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PDA Technical Report 5, (TR 5) Sterile Pharmaceutical Packaging: Compatibility and Stability (print version)

The report provides a comprehensive review of sterile packaging systems, product-packaging interactions, stability and compatibility. It is arranged by the type of interaction between formulation and packaging components and is important to manufacturing chemists involved in the development and production of sterile pharmaceutical products. 1984 Softcover 137 pages

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PDA Technical Report 9, (TR 9) Review of Commercially Available Particulate Measurement Systems (print version)

This technical report, the result of a grant to Julius Knapp and Patrick DeLuca, Ph.D., describes the various types of particulate measuring systems and the advantages inherent in their use. It also contains an extensive annotated bibliography on particulate matter. 1988 Softcover 30 pages

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PDA Technical Report 10, (TR 10) Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers (print version)

This paper, written by Drs. John Wang and Musetta Hanson, is a review of concerns in formulating injectable products containing peptides and proteins. It covers degradation and experimental methods to study denaturation, and evaluates stabilizers and the use of stabilizing excipients. 1988 Softcover 26 pages

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PDA Technical Report 11, (TR 11) Sterilization of Parenterals by Gamma Radiation (print version)

This report provides general information concerning development and validation of gamma sterilization processes employing cobalt-60 and cesium-137 isotopes as a source of ionizing radiation. 1988 Softcover 9 pages.

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PDA Technical Report 16, (TR 16) Effect of Gamma Irradiation on Elastomeric Closures (print version)

This report examines the effects of gamma irradiation emitted by the cobalt-60 isotope on elastomeric closures used in parenteral vial packaging. 1992 Softcover 13 pages

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PDA Technical Report 17, (TR 17) Current Practices in the Validation of Aseptic Processing – 1992 (print version)

This report contains the results of a 1992 PDA survey about current practices in validating aseptic processing. The survey questionnaire was sent to PDA members representing about 450 sites, worldwide. 1993 Softcover 21 pages

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PDA Technical Report 18, (TR 18) Validation of Computer-Related Systems (print version)

This report identifies factors to be considered and steps to be taken in selecting, installing, and validating Computer-Related Systems used in pharmaceutical GMP functions. 1995 Softcover 17 pages

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PDA Technical Report 19, (TR 19) Rapid/Automated ID Methods Survey (print version)

This survey conducted by PDA Microbial ID Task Force summarizes microbial identification practices within the pharmaceutical industry, based on responses to questionnaires sent to 55 member companies. 1990 Softcover 7 pages

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PDA Technical Report 20, (TR 20) Report on Survey of Current Industry Gowning Practices (print version)

A survey of selected member companies of the PDA was taken by the Gowning Task Force to determine gowning practices within the parenteral drug industry. 1990 Softcover 5 pages

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PDA Technical Report 24, (TR 24) Current Practices in the Validation of Aseptic Processing – 1996 (print version)

This survey updates PDA 1992 aseptic processing survey published in Technical Report No. 17. The survey consists of 136 questions encompassing many different aspects of aseptic processing and includes separate sections on manual, semi-automated, conventional, and advanced conventional filling, plus sections on blow-fill-seal and closed isolator filling. 1997 Softcover 23 pages

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PDA Technical Report 31, (TR 31) Validation and Qualification of Computerized Laboratory Data Acquisition Systems (print version)

The purpose of this Report is to provide guidance to laboratory scientists, technicians and managers responsible for the implementation, testing, control and usage of Laboratory Data Acquisition Systems (LDAS) used within a GMP-, GLP-, or GCP-regulated environment. 1999 Softcover 12 pages

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PDA Technical Report 32, Revised, (TR 32) Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations (print version)

This current revision to the technical report by the PDA Industry Advisory Board (IAB) reflects the lessons learned in four years of successful implementation. Also described is how the original Supplier Auditing and Qualification Task Group developed and tested a Process Model and Data Collection Tool. Use of these tools will provide consistent audit information that can be shared within the industry. 2004 Softcover 150 pages

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PDA Technical Report 35, (TR 35) A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry (print version)

This Technical Report was produced by the PDA Subcommittee on Microbiology Training, formed in January 2001, to develop an industry vision and guidance for instituting a step-wise, competency-based training program for microbiological training of individuals engaged in work activities connected to contamination control and microbiological testing of pharmaceutical articles. 2001 Softcover 24 pages

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Environmental Monitoring: A Compilation of Papers from the PDA Journal of Pharmaceutical Science and Technology (print version)

A Compilation of Papers from the PDA Journal of Pharmaceutical Science and Technology. In response to a need for finding historical papers, members of the PDA Microbiology Committee conducted a review of the PDA Journal of Pharmaceutical Science and Technology from 1985 to 1995, and selected these papers. 1996, 220 pages.

