomy & Physiology, College of Veterinary Medicine, Kansas State University. Email: blutjeme@vet.k-state.edu.

Screening of applicants begins November 30, 2012 and continues until the position is filled. KSU is an equal opportunity employer and actively seeks diversity among its employees. Background check is required.
The objectives of the Academy are:

To support and promote the education and research in comparative pharmacology, clinical veterinary pharmacology and other aspects of pharmacology of interest to the veterinary profession.

To sponsor a periodical Journal of the Academy which will publish reviews, summaries and original treatises on all aspects of veterinary pharmacology and therapeutics. The *Journal of Veterinary Pharmacology and Therapeutics* shall be an official instrument of the Academy.

To sponsor and conduct workshops, symposia or other scientific and educational meetings in veterinary pharmacology and therapeutics.

To enhance the exchange of educational materials and ideas among veterinary pharmacologists.

To organize committees of experts to research and make recommendations to the profession on current problems in veterinary therapeutics.