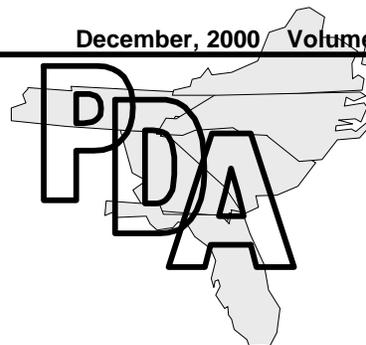


# NEWSLETTER



## SOUTHEAST CHAPTER

<http://www.pdase.org>

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Robert Guardino, AAI  
Cindy Smith, Serentec, Inc.

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## PRESIDENT'S CORNER

*Bill Jones  
President, PDA Southeast Chapter*

**WOW!!!** The PDA Southeast Chapter held its second meeting of the year 2000 on October 31 at the Sheraton Imperial Hotel and Convention Center, RTP, North Carolina. This was the largest and best attended meeting to date for our chapter. We had over 30 vendors and over 170 registered participants.

This meeting was sponsored by: Bio Merieux, Charter Medical, and Clark Richardson & Biskup. The break sponsors were Pharmaceutical Calibration and Instrumentation and the Texwipe Company. Also, many vendors donated door prizes that were won through numerous drawings held during the vendor show.

The featured speakers were John Welsh, Technical Specialist for Network Data Systems with Agilent Technologies, and Bob Coleman with the FDA. John Welsh presented, "21CFR part11: Understanding FDA Requirements for Electronic Records and Signatures". Bob Coleman presented, "Current Compliance Issues: Inspectional Issues, OOS/Deviations, Nonconformances and Drug cGMP Inspections." Additionally, the Interest Group for Isolator Technology met which included a presentation on glove integrity testing. Jennifer Raynor and Don Eddington led this session.

Again, the meeting was a huge success. The success of the meeting was largely due to our vendors, excellent speakers, our sponsors, the efforts of committee and to each of

you for attending and showing an active interest in the chapter. A special thanks also goes to our program committee.

The executive committee met on Nov. 28 to discuss plans for the upcoming year. Additionally, we will be preparing the committee chairs for the upcoming year. As previously announced, Cindy Smith will be leaving her position as the communication committee chair. Jim Bufano has accepted the position that Cindy is vacating. I want to thank Cindy for her leadership in this role and wish Jim the best of luck. I want to again express my gratitude to all the members of the executive committee and to recognize the special contributions of these individuals.

In closing, thanks for your support. We appreciate your continued feedback, help, and participation in chapter activities and on project committees. If you are interested in serving on a committee, then please contact me (Bill Jones) at the following: Phone No. (919-359-7906) or email (William.Jones.B@Bayer.com). We welcome your suggestions and input and look forward to the next meeting. The next meeting is tentatively planned for the Spring 2001. The content, location and date of the meeting will soon be announced. Please look at our website at WWW.PDASE.org for the latest information.

*Have a great holiday,  
and we look forward to  
the New Year.*

# MERGER MANIA RAMPANT IN RTP!

*By Don Eddington*

Few companies remain unaffected in recent years by the trend to get bigger and better. Last year's activities resulted in the formation of AstraZeneca and the creation of Aventis. This year's combinations include acquisitions of Monsanto by Pharmacia-Upjohn and the purchase of Warner-Lambert by Pfizer. The trend has been so prevalent that new names for the resulting conglomerates are absorbed into our vocabulary nearly immediately. Names like Novartis and Aventis are inserted into our conversations without hesitation.

Many PDA members have memories of the 1995 takeover that rocked the North Carolina pharmaceutical industry from RTP to Greenville, and resulted in the formation of Glaxo Wellcome. Most people are aware that an even bigger merger is in the works between Glaxo Wellcome and SmithKline Beecham that would create one of the world's largest pharmaceutical companies. The name of the resulting company is expected to be Glaxo SmithKline.

The two companies had a failed round of merger talks and negotiations in 1998. The current merger plan was first announced in January, 2000. Glaxo Wellcome is the number one producer of AIDS, asthma and migraine drugs. SmithKline's strongest product lines include the anti-depressant, Paxil and vaccines. The projected merger finalization date has successively slipped from August 21, to September 25 to the end of the year. Financial analysts agree that the merger is eminent.