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PDA Technical Information Bulletin 2, Generic Test Procedures for Elastomeric Closures (print version)

As a result of a CGMP requirement that the parenteral manufacturer confirm supplier certification on packaging components, PDA Research Committee Task Group No. 14 developed test procedures that may be helpful in establishing the identity of elastomeric closure formulations. 1979, 4 pages.

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PDA Technical Information Bulletin 4, Aspects of Container/Closure Integrity (print version)

This bulletin presents information on the various aspects of container/closure integrity and offers generic physical and microbiological tests that may be used as alternatives to the USP Sterility Test in determining container/closure integrity. The methods described in this bulletin are intended for investigational use in determining integrity during product development phases. 1983, 7 pages.

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PDA Technical Methods Bulletin 1, Extractables from Elastomeric Closures: Analytical Procedures for Functional Group Characterization/Identification (print version)

This is the first in a series of technical methods bulletins designed to give guidance in the development of important procedures relating to parenteral technology. 1980, 24 pages.

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PDA Technical Methods Bulletin 2, Elastomeric Closures: Evaluation of Significant Performance and Identity Characteristics (print version)

This bulletin is to provide a guide, specifically detailing methods and procedures for elastomer evaluation. It provides a basis to compare the physico-mechanical properties of elastomeric formulation as they are used as closures for parenteral products. 1981, 27 pages.

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PDA Technical Methods Bulletin 3, Glass Containers for Small Volume Parenteral Products: Factors for Selection and Test Methods for Identification (print version)

This bulletin is intended as a review of representative methods used by glass manufacturers to rapidly identify the various types of glass containers used by the parenteral drug industry. 1982, 19 pages.

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Proceedings from the PDA Workshop on Mycoplasma Contamination by Plant Peptones

The proceedings contain important presentations which will provide readers with recent information offered by subject matter experts who presented at the 2005 PDA Workshop on the contamination of plant peptones. 2007, 257 pages.

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Part 1 - Good Electronic Records Management (GERM)

This document was produced through the collaboration of several industry groups (FDA regulated companies, system suppliers, legal experts, and consultants). It represents a compendium of current thinking on good electronic record management from an FDA regulated industry perspective. 2003, 150 pages.

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Part 2 - Complying with 21 CFR Part 11 Electronic Records and Electronic Signatures

This document has been produced by a Special Interest Group of the GAMP Forum (pharmaceutical companies, suppliers, consultants and the Medicines Control Agency in the UK) in order to promote a better understanding of 21 CFR Part 11. 2003, 80 pages.

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Good Practice and Compliance for Electronic Records and Signatures — Part 3: Models for Systems Implementation and Evolution

Part 3 of the series Good Electronic Records Management Parts 1 and 2, this document provides further discussion for enhancing information technology practices used in the engineering of new computing environments, the remediation of already-installed computing bases, and the subsequent maintenance of both types of computer systems. 2004, 66 pages.

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PDA Video: Keep it Clean

In the manufacturing process, special procedures must be followed when working in aseptic areas. Keep It Clean provides a detailed look at procedures that protect the sterility of parenteral products. 1992

Item No.07009 English Version, NTSC Format

Item No. 07011 Spanish Version

Member	~~$175.00~~	$87.50
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Understanding the Operation and Validation of Autoclaves: A Practical Approach

By Brian Reeks

Emphasis on the importance of complying with current and future Quality Assurance and Good Manufacturing Practice standards when operating autoclaves. 1999, 104 pages.

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The Use of Process Simulation Tests in the Evaluation of Processes for the Manufacture of Sterile Products — PHSS Technical Monograph No. 4

This Monograph provides up-to-date, concise statement on the use of process simulation tests as an element in the evaluation of sterile product manufacturing processes. 1993, 40 pages.

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Guideline on Limulus Amoebocyte Lysate Testing — PHSS Technical Monograph No. 6

This publication contains up-to-date information on all phases of LAL testing. 1994, 84 pages.

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The Japanese GMP Regulations 2003

A combined edition of English/Japanese. The text is intended to provide foreign understanding with information on GMP for drugs formed in Japan according to the Ministry of Health, Labour and Welfare (MHLW) Ministerial Ordinances and Notification related to GMP for Drugs. 2003, 181 pages.

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PDA/DHI Technical Books

Biological Indicators for Sterilization Processes

Editors: Margarita Gomez and Jeanne Moldenhauer

This book will be of great interest to laboratory supervisors, regulatory and compliance personnel, validation specialists and professionals engaged in other aspects of pharmaceutical and biopharmaceutical manufacturing. 2008, 536 pages.

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Chinese Drug GMP: An Unofficial Translation Including Related Sections of the Taiwanese, U.S., and ICH-API GMP

Editors: Steven Kuwahara and Simon Xiuwei Li

This careful translation and relevant documentation will prove to be an invaluable tool for those working with or in China in a variety of healthcare manufacturing capacities. 2007, 316 pages.

