



NATIONAL CAPITAL AREA CHAPTER
SOCIETY OF TOXICOLOGY NEWSLETTER
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Editor—Gary Burin (gburin@tsgusa.com)

DON'T FORGET TO REGISTER EARLY FOR THE SOT ANNUAL MEETING
REGISTER AT <http://www.toxicology.org/memberservices/meetings/am2005/index.html>

Message from the President.....	2
Bern Schwetz Student/Postdoc Travel Award.....	4
NCAC-SOT Membership.....	4
Fall Symposium Symposium Abstracts	5
Synergism, Antagonism, or Additivity of Dietary Supplements	6
Industry Perspective on the Toxicology of Dietary Supplements.....	6
The National Academy of Sciences Monograph on Dietary Supplements: A Framework for Evaluating Safety	6
The Life Sciences Research Office Report on Recommendations for Adverse Event Monitoring Programs for Dietary Supplements.....	7
The Roles of the Nuclear Receptors PXR and CAR in Xenobiotic Response	7
Regulatory Framework for Dietary Supplements	8
Botanical Dietary Supplements: Perspectives and Problems.....	8
2004 Career Day	9
Advice on Writing a Scientific Paper.....	9
Writing Abstracts	10
Behind-the-scene factors in writing a competitive grant.....	10
Reviewing Manuscripts: Making Effective Comments.....	10
Graduate Student and Post-Doc Events at the Annual SOT Meeting in March.....	11
NCAC-SOT Treasurer Report	12

Message from the President
by David Jacobson-Kram

In my six months as President of the NCAC SOT I have had extensive opportunity to meet and work with the President Elect (Dr. Harry Milman) and other officers and members of the chapter. It is becoming increasingly clear to me what important role the local chapters play. The greater Washington DC area has an impressive mix of academic centers, government agencies, contract laboratories and pharmaceutical companies. The local chapter provides a forum for toxicologists from different venues to come together, share ideas, points of view and "network." In addition, our semi annual symposia and annual Student's day afford graduate students in toxicology the opportunity to crystallize career goals and meet potential employers. Our latest symposium on Toxicology of Dietary Supplements was a huge success. We had a record number of attendees, including a media representative and outstanding presentations. Congratulations to Harry Milman and all the other folks who helped out with the arrangements. Our recent career day with its focus on scientific writing was also enormously successful. Special thanks to all the speakers who prepared for and spent the day at this event.

We are entering a long-term phase of austere research budgets. It will become increasingly more important to collaborate as much as possible to conserve dwindling resources. Our local chapter is a great place to meet scientists with common interests and develop important collaborations. See you at the next meeting!

Please send in your nominations for NCAC SOT President Elect and Treasurer. Nominations can be sent to David Jacobson-Kram at jacobsonkram@cder.fda.gov by March 1st. Elections will take place in mid March.

NCAC-SOT Executive
BoardMembers – 2004-2005

President: David Jacobson-Kram ('03-'04)
Food and Drug Administration
301-594-5671; jacobsonkram@cder.fda.gov

Vice-President/
President-Elect Harry Millman ('04-'05)
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Representative Melinda Pomeroy ('04-'05)
Virginia Polytechnic Institute and State University
540-231-1887; mpomeroy@vt.edu

Student
Vice-Representative Mashaeh Al-Namaeh
Howard University

Bern Schwetz Student/Postdoc Travel Award

Deadline is January 14, 2005.

All students enrolled full time in a graduate or post-graduate program and who will be presenting posters at our upcoming annual SOT meeting in New Orleans, LA, are encouraged to apply for our chapter's student/postdoc travel awards.

Award requirements: Eligible students and post-doctoral associates must have a research abstract that has been accepted for the 2005 annual meeting and must not be receiving a concurrent travel award from the national SOT or any of the Specialty Sections. In addition, the applicant's mentor must be a member of SOT and/or NCAC-SOT.

Application procedure: Email or send a hard copy of your abstract submitted for the 2005 annual meeting along with a confirmation that the abstract was accepted. In addition, the submission packet must include a letter signed by your mentor verifying that you are enrolled full-time in a graduate student or post-doctoral research training program.