The shareholders of Glaxo and SmithKline approved the deal by the end of July and the merger gained regulatory approval in Europe. The recent delays have been caused by the US Federal Trade Commission

(FTC). SmithKline has divested the herpes medication sold as Famvir, Vectavir and Denavir to Novartis for \$1.63 billion. Roche is purchasing SmithKline's Kytril, an anti-nausea drug for cancer patients for about \$1.23 billion. While these moves satisfied the European Commissions, the FTC has also focused on smoking cessation products as an area where the combined company would have a dominant position. Local interests are also at stake in this product category because Glaxo's prescription stop-smoking product, Zyban, is manufactured at Catalytica in Greenville.

As this deal has unfolded, some shifts in plans for the US corporate headquarters have occurred. Originally it was announced that a new US headquarters would be established in the New York City area. More recently, twin bases of operation have been proposed, one in RTP and one in Philadelphia, where SmithKline recently built a new office tower. This revised plan is more palatable to the existing US employees of both companies, and to the communities that house them.

As of press time, this new combination of giants has not been finalized. One can only wonder if the holidays will bring the gift of new business cards for nearly 6000 employees of Glaxo Wellcome in North Carolina.

## PROGRAM COMMITTEE UPDATE

*By: Lisa Eklund, Co-Chair*

The Program Committee would like to thank everyone for the tremendous participation in the Fall Vendor Show and Meeting 2000. We also appreciate the positive feedback we received. Our committee and our chapter are continually striving to improve our services for our members. The meeting was highlighted by the interesting yet informative presentations given by our

two speakers. Our first speaker was Jon Welsh, the Technical Specialist for Network Data Systems for Agilent Technologies. The second speaker was Robert Coleman, National Drug Expert for the FDA.

Jon Welsh's presentation was titled "E-Records and E-Signatures: Overview and Review of FDA Enforcement Trends". Jon gave an overview of FDA's regulation 21 CFR Part 11 on electronic records and signatures. He included information on the development of the regulation and its contents. Jon also discussed FDA's enforcement and inspection practices and the most commonly found deviations. He also presented the response of the pharmaceutical industry and a guide on how to implement the regulation in analytical laboratories. Finally, he presented some resources ([www.fda.gov/ora/compliance](http://www.fda.gov/ora/compliance) and [www.labcompliance.com](http://www.labcompliance.com) and [www.interpharm.com](http://www.interpharm.com)) to aid in achieving compliance.

There were a few main highlights in Jon's presentation. 1) Administrative controls must be implemented immediately, but technical controls may take longer. A general compliance strategy and procedures must be defined. An implementation plan must be developed and actively followed. 2) Paper printouts can NOT be substituted for raw data. 3) Effective immediately, there must be no compromise on data integrity.

Robert Coleman's presentation was titled "Current Compliance Issues: Inspectional Issues, OOS/Deviations/Nonconformances, and Drug GMP Inspections". Lab controls, process Validation, and Process Controls are the three most common reasons why the FDA withholds recommendations for GMP approval both domestically and in foreign inspections. Two other important concerns are records and stability. He included information on how FDA prepares for an inspection and how a manufacturer should prepare also. Bob highlighted that OOS investigations may also include unexpected results (out of trend). He suggested that the OOS procedure

should describe the chain of events and must allow for input by all personnel including Engineering and Regulatory Affairs.

Mr. Coleman also discussed a new pilot inspection program in the FDA. This program will begin in New York, New Jersey, Dallas, Philadelphia, San Juan, and Los Angeles districts. There are **6 systems** that will be covered:

- 1) Quality system
- 2) Materials system
- 3) Manufacturing system
- 4) Packaging and Labeling systems
- 5) Laboratory systems
- 6) Facilities and Equipment

This pilot program will begin 1/1/01 and end 7/1/01. Each inspection will include a minimum of a **Quality System inspection and 1 of the 5 other areas**. The second system will be chosen by the Drug Coordinator at the FDA. **Per Mr. Coleman, if any area is out of control, all are deemed out of control.** This program should lead to shorter FDA inspections, hopefully. This is a brand new program that is being announced at various association meetings like this one.

POST-MEETING NOTE: **At the meeting, Mr. Coleman inadvertently missed topic 6 above. He wanted to be sure that everyone knew that Facilities and Equipment will be included as one of the systems.**

## ISOLATOR GLOVE INTEGRITY TESTING DISCUSSED AT OCTOBER 31<sup>ST</sup> CHAPTER MEETING

By: James R. Rickloff  
Advanced Barrier Concepts, Inc.

The objective of this Isolation Technology Interest Group roundtable session was to present an overview on both Environmental

Monitoring (EM) and glove integrity test methods since many equipment users do not know how to approach this issue. The traditional fall back for users has been to rely on standard EM methods, but emerging technology may make it practical and economical to begin performing actual integrity tests on an as-needed basis.

The following presentations were provided at the last roundtable:

- Gabor Lederer and Chuck Ward (Cygnus Inc., Paterson, NJ) presented the IGM (Industrial Glove Monitoring) Device. The device provides real time monitoring by utilizing the electrical conductance of the operators skin to detect glove breaches. For further information, contact Chuck Ward at (800) 790-9978.
- J.C. Fulghum (Abbott Laboratories, Rocky Mount, NC) discussed the Glove Rinse Test mentioned in the USP chapter on the Validation of Sterility Test Isolators.
- Chartrece Marks (Holopack International, Columbia, SC) discussed the use of swab monitoring on gloves.
- Ericka Charleston Richardson (Wyeth Lederle Vaccines and Pediatrics, Sanford, NC) discussed the methodology of an air inflation test utilizing compressed air for a visual inspection.

Don Eddington (STERIS Corporation) and Jim Rickloff (Advanced Barrier Concepts) were introduced to the attendees as the new co-chairs of the Interest Group. They both have agreed to search for interesting production isolator applications to share with the chapter members during future meetings, but ensuring that lab

application issues will remain an integral part of the Group's focus. Finally, the Chapter would like to sincerely thank Jennifer Raynor of Serentec (formally of Abbott Labs) for her past work in forming SITUG and in her efforts to help incorporate the Interest Group into the PDA SE Chapter over the past year. Her efforts have helped advance the use and understanding of Isolation Technology throughout the region.

If you have any questions, please contact Don Eddington at [don\\_eddington@steris.com](mailto:don_eddington@steris.com) or James Rickloff at [james\\_rickloff@advancedbarrier.com](mailto:james_rickloff@advancedbarrier.com)

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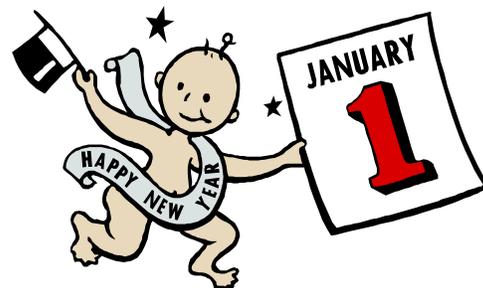
Anyone interested in joining the PDA Southeast Chapter should contact:

Susan Moore  
Millipore Corporation  
Phone #: (800) 645-5476 ext. 6929  
Fax #: (919) 831-2349  
E-mail: [susan\\_moore@millipore.com](mailto:susan_moore@millipore.com)

Please include all available information:

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E-mail Address

Or visit our website at [PDASE.org](http://PDASE.org).



## PDA Southeast Chapter Officers, Committee Chairs and Contacts

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Secretary - Kim Hughes	(919) 269-1512	<a href="mailto:Kah14233@Glaxowellcome.com">Kah14233@Glaxowellcome.com</a>
Treasurer - John Shirtz	(252) 707-2848	<a href="mailto:Jshirtz@catalytica-pharm.com">Jshirtz@catalytica-pharm.com</a>
Program Chair - Lisa Eklund	(919) 553-3831, ext 1901	<a href="mailto:lisa.eklund@fresenius-kabi.com">lisa.eklund@fresenius-kabi.com</a>
Membership Chair - Susan Moore	(800) 645-5476, ext 6929	<a href="mailto:Susan_Moore@Millipore.com">Susan_Moore@Millipore.com</a>
Communications Chair - Cindy Smith	(252) 756-9611	<a href="mailto:cindy_smith@serentec.com">cindy_smith@serentec.com</a>
Webmaster - Mike Clendenen	(252) 707-2422	<a href="mailto:mclendenenhsd@earthlink.net">mclendenenhsd@earthlink.net</a>
Sponsorship - Jerilin Paith-Kenny	(800) 596-3462, ext 226	<a href="mailto:jepaith@mindspring.com">jepaith@mindspring.com</a>
Program Co-Chair - Teresa Frisone	(800) 645-5476 ext 6137	<a href="mailto:Teresa_frisone@millipore.com">Teresa_frisone@millipore.com</a>

## WWW.PDASE.ORG WEBSITE PROBLEMS RESOLVED

*Cindy Smith, Serentec, Inc.*

For those of you who were trying to access our website before mid-October, we have good news! The problems accessing the website have been resolved.

Evidently there is a common name used for websites as opposed to the digital access code. This common name is called a domain name. These names are leased and renewed periodically. Evidently there is no mechanism currently in place to make sure that the domain name leases are renewed if and when renewal is necessary. We only know this after several troubleshooting calls to the technical support team who handle such troubles in cyber-space. Thank you, Lee Stewart of Serentec, Inc., for steering down the solution to this problem for us. Thanks also goes to Bill Jones and John Shirtz. Their desire to access the website kept them checking until the problem was resolved.

Please contact our new Webmaster if you have questions, problems or suggestions for our website. The PDA Southeast Chapter web address is [www.pdase.org](http://www.pdase.org). Our new webmaster is Mike Clendenen. He has agreed to contract his services to maintain our Website. Mike can be reached at either [mclendenenhsd@earthlink.net](mailto:mclendenenhsd@earthlink.net) or (252)707-2422.

The website maintenance costs will continue to be underwritten by Serentec, Inc.

## CHAPTER FINANCES

*John Shirtz, Catalytica*

The PDA Southeast Chapter started out with a wing and a prayer about three short years ago. Like any other new chapter, PDA provided \$2,000 up front money in order for the chapter to get started, and much of that was used for start-up costs like postage, checking account expenses, etc. The first few events were tenuous since we had little idea of how many attendees we would draw, so we just hoped to at least cover the expenses and get the word out about the chapter. The chapter sponsored a Meet and Greet session at the Spring 1999 PDA Meeting in Orlando, and, since we didn't have much in the way of financial assets, we negotiated a minimal contribution to cover the expenses. (The truth of the matter is we "plead poverty"!)

Had that event happened today, our chapter could have done much more.

As these three years have gone by, attendance at the meetings has gradually increased to the point where the last meeting was sold out. In addition, some of our pharmaceutical vendors have supported us by sponsoring various parts of the newsletter, the meetings, our website, and even the breaks at meetings. The vendor area of the last meeting was also sold out.

Suffice it to say, the chapter is now in good financial shape, so we have money to use to provide the additional necessities that will make our meeting run smoother and to give the chapter some visibility. Serentec has generously sponsored the website we are using, and we are now using that sponsorship money to purchase services which will improve this existing site and make it the best of all the PDA chapters. We want our website to be one of the primary means for communicating current

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information about the chapter to the membership. We will also be purchasing some additional display items for our meetings so we have better visibility, and we hope to use other money to provide tokens of appreciation for attendees at future meetings.

One thing we will be unable to provide at this time is the ability to register for meetings using a credit card. We looked into the possibility of doing this and found the expenses for such services to be beyond reasonable for the few times each year this would be needed. There is a substantial expense for the equipment, the services, and there are even expenses for those months in which the service is not being used. In the future we may be able to consider providing this service but for the present it seems like it would not be cost effective.

The chapter is also looking into ways to use some of this money to further support the local pharmaceutical community, and we are setting up a Philanthropy Committee whose charge it will be to seek out candidates for a monetary recognition. That committee is still in the formative stages so if anyone has an interest or experience in this area, please have them contact John Shirtz at 252-707-2848.

## WEBSITE RENOVATION

*John Shirtz, Catalytica*

Be on the lookout for a new "face" for our website: [www.pdase.org](http://www.pdase.org). Mike Clendenen, our Webmaster, has plans to jazz it up and make it the best of all PDA chapters. Check it out!

## PDA-TRI COURSES AND CHAPTER MEETING AT RTP

*John Shirtz, Catalytica*

The PDA Southeast Chapter and the PDA Training Institute are making plans for PDA courses and a Spring meeting in the Raleigh-RTP area. The courses to be offered will be in response to a questionnaire we circulated last year in which we asked for your comments on what types of subject matter you the membership would like to see. Be on the lookout for further information coming soon.

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# PDA VENDOR LIST

## FALL MEETING, OCTOBER 31, 2000

<u>Authorized Representative</u>	<u>Address</u>	<u>City</u>	<u>State</u>	<u>Zip</u>	<u>Phone</u>
Catherine Cates	2320 Scientific Park Dr.	Wilmington	NC	28405	919-493-5748
James Rickloff	150 Iowa Lane	Cary	NC	27511	919-469-8876
Dave Jenkins	1906 N. Hamilton St.	Richmond	VA	23230	804-340-0223
Mary Gavach	595 Anglum Rd.	Hazelwood	MO	63042	314-506-8073
Tammy Lauvray	3948-A West Point Blvd.	Winston-Salem	NC	27103	919-388-9841
Bob Chew	1515 N. Girls School Rd.	Indianapolis	IN	46214	317-241-7120
Bo Crouse Feurerhelm	1200 Crescent Green, Ste 100	Cary	NC	27513	919-852-5436
Jerilin Kenney	1301 Person St.	Durham	NC	27703	919-598-1986
Coleman Clark	2936 Forest Hills	Rock Hill	SC	29732	800-648-4827
James Costie	57 South Main Street	Harrisonburg	VA	22801	540-432-1514
Bobbi Palmer	172 N. 6th Street	Philadelphia	PA	19122	215-763-8200
Lisa-Paula da Silva	200 Business Prkwy. Suite F	Royal Palm Beach	FL	38417	561-790-2025
Geoffrey Reichert	511 Harvest Court	Wyckoff	NJ	7481	201-848-7716
Nick Honko	7120 Topsail Circle	Fort Mill	SC	29715	803-548-1422
Meg Scott	15 DeAngelo Dr.	Bedford	MA	1730	781-275-0300
Jenny Sprung	8811 Prospechr Ave.	Kansas City	MO	64132	816-822-3723
Ernie Gaudio	2220 91st Street	North Bergen	NJ	7047	570-586-5117
Lori Banks	80 Ashby Road	Bedford	MA	1730	781-533-8523
Andy Ferrell	8100 Brownleigh Drive Ste 100-A	Raleigh	NC	27617	919-781-7787
David Dills	(they didn't fill this info in on reg. Form)	Jacksonville	FL		904-519-8040
Paul Canavin	1652 Eldridge Drive	West Chester	PA	19380	610-436-6519
Russ Nyberg	8607 Park Drive	Omaha	NE	68127	402-593-0781
Pat McElraft	12076 Santa Fe Drive	Lenexa	KS	66215	800-255-6730
Robert Davis	PO Box 33424	Charlotte	NC	28233	704-375-4464
Russell James	31 Thurman Road	Troy	VA	22974	804-293-7490
John Davis	410 Glenwood Ave., Ste 130	Raleigh	NC	27603	919-831-1166
Dave Lane	8732 Steeleberry Drive	Charlotte	NC	28217	704-588-8706
Pam Webb	5960 Heisley Road	Mentor	OH		800-989-7575
Kathy Wiglesworth	3523 Terrault Drive	Greensboro	NC	27410	336-856-2162
Lee Warren	1100 E. Hector St, Suite 415	Conshohocken	PA	19428	610-940-9860
Brent Watkins	4009 Carybrook Ct.	Rocky Mount	NC	27803	252-451-0924
Charles Clauman	133 Southcenter Court, Suite 700	Morrisville	NC	27560	800-348-6388
W. Allan Rainwater	2 Dart Road	Newnan	GA	30265	770-254-0400

### ***PDA – Southeast Chapter Sponsorship Opportunities***

The PDA-SE chapter new sponsorship policy that will be effective January 1, 2001. Sponsors need to forward their information to the PDA Southeast Chapter as soon as possible. Acknowledgement of sponsorship levels will published in the chapter the newsletter beginning with the first volume issued in March of 2001. Please fill out the attached form and mail it to Jerilin Kenny. This form is also available on our Website at [www.pdase.org](http://www.pdase.org) with a link to Jerilin for your convenience. Those sponsors who underwrite chapter activities are encouraged to complete the sponsorship form and estimate the cost of the services they provide to ensure proper recognition.

# ***PDA – Southeast Chapter Sponsorship Opportunities***

The PDA-SE chapter has recently adopted a new sponsorship policy that will be effective January 1, 2001. We truly appreciate the generosity of our sponsors and we intend to show our appreciation by acknowledging your contribution. To ensure we understand your intentions, please complete the sponsorship form and forward it to the address provided. Thank you for your generous support.

## **Bronze Level Sponsorship \$250.00**

- Appreciation letter acknowledging the contribution
- Verbal recognition at the next meeting
- Bulletin board recognition at next meeting
- Appropriate recognition in each newsletter during one year

## **Silver Level Sponsorship \$500.00**

- Certificate of Appreciation
- Appreciation letter acknowledging the contribution
- Recognition of sponsorship at a snack table at the next meeting
- Verbal recognition at the next meeting
- Bulletin board recognition at next meeting
- Appropriate recognition in each newsletter

## **Gold Level Sponsorship \$1,000.00**

- “Gold” Plaque of Appreciation
- Appreciation letter acknowledging the contribution
- Recognition of sponsorship at a snack table at the next meeting
- Verbal recognition at the next meeting
- Bulletin board recognition at next meeting
- Appropriate recognition in each newsletter
- 2 attendees admitted into the next meeting
- \*

## **Platinum Level Sponsorship \$2,000.00**

- “Platinum” Plaque of Appreciation
- Appreciation letter acknowledging the contribution
- Recognition of sponsorship at a snack table at the next meeting
- Verbal recognition at the next meeting
- Bulletin board recognition at next meeting
- Appropriate recognition in each newsletter
- 4 attendees admitted into the next meeting
- Special display at a meeting \*\*
- \*

\*Special requests may be honored with executive committee approval.

\*\*Premium spaces are limited and are honored on a first come, first serve basis.

# PDA Southeast Chapter Corporate Sponsorship

## Sponsor Information:

Date: \_\_\_\_\_

Company Name \_\_\_\_\_

Representative \_\_\_\_\_

Address \_\_\_\_\_

City, State, Zip \_\_\_\_\_

Telephone Number \_\_\_\_\_

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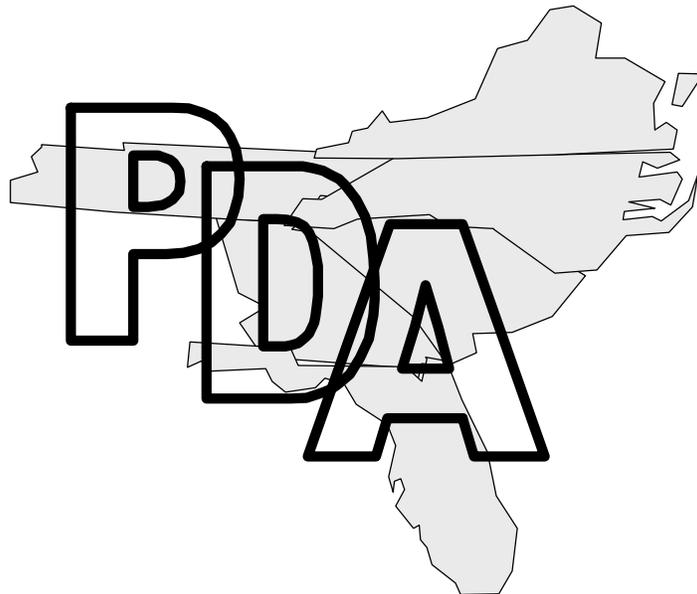
Please make payments payable to: PDA Southeast Chapter

Please mail this form along with contribution to:

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c/o Doe & Ingalls of NC  
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# December 2000 Newsletter



***SOUTHEAST CHAPTER***

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