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Computer Infrastructure Qualification: For FDA Regulated Industries

Author: Orlando Lopez

Keeping computer infrastructure in a compliant state is becoming more of a key issue for both companies and regulatory authorities. Using a life cycle approach during Infrastructure Qualification Master Planning is vital to success. 2006, 272 pages.

Item No.17251

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Confronting Variability: A Framework for Risk Assessment

Editors: Richard Prince and Diane Petitti

Provides a new perspective on the meaning and relationship of variability in relation to work performed, as well as an insightful framework for the quality assessment of risk in the pharmaceutical industry. 2007, 222 pages.

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Encyclopedia of Rapid Microbiological Methods, Volume I

Editor: Michael J. Miller

Microbiologists and management alike are working together to remove the perceived barriers to implementing RMM within many companies. Volume I provides an overview of microbiological methods and opportunities for industry, regulatory and pharmacopoeial perspectives, and validation strategies. 2005, 404 pages.

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Essential Microbiology for QP Candidates

Author: Nigel Halls

This book explains essential microbiology for both those readers planning to take the Qualified Person (QP) examination as well as readers interested in a thorough discussion of microbiology as it applies to the healthcare manufacturing industry. 2007, 314 pages.

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Laboratory Systems Validation Testing and Practice

Author: Paul Coombes

Practical advice on the validation of laboratory equipment and systems. Written for those with knowledge of computer system validation (CSV) and those who rely on the results produced in analytical laboratories. 2002, 150 pages.

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Non-Member	~~$119.00~~	$59.50
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Laboratory Validation: A Practitioner's Guide

Editor: Jeanne Moldenhauer

Provides an overview of validation from a laboratory perspective. 2003, 1224 pages.

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Pharmaceutical Contamination Control Practical Strategies for Compliance

Editor: Nigel Halls

This is an invaluable guide and desk reference for readers in need of guidance in the assessment and management of contamination risk. 2007, 289 pages.

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Pharmaceutical Excipients: A Manufacturer`s Handbook & CD

Author: Brian Matthews

Helps manufacturers by providing a better picture of what excipients are in use in the EU and comes with a fully searchable CD-ROM to assist the reader. 2005, 184 pages.

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Pharmaceutical Quality

Editor: Richard Prince

An examination of quality written from the perspective of senior experts from around the world working in industry, government and academia. 2004, 758 pages.