Applications should be emailed or mailed to ksquibb@umaryland.edu or:

Katherine Squibb, PhD
Program in Toxicology
University of Maryland
10 South Pine Street, MSFT 7-34F
Baltimore, MD 21201
Phone: 410-706-8196

Deadline for submission is: January 15, 2005. Detailed information is also available on the SOT website: www.toxicology.org.

NCAC-SOT Membership

Over the past year, membership in NCAC-SOT has increased substantially. This is partly related to the fact that headquarters SOT maintains the membership records for its regional chapters. This method of doing business has several tangible benefits for NCAC-SOT and its members. SOT provides members with annual notification that membership fees are due in December, provides on-line renewal capabilities, takes secure credit card payments, and immediately deposits membership renewal fees into the NCAC-SOT checking account. Annual membership fees for NCAC-SOT are only \$20 for regular memberships and \$10 for full-time students. These negligible fees (which may be less than your weekly Starbucks budget!) are used to fund two fantastic symposia each year, and to support a myriad of student activities, including career enhancement programs and student awards. If you have not yet renewed your regional chapter membership, please do so today! If you already renewed your SOT membership and forgot to renew your NCAC-SOT membership at the same time, or if you are not a member of SOT, then contact Rosibel Alvarenga at Society of Toxicology, 1821 Michael Faraday Drive, Suite 300, Reston VA 20190, phone: 703-438-3115, e-mail: sothq@toxicology.org or rosibel@toxicology.org. It's never too late to renew your NCAC-SOT membership for 2005!

Fall Symposium Symposium Abstracts

Topic: Toxicology of Dietary Supplements

Location: National Library of Medicine, Bethesda MD

Date: November 2, 2004

Natural Toxins in Botanical Products

Joseph M. Betz
National Institutes of Health

Impurities in botanical products may be microbiological, botanical, and non-botanical. Means of measuring microbial loads, pesticides, mycotoxins, and toxic elements in foods are reasonably well established, and extension into dietary supplements should be reasonably straightforward. Determination of natural toxins or synthetic drugs in botanical raw materials and finished products may be more problematic.

There are two scenarios surrounding impurity analysis that pose particular challenges to the QA/QC manager. The first is presence of a toxic constituent known to occur naturally in the ingredient. An example is the occurrence of pyrrolizidine alkaloids (PA) in comfrey. These compounds are known hepatotoxins and toxicity is thought to be cumulative. European authorities limit PA content of plant material to 1 ppm, Canada's Natural Health Products Directorate has prohibited sale of Russian comfrey as a Natural Health Product, and the FDA has expressed concern about products that contain these compounds. Pyrrolizidine alkaloids in "PA free" products could reasonably be called impurities. Since the identities of the impurities are known, this would seem to be a straightforward problem for the analyst. The challenges are a lack of commercially available analytical standards and a dependence on risk assessors to establish the requirements for sensitivity, specificity, and accuracy of the method. If the regulatory authorities establish a "zero tolerance" policy, the method will have to be pushed as hard as possible to achieve the best available sensitivity. Specificity and accuracy will also need to be carefully established for economic and regulatory reasons.

The second scenario is detection and quantitation of plant toxins that are present in the botanical product because the wrong plant or plant part has been substituted for or added to the intended ingredient. Contamination with the "wrong" plant may be accidental or intentional, and the "needle in a haystack" aspects of the challenge are ameliorated somewhat if there is a history of a particular type of contamination associated with a particular ingredient. An example of this is the substitution of *Aristolochia fangchi* for *Stephania tetrandra*. Dealers in *Stephania* would be well advised to have systems in place for the detection of the nephrotoxic aristolochic acids that are known to occur in *Aristolochia* spp. Contamination of the intended ingredient with some extraneous plant material such as a weed or weed seed (especially in small amounts) is the ultimate challenge for the analyst. General approaches to ensuring purity of botanical products range from establishing identity of raw materials by physical inspection to genetic or chromatographic fingerprinting to determination of specific toxic constituents by LC/MS or GC/MS. Limitations include a lack of analytical standards for known compounds, lack of widely available methodology, and lack of spectral databases for natural toxins.

Synergism, Antagonism, or Additivity of Dietary Supplements

Christopher J. Borgert

Applied Pharmacology & Toxicology, Inc.

Interactions between dietary supplements, nutraceuticals, functional foods and drugs are possible but probably not prevalent. The literature provides a base of information from which to begin an analysis of the likely incidence and severity of interactions between these various agents, but several caveats must be kept in mind. Reported interactions are not always relevant to clinical experience. Many reported interactions are based on flawed study designs that cannot support the interpretations and conclusions drawn from the data. A critical analysis of reported interactions among dietary supplements reveals the difficulties inherent in assessing interaction dose-response, interaction thresholds, and magnitude of interactive effects. These concepts, however, will be critical to developing a rational path forward for assessing potential interactions among dietary supplements, nutraceuticals, functional foods and drugs. Essential information for such assessments includes data demonstrating the mechanisms by which broad classes of clinically relevant interactions can occur and the available pharmacological, toxicological and mechanistic information on the products being assessed.

Industry Perspective on the Toxicology of Dietary Supplements

Steven Dentali

American Herbal Products Association

Dietary supplement toxicology is a subset of the toxicology of natural products. Sometimes segments of the academic community do not attend to basic principles when reviewing materials sold as dietary supplements. This apparent bias emerges when questions of toxicity are raised without regard to proper identification of materials, the known phytochemistry of particular botanicals, or the biological properties of specific chemicals. Nevertheless, and notwithstanding poor science from some critics, particular toxicological issues are known to exist for some dietary supplements and they require appropriate attention. This presentation evaluates some examples of speculative dietary supplement toxicity where more factual information could have resulted in a better informed approach. Industry recommendations are also provided where some known toxicological issues exist.

The National Academy of Sciences Monograph on Dietary Supplements: A Framework for Evaluating Safety

Norman R. Farnsworth

College of Pharmacy, University of Illinois at Chicago

The Committee on the Framework for Evaluating the Safety of Dietary Supplements (based on the current law as it relates to DSHEA) of the Institute of Medicine of the National Academy of Sciences, was asked by the Food and Drug Administration to develop a method for evaluating the safety of dietary supplement ingredients. The lecture will briefly describe the use of existing human, animal and *in vitro* data and other factors in developing the Framework.

The Life Sciences Research Office Report on Recommendations for Adverse Event Monitoring Programs for Dietary Supplements

Catherine J. Klein
Life Sciences Research Office

Under the Dietary Supplement Health and Education Act of 1994, dietary supplements are regulated as a subcategory of food. Currently, there is no federal guidance or mandate for the collection, documentation, or evaluation of consumer health complaints associated with the use of dietary supplements. The Life Sciences Research Office (LSRO) made recommendations for the design and development of adverse event monitoring programs specifically tailored for dietary supplements. Adverse event monitoring programs for foods or drugs identify potential product-related health problems or signals, which are further quantified and evaluated to determine whether they represent coincidence, artifact, or a genuine problem in toxicity that might lead to changes in labeling and/or restrictions in use. LSRO convened an *ad-hoc* independent, expert advisory panel and divided this overall project into two phases: (1) the review and comparison of individual data records associated with the use of dietary supplements and evaluation of their usefulness for generating signals of potential product problems; and, (2) the review of postmarketing surveillance programs described in the scientific literature and recommendations for 25 minimal elements of a postmarketing surveillance program for dietary supplements, including recommendations for collecting, documenting, organizing, and analyzing adverse events. If implemented, such programs better inform risk management choices by manufacturers, regulators, and product users, and thereby reduce potential health risks from dietary supplements. This project was sponsored by Metabolife International, Inc. (San Diego, CA), through its counsel, Patton Boggs, L.L.P. (Washington, DC).

The Roles of the Nuclear Receptors PXR and CAR in Xenobiotic Response

John T. Moore
Glaxo Smith Kline

The nuclear receptors PXR (NR1I2) and CAR (NR1I3) are activated by an overlapping set of ligands, regulate a subset of common genes, and signal through the same response elements. Both receptors have been proposed to function as xenosensors, but the details of their respective roles are still being elucidated. We have contrasted these two receptors in a variety of experiments including gene expression arrays, cell-based ligand profiling assays, and crystallographic/structural modeling analyses in order to further differentiate their physiological roles. Affymetrix gene array studies revealed that CAR and PXR regulate overlapping but distinct gene expression pathways. Generally, both receptors regulated genes involved in xenobiotic metabolism including phase I, phase II, and transporter genes, but distinct differences in their gene expression profiles were evident within each of these categories. Notably, we linked the changes in gene expression to a distinct role for CAR in response to nutritional stress. Physiological measurements in CAR knock-out animals supported the model suggested by the gene expression data. These studies extend the physiological role of CAR beyond xenobiotic protection. Finally, we provide evidence that the unique structures and ligand activation characteristics of CAR and PXR reflect their contrasting physiological roles.

Regulatory Framework for Dietary Supplements

Linda S. Pellicore
US Food and Drug Administration

Section 413 of the act sets forth the requirements that must be met by dietary supplements containing certain new dietary ingredients. Section 413(c) of the act defines the term new dietary ingredient to mean a dietary ingredient that was not marketed in the United States before October 15, 1994. Section 413(a) of the act provides that a dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of two requirements: (1) it contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or (2) there is a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, is reasonably expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary (and by delegation, FDA) with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

Botanical Dietary Supplements: Perspectives and Problems

Larry A. Walker
School of Pharmacy, The University of Mississippi

Plants comprised the main source of medicinal agents for most of the history of man, and plant-derived natural products shaped many of the basic constructs of our modern disciplines of pharmacology and toxicology. Much of the emphasis on natural products waned in the middle of the 20th century, the 'age of chemistry', when it was envisioned that synthesis of 'magic bullets' would make natural medicines obsolete. Crude botanical drugs largely disappeared from western medicine, and until the 1990s were relegated to health food stores and herbalists' shops. In 1994, with the passage of the Dietary Supplement Health and Education Act, a regulatory context was set for 'herbal products' that considered botanicals as food supplements as opposed to drugs; this ushered in a decade of robust growth in the widespread and relatively unregulated use of botanicals. Proponents argue that many traditionally used and beneficial products are now readily available. Opponents contend that unproven, and in some instances unsafe, products are widely distributed, aggressively marketed, and ill-used, resulting in unnecessary risks. Sorting out the real risks and benefits is complicated because of the complexity and variability of botanical mixtures. This talk will focus on key developments that shaped the current environment, illustrations of the nature and complexity of toxicological problems with botanicals, and a look at the future of botanical medicines.

2004 Career Day

On November 3, 2004, graduate students and post-docs from the University of Maryland, Virginia Tech, Howard University, Georgetown University, George Washington University and the USFDA met at the National Library of Medicine to attend the third annual NCAC Career Enhancement Day. Organized entirely by Melinda Pomeroy-Black (Virginia Tech) and Mashael Al-Namaeh (Howard University), with support from the NCAC Executive Board, the day was entitled "Writing in the Sciences." Attendees were treated to a day of talks and Q&A on the skills necessary for writing grants, theses, and publications. Feedback on the day was once again extremely positive, and a fourth Career Day is in planned for Fall 2005. Abstracts of some of the speakers are below.

Advice on Writing a Scientific Paper

Ken Kellar, Ph.D.

It's easier to write clearly than to speak clearly because you get a chance to edit what you write if you don't like how it comes out the first time (remember: three things don't come back and one of them is the spoken word). Therefore, the most important advice I can offer is Rule 1: Read and Edit, Read and Edit, and then repeat. (Thomas Jefferson did 23 drafts of the Declaration of Independence before it was edited some more by Ben Franklin and John Adams.) Know what the main point of your study is and what you want to say, at least in a general sense, even before you begin writing the paper. It will usually help you to begin by laying out the order of figures and tables. Does the order of data presented flow logically to aid understanding of the ideas and/or the hypotheses being tested? Sometimes the best order of presentation does not follow the order in which the experiments were done. Write the legends to the figures so that someone can look at each figure and its legend and get a pretty good idea of what was done and what the main points of the data are (but that doesn't mean you have to re-write the methods in the figure legend). Once the Results section is laid out, your approach to writing the Introduction and Discussion should become clearer. Many journals limit Introductions to 500 -750 words, so be concise (you're usually not writing a review and your Introduction should not sound like one). An Introduction often begins with a few sentences that give a fairly broad view of the question being addressed and then narrows down to a few sentences focused on the specific aspect of the question(s) that your data addresses. The Methods sections should provide enough information to allow the reader to understand where you got the materials used in the study and what methods/techniques you used; but seldom does a Methods section of a research paper need to provide a cookbook list of steps (a useful rule to follow is to provide enough methodological details to allow an experienced worker in the field to repeat the experiments). The Results section is not an exercise in creative writing, but it helps the reader if you provide a clear rationale for each study presented in the form of transitional sentences. If you follow the advice about laying out the figure and tables for the Results, writing this section should be quite straightforward and maybe even easy. Finally, the Discussion (usually limited to about 1,500 words) should give the reader a brief overview of the question(s) your study addressed and the results (in other words, summarize in a few sentences what you just told them in the Results). Then, put your results into a context of what is known or been reported about the subject matter of your study. What information does your study build on? How does your study extend or challenge the already published information? You're usually allowed some latitude for a limited degree of speculation about what your results might mean in a larger context, and you can exercise your creative thinking. This speculation, however, is most useful and rewarding when you have confidence in your methods and results and believe that they can be repeated by others. Finally, see Rule 1.

Grammar and Syntax

Tony Scialli, Ph.D.

The purpose of language is to communicate, and most of us can manage to communicate reasonably well. Sometimes, however, our writing is not reader-friendly, either because of errors of grammar, problems in sentence construction, or excessive wordiness. Writing well makes editors and readers happy and increases the effectiveness of the communication. This session will explain some of the most commonly misunderstood rules of grammar and principles of sentence construction.

Writing Abstracts

Susan Makris, M.S.

The abstract, defined as a concise summary of a paper, poster, or presentation, is an important communication tool for research. Writing a clear, concise abstract can have a powerful impact on the way in which research (or other information) is accessed and/or utilized. A well-written abstract should allow the reader to identify the basic content of a document quickly and accurately, to determine whether the content is relevant to their interests, and to decide whether to examine it in its entirety. Some consideration should be given to the timing and purpose of the abstract and to the anticipated audience. Although these factors may have some influence on the content, most abstracts will generally follow a standard formula. The abstract should concisely state the main objectives and scope of the investigation, briefly characterize the methods used, and concisely summarize the results and principle findings and/or conclusion. Excessive, unnecessary detail should be avoided. The author should take care to conform to any specified format and length requirements (e.g., font, number of words or characters). Tables, figures and literature references should not be included in an abstract; and the use of acronyms or abbreviations should be minimized. The final abstract, in combination with the title, should provide a useful, stand-alone summary of the document or presentation.

Behind-the-scene factors in writing a competitive grant

Toshi Narahashi, Ph.D.

Research grants in biomedical sciences are becoming extremely competitive. Many research-oriented universities especially medical schools require tenured and tenure-track faculty members to generate a large fraction of their salaries from external grants, not to mention the entire salaries of all members of a laboratory. Whereas NIH publishes the detailed instruction of grant proposal preparation, it is absolutely essential to understand hidden "grantsmanship" to become successful. This presentation emphasizes the importance of the behind-the-scene factors including, but not limited to, the psychology of reviewers, reviewer-friendly writing, exercising/not exercising your ego, yes-man attitude for revising the proposal, proper understanding of the publish-or-perish anecdote. Although the sound scientific merit of a proposal is a must, it is not sufficient to win the highly competitive game.

Reviewing Manuscripts: Making Effective Comments

Carole Kimmel, Ph.D.

Reviewing manuscripts is something all scientists are called on to do as part of their professional responsibilities. Giving a good review and ensuring that strong papers are published in the literature is beneficial for everyone. There are several things to consider in reviewing manuscripts that will ensure a good review and provide adequate information for the author to make appropriate revisions. Do not review manuscript for which you are not qualified; rather, suggest to the editor others who may be better suited than yourself. If you agree to review a manuscript, the following pointers are offered. First, read the manuscript through completely before making comments. You may want to make notes in the margin as you go, but don't try to write the review until you've read the paper through at least once. Second, go through the paper in detail and develop comments about points that you think the author should reconsider or address.

For reviews of original research publications:

1. Restate the objective of the study.
2. Determine what the hypothesis is, and whether you think the study design has addressed the hypothesis directly.
3. Indicate your overall evaluation of the paper.
4. Provide major comments first so the author knows what your primary concerns/criticisms are.
5. If you think the paper is publishable, suggest ways in which the author might address your comments. Think about what might be helpful to you as an author.
6. List detailed comments by page and line or paragraph number.
7. Determine whether you think the paper should be accepted with major, minor, or no revisions, or whether it should be rejected. Sometimes justifying a rejection is more time-consuming than reviewing a well thought-out study and a good manuscript.
8. Papers authored by investigators for whom English is not the primary language may need additional attention to grammar and language usage. Check with the editor to see if he/she wants suggestions for improvement.

For other types of publications (reviews, letters to the editor), the same principles apply, except that the objective of the manuscript should be stated and your review should consider how well the paper has achieved its goals. For example, has the literature for a review been adequately searched? Is the paper well-organized to provide enough information for an overall conclusion? Have the authors justified their interpretations and conclusions?

Many publishers now provide online review sites that greatly facilitate the review process.

Graduate Student and Post-Doc Events at the Annual SOT Meeting in March

The 44th Annual national SOT meeting in New Orleans offers several events for students and post-docs. The Student Advisory Committee, which is composed of the student representatives from each of the regional chapters, is organizing several of these events. The events are outlined below:

- Student/Post-Doctoral Fellow Mixer on Sunday, March 6 at 7:30 P.M
- Lunch with an Expert program. Small groups of students and post-doctoral fellows meet with a SOT member for informal discussion over lunch. About a dozen students are grouped with each expert based on research interests. The expert will choose the place and time for the meeting, and meal costs will be shared. Students and post-docs who sign up for Lunch with an Expert will be notified by March 1st with details of their meeting time and place.
- The *In Vitro* Toxicology Lecture will be held on Tuesday, March 8 at 12 noon. The topic this year is *In Vitro* methods for Dermatotoxicology Studies.
- Finally, SOT Council will meet with students and post-docs on Wednesday, March 9 at 4:45 P.M. At this informal forum, we can suggest improvements to Council about student/post-doc services offered by SOT and explain why we like certain aspects of the meeting or of SOT services, for example.
- In addition, the 2003 NCAC Student Day "Interviewing Skills for Graduate Students and Post-Docs" will be held as a sunset session on Monday, March 7 at 4:30 P.M. This session, chaired by Rob Mitkus and Melinda Pomeroy-Black, will include several of the speakers who attended Student Day. We hope to see you there!

NCAC-SOT Treasurer Report

November 2, 2004

Fall Meeting: November 2, 2004

Meeting-related income:

Donations				\$ 600.00 (SRA)
Registration:	Cost	Rc'd		
Members				
Students (early-bird)	(\$0)	12	\$	0.00
Students (on-site)	(\$5)	2	\$	10.00
Regular (early-bird)	(\$35):	27	\$	945.00
Regular (on-site)	(\$40)	9	\$	360.00
Non-Members:				
Students (early-bird)	(\$10)	5	\$	50.00
Regular (early-bird)	(\$45)	71	\$	3195.00
Regular	(\$50)	25	\$	<u>1250.00</u>
Gross Symposium income				\$ 6410.00

Meeting-related expenses (estimated):

Printing (programs)			\$	96.55
Supplies (Badges)			\$	180.54
Speaker(s):	Dr. Dentali (estimated)	\$ 250.00		
	Dr. Borgert		\$	438.57
	Dr. Moore		\$	148.19
Room rental			\$	0.00
Catering:			\$	1700.00
Audio visual			\$	<u>0.00</u>
Total meeting expenses:				\$ 2813.85

Net meeting income: ~\$ 3596.00

SRA Co-sponsorship (estimated)

Donation	\$ 600.00
Expenses	\$ 2814.00
Percent expenses	21%

Net income	\$ 3596.00
Multiplied by 21%	\$ 767.00

Profit percentage to NCAC-SRA ~\$ 767.00
Profit percentage to NCAC-SOT ~\$2829.00

Current Assets:

Checking account (9/30/2004): \$ 10,797.40
Annual net assets (11/17/2004): ~\$ 12,500.00

Respectfully submitted: Laurie Roszell
November 17, 2004