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Practical Change Control for Healthcare Manufacturers
Author: Angie Jamison
Provides a concise and practical approach for introducing or improving change control within your organization. 2001, 124 pages.
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Practical Safety Ventilation in Pharmaceutical and Biotech Cleanrooms
Authors: Bengt Ljungqvist and Berit Reinmueller
Describes factors concerning risks of airborne contaminants in pharmaceutical cleanrooms. 2006, 224 pages.
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Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections
Author: Lucia Clontz
Produce timely, compliant results through each phase of microbiology laboratory work using this guide that focuses on current issues and inspection trends. 2001, 175 pages.
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Sorting Out the Critical Variables: A Worked Example for the Non-Statistician
Author: Alfred Wachter
Step-by-step look at the processes and tools used to understand the critical variables in the manufacturing validation process. 2002, 47 pages.
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Steam Sterilization: A Practitioner's Guide
Editor: Jeanne Moldenhauer
Complete collection of practical instructions covering sterilization processes including templates of procedures, protocols, and documents. 2002, 740 pages.
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Successfully Validating ERP Systems (and other large, configurable applications)
Author: David Stokes
Recognizes and discusses the real world human and contractual issues that lead to unsuccessful validation and the lengthy validation of ERP systems. 2006, 270 pages.
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The Manager's Validation Handbook: Strategic Tools for Applying Six Sigma to Validation Compliance
Author: Siegfried Schmitt
Modern methodologies and tools that deliver the best validation practice processes and results, while achieving compliance with regulatory requirements for the healthcare industry. 2005, 120 pages.
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Understanding the United States Pharmacopeia and National Formulary: Demystifying the Standard Setting Process
Author: Susan Schniepp
This book does an excellent job of teaching you the proper way to use our Pharmacopeia as well as how to change it when needed. 2006, 122 pages.
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A Basic Primer on Pharmaceutical Microbiology (print version)
Author: Hans Von Doorne
Chapter excerpted from the book of "Microbiology in Pharmaceutical Manufacturing, First Edition"
2004 Softcover 57 pages.
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Analytical Method Validation in the Chemical Analysis Laboratory (print version)
Author: Robert Kirsch
Chapter excerpted from the book of "Laboratory Validation: A Practicioner's Guide" 2003 Softcover 40 pages.
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Designing a Contamination Control Program (print version)
Author: Sandra Lowery
Chapter excerpted from the book of "Microbiology in Pharmaceutical Manufacturing, First Edition"
2004 Softcover 67 pages.
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Environmental Control Systems Used in Parenteral Facilities (print version)
Author: Franco De Vecchi
Chapter excerpted from the book of "Environmental Monitoring: A Comprehensive Handbook, Volume I" 2005 Softcover 50 pages.
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Environmental Impact on Media Fills (print version)
Author: John Lindsay
Chapter excerpted from the book of "Environmental Monitoring: A Comprehensive Handbook, Volume II" 2005 Softcover 36 pages.
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Environmental Monitoring for Sterilization Process Development (print version)
Author: Anne Booth
Chapter excerpted from the book of "Environmental Monitoring: A Comprehensive Handbook, Volume II" 2005 Softcover 26 pages.
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Identification of Environmental Isolates (print version)
Author: Klaus Haberer
Chapter excerpted from the book of "Environmental Monitoring: A Comprehensive Handbook, Volume II" 2005 Softcover 32 pages.
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Microbiological Validation Master Plan (print version)
Author: Trevor Deeks
Chapter excerpted from the book of "Microbiology in Pharmaceutical Manufacturing, First Edition" 2004 Softcover 42 pages.
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Packaging Considerations for Steam Sterilization (print version)
Author: Edward Smith
Chapter excerpted from the book of "Steam Sterilization: A Practitioner's Guide" 2002 Softcover 32 pages.
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Quality Management in the American Pharmaceutical Industry (print version)
Author: Richard Friedman
Chapter excerpted from the book of "Pharmaceutical Quality" 2006 Softcover 40 pages.
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Training and Learning Critical Contributors to Quality (print version)
Author: James Vesper
Chapter excerpted from the book of "Pharmaceutical Quality" 2006 Softcover 34 pages.
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Author: Lynn Torbeck
Chapter excerpted from the book of "Pharmaceutical Quality" 2006 Softcover 42 pages.
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Validation of Environmental Monitoring Methods (print version)
Author: Dawn McIver
Chapter excerpted from the book of "Laboratory Validation: A Practitioner's Guide" 2004 Softcover 23 pages.
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Validation of Microbial Identification Systems (print version)
Author: Jeanne Moldenhauer
Chapter excerpted from the book of "Laboratory Validation: A Practitioner's Guide" 2004 Softcover 86 pages.
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Validation of Sterilization Processes (print version)
Author: James Agalloco
Chapter excerpted from the book of "Microbiology in Pharmaceutical Manufacturing, First Edition" 2004 Softcover 51 pages.
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Validation Procedures for the Bacterial Endotoxins Test (print version)
Authors: James F. Cooper and Cheryl Moses
Chapter excerpted from the book of "Laboratory Validation: A Practitioner's Guide" 2004 Softcover 28 pages.
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$15.01 75.00	$8.95
$75.01 150.00	$10.95
$150.01 250.00	$12.95
$250.01 500.00	$14.95
$500.01 or more	$17.95

Subtotal	
Shipping & Handling	
6% Tax *(Maryland residents only)*	
TOTAL	

3 Payment Options

Please check one. Credit cards are charged in US$.

PDA Federal Tax I.D. #52-1906152

☐ **By Credit Card** (American Express, MasterCard/EuroCard, VISA) clearly indicating account number and expiration date and billing address.
Please bill my: ☐ American Express ☐ MasterCard/EuroCard ☐ VISA
Total amount:

Account Number Credit Card Verification # Exp. Date

Name (exactly as it appears on card) Signature

☐ **Wire Transfer Payments**
SunTrust Bank, 25 Park Place, Atlanta, GA 30303, U.S.A.
PDA Account No. 209364254 | Routing number: ABA# 061000104 | Swift number: SNTRUS3A
Required if paying in foreign currency, exchange rates at date of submission apply, please include all bank charges. Please contact PDA at 301-656-5900 or chua@pda.org for quote in various currencies.

☐ **By Bankers' Draft Check** forwarded together with the document order form payable to: PDA, P.O. Box 79465, Baltimore, MD 21279-0465 USA
Overnight Deliveries: PDA, c/o Suntrust Bank, Lockbox 79465, 1000 Stewart Avenue, Glen Burnie, MD 21061 USA

Check below to become a PDA member and pay the discounted member price for your order.
All PDA members are individual memberships; Standard includes full membership benefits and privileges. All other discounted member types listed are electronic only, require proof of qualification and are for 1 year of membership. All rates are in USA dollars.

☐ Standard ..... $249 ☐ Government ..... $100 ☐ Academic $100
☐ Emerging Economy ..... $100 ☐ Retired ..... $25 ☐ Student $30

For more details on PDA and the benefits of becoming a member, visit:
www.pda.org/join

PDA USE ONLY Date: Check: Amount: Account: