Overview of FY 94 Activities to Date

Because of high backlogs of New Drug Method Validation Packages (MVP), Abbreviated New Drug Validation Submissions (ANDA), USP proposed reference standards, and special high priority assignments, in addition to the Commissioner's tobacco initiative, all DDA initiated research and method development projects were suspended until these higher priority backlogs could be brought under control. Before this drastic measure was taken the unassigned MVP and ANDA packages reached 18, which is significantly higher than our internal target of not-more-than (NMT) four unassigned. In addition, the assignment of the USP antibiotic proposed reference standards pushed that backlog over 130, which is significantly higher than our internal target of NMT 95.

In addition to curtailing our research and development projects, we encouraged the use of overtime and allowed analysts to work up to ten hours per day and up to seven days per week with supervisory approval and justifications. As a result of these severe measures, we expect that by the end of this fiscal year, our backlogs will be within our control limits provided there are no further crises. We then can proceed to restore resources to our research and method development activities.

USP Proposed Reference Standard Activities (7/1/94)

Total Candidate Samples:	75	Received last month:	0
		Received this FY:	99
Assigned at DDA:	16	Completed last month:	19
Assigned at Field Labs:	2	Completed FY 94:	137
		Completed FY 93:	98

Of the 137 samples completed to date eight were completed by Field Laboratories and seven were completed by the Anti-microbial Drug Branch.

NDA Method Validation Packages and ANDA Validation Packages (7/1/94)

		Month		
Total (A)NDA-MVP: 36	Received	Last	This	MVP Completed This Month: 0
MVP with Samples: 20	MVP:	1	0	MVP Completed This Year: 19
MVP Assigned: 19	Samples:	5	2	MVP Completed Last Year: 34

Other Assignments

NDE

Characterization of Antineoplaston Samples:

These samples were analysed at the request of a Reviewer who was montioring an investigation being conducted by the Houston Resident Post. The individual components were isolated by LC and independently synthesized which allowed the definitive analysis of the submitted samples by H^{1}, C^{13}, N^{15} and 2-dimension cross-correlational NMR; LC and LC/MS. Methods were developed for the selective separation of antineoplaston A10 and its chiral impurities and precursors. It was found that Cellulose OJ was a superior chiral stationary phase under normal phase conditions and that organic acid and base play a significant role in the enhancement of chiral selectivities.

ICH:

A procedure to test photostability of bulk drugs and finished dosage forms, based on the submission of the Japanese ICH representatives, was developed and tested by DDA analysts. The protocols for a collaborative study were written by DDA analysts and were discussed with scientists representing Pharmaceutical Research and Manufacturers Association (PhRMA). Currently, the procedure is being collaboratively studied by the PhRMA representatives and an independent DDA analyst.

Propylthiouracil Samples:

Seven bulk drug substance samples were submitted for examination as a part of an investigation into a report of therapeutic adverse events. They were submitted to our screening protocols, Differential Scanning Calorimetry, X-ray Powder Diffraction, Hi/Lo LC Chromatography, the United States Pharmacopeia XXII TLC method and the British Pharmacopeia (1992) TLC method. There were no significant differences in the samples.

Histamine Diphosphate Samples:

The Office of Generic Drugs plans to conduct a histamine clinical challenge test and the NDE reviewers requested DDA to supply data on the chemical quality of the available materials. Samples of these materials were submitted to thermal and photolytic stress conditions to induce the formation of degradant impurities. Using this information, it was demonstrated that the two bulk drug substance samples of concern did not contain these degradation impurities.

Thalidomide:

Content uniformity, impurity analysis, and dissolution testing of three samples of thalidomide tablets intended for clinical use has been completed. A method for the simultaneous analysis of thalidomide and five related impurities using HPLC with triple-wavelength monitoring was developed. The characterization of thalidomide polymorphism using thermal analysis and crystal structure evaluations in collaboration with NIH has been completed.

Chlorhexidine Digluconate (CHD):

CHD is a potent antimicrobial compound used in many commercial products including surgical scrubs. Since surgeons and nurses may scrub with CHD formulations several times a day, knowledge of CHD's impurities and degradation products is important. Method development work on CHD which had been conducted over the past several years was completed. A comprehensive study of the impurities and degradation products of CHD has been published. Numerous inquiries on this publication have been received from researchers in the U.S. and six foreign countries. Degradation products of CHD formed by stress with heat and light were synthesized and provided to the St. Louis University Medical Center for acute and chronic toxicology testing. A definitive HPLC gradient method has been developed and is planned for publication.

DQA

Digoxin Certification Samples:

Two samples were received and found to meet specifications.

Fraud Investigation:

Twenty-four samples of product were extensively investigated to determine if fraud or substitution had occurred.

Survey of Niacin Tablets:

Niacin is often used as a treatment for high cholesterol levels. Several reports have implicated high dose sustained release formulations with liver toxicity. Of the 56 samples in the survey, one sample failed to meet disintegration requirements and one sample of sustained release tablets released the active ingredient similar to simple compressed tablets. Methodology for dissolution testing of sustained release tablets and compressed tablets has been submitted to the United States Pharmacopeia, Inc. for consideration as the official methods for these two products.

Miconazole:

This study was a routine surveillance assignment. A total of 19 samples were analyzed by a Gas Chromatographic method, with none found outside USP limits. The dosage forms included vaginal suppositories, vaginal creams, and combination products which have both cream and suppositories in a single package.

Zidovudine:

This study was a routine surveillance assignment which contained 7 samples, including 3 capsules, 2 syrups, and 2 IV infusions. All samples in the survey complied with the NDA requirements for Assay, Content Uniformity, Dissolution, and Identification.

Cefazolin:

This study was a routine surveillance assignment in which 22 samples which were analysed and one was found out-of-limits.

Nitroglycerin capsules:

At the request of KAN-DO, check analysis was performed on three samples of sustained release nitroglycerin capsules.

Digoxin tablet products:

Dissolution testing for two certification samples and one NDA sample showed that they met all specifications.

USP Dissolution Test Calibrators-PhRMA Collaborative Study:

Two DDA analysts participated in this collaborative study, and in addition performed extensive testing of the proposed calibrator tablets under varying conditions. DDA's historical data on calibrator testing were reviewed and collated for distribution to the PhRMA Committee and the USP. One of the DDA analysts attended the meeting of the PhRMA Committee to present our findings.

Compliance Review:

At the request of NWK-DO, two analysts was detailed to NWK-DO to assist in inspections of firms suspected of being out-of-compliance and to review of documents associated with an injunction.

Collaborative Studies:

An HPLC method for Terfenadine has been developed and validated, and a collaborative study will soon be initiated.

Methods for the analysis of Atenolol, Guaifenesin, and Histamine have been developed and are undergoing robustness testing prior to submission for a collaborative study.

DDA analysts participated in collaborative studies of methods for thromoplastin and heroin.

Public Standards in the USP:

DDA continues an on-going effort to improve public standards in the USP not only by serving as a collaborator on testing proposed USP standards but also in reviewing monographs and comments submitted to the USP on selected topics. Major compendial reviews are underway concerning the quality of the General Chapters/Notices and monographs which involve the use of mercury compounds as a reagent, indicator electrodes or working electrodes. An article is being developed for publication in the Pharmacopeial Forum recommending the elimination or reduction of mercury and mercury compounds in USP methods and soliciting the submission of alternate methods to assess the involved products.

During the course of some of our laboratory investigations, proposed monographs have been developed and submitted to the USP for nandrolone decanoate, niacin tablets, and albuterol metered dose inhalers.

OGD:

Sulindac Study:

Generic Drug Reviewers encountered peculiarities in bioequivalence studies for this drug product and requested DDA analysts to attempt to relate their observations to differences in the chemical or physical properties. The study consisted of 28 lots of bulk drug substance and 12 samples of tablets from two different manufacturers. Each bulk drug substance was examined by FTIR, Particle Size Laser Analysis (Malvern 2600), NIR, TGA, and X-ray Diffraction. A dissolution profile was run on 6 tablets from each of the 12 tablet samples, with sampling every 15 minutes for 1 hour. The profiles were different for the two companies, but consistent between lots from the same company. Powdered tablet material was also examined by NIR, TGA, and X-ray Diffraction.

Piroxicam:

The Office of Generic Drugs has contracted with the University of Maryland to investigate the quality dimensions of drug formulation and manufacture. As a part of that effort DDA has conducted "fingerprint" and polymorphism studies submitted by the University of Maryland.

Erythromycin:

Substitution of chemical methods of analysis for microbiological assays is desirable because of the improved speed of analysis, and better reproducibility. An HPLC method capable of separating and quantifying all erythromycin impurities, including erythromycin e, in bulk and solid dosage forms, has been developed.

Other Items:

Analysts from all laboratory units have been involved to varying degrees in the Commissioner's tobacco initiative.

A compendium of unofficial rapid TLC methods for the analysis of essential drugs selected from a list developed by the World Health Organization has been prepared. The compendium has been published by the Pharmaco Information Centre, Cairo, Egypt. An audio-tape/slide training program to develop the TLC skills required to perform the analyses of the drugs in the compendium has been prepared and the training script and slides also have been translated into French and Arabic.

Several of our analysts participated in career days and made presentations at high schools.

Seminars Presented at DDA:

10/13/93: Dr. James Drennen (Graduate School of Pharmaceutical Sciences, Duquesne University, Pittsburgh, PA): "PHARMACEUTICAL APPLICATIONS OF NEAR-INFRARED SPECTROSCOPY"

10/21/93: Dr. Allen Kenyon (FDA Division of Drug Analysis, St. Louis, MO): "DEVELOPMENT OF A RAPID SCANNING PORTABLE TLC ANALYSIS OF PHARMACEUTICALS FOR EGYPT AND THE WHO"

DDA Support Activities

SAMPLE ACCOUNTABILITY SYSTEM. - Our sample accountability system has been re-developed and transported to an ORACLE database platform. The new system uses our VAX computer to track samples from the time that they arrive at our laboratory until the time that they shipped out or destroyed. The database allows great flexibility in controlling the handling of samples, in the preparation of managerial reports, and in the taking of physical inventories of samples on hand.

DATABASE OF FTIR SPECTRA. - The Division has produced a large database fo FTIR spectra from the "fingerprinting" generic and innovator drug products and from bulk drug substances. The database has been successfully transferred from the Nicolet proprietary file system to JCAMP format on the VAX system. It is planned to make this database electronically available to all of FDA.

DATABASE OF ALL SAMPLES ANALYZED AT DDA. - The analytical data generated from all regulatory samples analyzed since the summer of 1971 have been successfully transferred from the Hewlett-Packard systems to an ORACLE database on the new VAX system.

CD-ROM LIBRARIES. - A number of DDA publications[1] and extensive HPLC databases have been placed on CD-ROMs. It is intended to supply CD-ROMs only to FOI requests for these DDA publications.

TIME AND ATTENDANCE. - A computerized time accounting system based on bar-coded identification cards that is accessible to our Local Area Network has been installed. The system accounts for all of the time accounting categories given on the card HHS 402 (Rev 10/90) in addition to credit leave. The time accounting database may be directly transmitted to the DFM85 VAX system in headquarters. That system automatically performs a check on the DDA file and sends a report to a DDA printer which indicates any errors that were found in the payroll file and confirms that the file was received. Both the number of errors made and the time required to get the payroll in have been significantly reduced.

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1. The CD-ROM contains the following DDA manuals and reports: Safety in the Laboratory; Chemical Hygiene and Waste Disposal; Training Modules for Instrumental Analyses; Chemists Certification Program; Standard Operating Procedures; Good Laboratory Practices; Script from the tape/slide training for Rapid Scanning TLC; Published papers on TLC; and Compendium of Unofficial Methods for essential drug analysis.

Manuscripts Published:

REEPMEYER, J., ZIELINSKI, W.L., Jr., Leakey, J., and Si Y.: "Synthesis and Stability of Isotopically-Labeled p-Chloro-m-Xylenol (PCMX)" (Pharmaceutical Research, 10, No. 10, 1466-1470 (1993)).

REVELLE, L.K., DOUB, W.H., Wilson, R.T., Harris, M.H., and Rutter, A.M.: "Identification and Isolation of Chlorhexidine Digluconate Impurities" (Pharmaceutical Research, 10, No. 12, 1777-1784 (1993)).

Manuscripts Accepted for Publication:

FARAG, S.: "Liquid Chromatography Assay of Diatrizoic Acid and Its Diiodo Degradants in Radiopaque Solutions" (journal: JAOACI).

FURMAN, W.B., LAYLOFF, T., and Tetzlaff, R.F.: "Validation of Computerized Liquid Chromatographic Systems" (journal: JAOACI).

KENYON, A.S., FLINN, P.E., and LAYLOFF, T.: "Rapid Screening of Pharmaceuticals by Thin-Layer Chromatography: Analysis of Essential Drugs by Visual Methods" (journal: JAOACI).

Kenyon, T.A., KENYON, A.S., and Sibiya, T.: "Drug Quality Screening in Developing Countries: Establishment of an Appropriate Laboratory in Swaziland" (journal: Bulletin of the World Health Organization).

LOGAN, S., GOLDSBY, S., JONES, L., and LAYLOFF, T.: "Purchase Requisition System: A Computer-Based, Internally Paperless, Purchasing and Inventory System" (journal: Managing the Modern Laboratory).

REEPMEYER, J.C., RHODES, M.O., and COX, D.C., and Silverton, J.V.: "Characterization and Crystal Structure of Two Polymorphic Forms of Racemic Thalidomide" (journal: Chemical Society (London), Perkin Transactions 2)(n.b.: crystallographic data also to be entered into the Cambridge crystallographic database, Cambridge Crystallographic Data Centre, Cambridge, U.K.).

REVELLE, L.K., d'Avignon, A., REEPMEYER, J.C., and ZERFING, R.C.: "Stability-Indicating Proton Nuclear Magnetic Resonance (NMR) Spectroscopic Method for Determination of S-Adenosyl-L-Methionine in Pharmaceutical Tablets" (journal: JAOACI).

Presentations:

At the AOAC International Special Symposium on Pharmaceutical Process Control and Quality Assessment by Non-Traditional Means - 1993: Sessions on Near-Infrared Spectroscopy and on Drug Fingerprinting, October 14-15, 1993, St. Louis, MO:

SPENCER, J.: "Neural Networks and Analytical Data in Drug Fingerprinting"

WELSH, W., LIN, W., TERSIGNI, S., CAREY, M., BROWER, J., ZIELINSKI, W., PAGE, S., SPENCER, J. and LAYLOFF, T.: "Neural Networks Analysis of Trace HPLC Profiles: Distinguishing Same Product Manufacturers"

At the 1994 Midwest AOAC International Meeting and Exposition, June 13-15, Columbia, MO; Symposium on "Challenges in Pharmaceutical Analysis":

FURMAN, W.B., LAYLOFF, T., and TETZLAFF, R.F.: "Validation of Computerized Liquid Chromatographic Systems"

NASR, M.: "Liquid Chromatography with Electrochemical Detection (LC-EC): Recent Applications in Pharmaceutical Analysis"

TANG, Y.: "Separation of Chiral Drugs via Chromatographic Methods"

WELSH, W., TERSIGNI, S., LIN, W., DUTA, R., BROWER, J., LAYLOFF, T.P., and ZIELINSKI, W.: "Applications of Chemometrics and Neural Networks to Drug Fingerprinting"

At the Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, Chicago, March 1994:

REEPMEYER, J.C. AND COX, D.C.: "Identification and Determination of Phthalimide and Other Impurities in Thalidomide by HPLC"

REEPMEYER, J.C., RHODES, M.O., COX, D.C., and Silverton, J.V.: "Characterization of Two Polymorphic Forms of Racemic Thalidomide"

At the AOAC International Special Symposium on Recent Advances in the Analysis of Pharmaceutical Inhalation Products for Process Control and Quality Assessment, April 4-6, 1994, St. Louis, MO:

DOUB, W. and MEHELIC, P.: "Identification of Leachable Materials in MDI Valves: What's There and What the Patient Sees"

NASR, M.: "Single-Puff Particle Size Analysis of Albuterol MDI's"

Other Presentations:

KENYON, A.: "Training and Quality of Drugs in Developing Countries," St. Louis Section of Pharmacists in Industry.

FY 95 PRESENTATIONS ACCEPTED THUS FAR:
(Work performed in FY 94)

At the Federation of Analytical Chemistry and Spectroscopy Societies (FACSS) Annual Meeting, October 2-7, 1994, St. Louis, MO:

EVALUATION OF TRACE HPLC IMPURITY PROFILES VIA NEURAL NETWORKS AND CHEMOMETRIC TECHNIQUES FOR DISTINGUISHING AMONG MANUFACTURERS OF L-TRYPTOPHAN (Welsh, Tersigni, Brower, Lin, Carey, Duta, Zielinski, Layloff, Spencer, Page)

TRACE ANALYTICAL CHARACTERIZATION OF p-CHLORO-m-XYLENOL (PCMX) METABOLISM (Zielinski, Reepmeyer, Leakey, Si, Welsh)

CONSISTENCY OF MOLECULAR MODELING WITH SELECTIVE CHROMATOGRAPHIC SEPARATIONS OF ISOMERIC COMPOUNDS (Zielinski, Welsh, Ciaramitaro, Tong)

ENANTIOMERIC SEPARATION OF ANTINEOPLASTON A10 AND RELATED CHIRAL COMPOUNDS VIA HPLC (Tang)

STEREOSELECTIVE SYNTHESIS OF L-3-PHENYLACETYLAMINO-2,6-PIPERIDINEDIONE (Wilson, Reepmeyer, Revelle)

CAPILLARY ELECTROPHORESIS CHIRAL SEPARATION OF ANTINEOPLASTON AND THALIDOMIDE ENANTIOMERS (Farag)

GRADIENT LC SEPARATION OF CHLORHEXIDINE BREAKDOWN PRODUCTS (Doub, Ruhl, Hart, Mehelic, Revelle)

USING NEURAL NETWORKS TO DETERMINE THE COMPOSITION OF MIXTURES FROM SPECTRAL DATA (Spencer, Pierce)

NEAR INFRARED INVESTIGATIONS OF PHARMACEUTICAL FORMULATIONS (Jefferson, Spencer)

HIGH-PERFORMANCE LIQUID CHROMATOGRAPIC ANALYSIS OF ERYTHROMYCIN (Nasr)

SYNTHESIS AND THERMOLYSIS OF CHLORHEXIDINE DIGLUCONATE IMPURITIES (Revelle, Rutter, Wilson)

ISOLATION, SYNTHESIS, AND CHARACTERIZATION OF ANTINEOPLASTON A10 HYDROLYSATES (Revelle, Wilson)

CHARACTERIZATION AND CRYSTAL STRUCTURES OF POLYMORPHIC FORMS OF CHIRAL THALIDOMIDE (Reepmeyer, Silverton, and Rhodes)

APPLICATION OF HMQC-TOCSY NMR METHODS TO IDENTIFY THE MAJOR DEGRADATION IMPURITIES IN NANDROLONE DECANOATE (d'Avignon, Zerfing, Tyler, Lay, and Heinze)

At the American Association of Pharmaceutical Scientists (AAPS) 9th Annual Meeting, November 6-10, 1994, San Diego, CA:

NASR, M. and ALLGIRE, J.: "Loading Effect on Particle Size Analysis of Albuterol Metered Dose Inhalers"

The following two symposia were organized and moderated by DDA technical staff. Participants and attendees included governmental, academia, and pharmaceutical industry representatives to present and mutually discuss the current technology status and potentials in these developing areas of pharmaceutical analysis. In each case, an FDA Reaction Panel comprised of FDA Headquarters and Field personnel having expertise and responsibility in these areas presented concluding remarks.

"Pharmaceutical Process Control and Quality Assessment by Non-Traditional Means - 1993: Near-Infrared Spectroscopy; Drug Fingerprinting" October 14-15, 1993, St. Louis, MO.

SESSION ON ON NEAR-INFRARED SPECTROSCOPY

"NIR Overview: Instrumentation, Applications, and Analysis" (Dr. Donald Dahm, University of Missouri-Rolla, Rolla, MO)

"Applications of NIR Spectroscopy to Monitoring Drug Substance Synthesis and Manufacturing of Drug Product" (Dr. Paul Aldridge, Analytical Research and Development, Pfizer Central Research, Groton, CT)

"Near Infrared Tablet Analysis" Dr. James Drennen, Duquesne University School of Pharmacy, Pittsburgh, PA)

"Non-Destructive Spectroscopy of Pharmaceutical Dosage Forms" (Dr. Eric Richmond, Merck and Co., Inc., West Point, PA)

"Near Infrared Reflectance Analysis for the Identification of Blister Packed Tablets used in Clinical Trials" (Dr. Brian MacDonald, Burroughs-Wellcome, Greenville, NC)

"Chemometrics and Novel NIR Applications" (Dr. Robert Lodder, University of Kentucky College of Pharmacy, Lexington, KT)

"Neural Network Analysis of Spectroscopic Data -- Some Successes and Pitfalls" (Dr. Paul Gemperline, East Carolina University, Greenville, NC)

SESSION ON DRUG FINGERPRINTING

"Chemometric Approaches to Pattern Recognition in Forensic Spectroscopy" (Dr. Thomas Brueggemeyer, FDA National Forensic Chemistry Center, Cincinnati, OH)

"Neural Networks and Analytical Data in Drug Fingerprinting" (Dr. John Spencer, FDA Division of Drug Analysis, St. Louis, MO)

"Neural Networks Analysis of Trace HPLC Profiles: Distinguishing Same Product Manufacturers" (Dr. William Welsh, Department of Chemistry, University of Missouri-St. Louis, St. Louis, MO)

FDA REACTION PANEL:

Office of Epidemiology and Biostatistics:
Dr. Yi Tsong
Dr. Thomas Hammerstrom

Office of New Drug Evaluation:
Dr. Linda Ng
Dr. Eric Sheinen

Office of Generic Drugs:
Mr. Donald Shostak

Division of Field Investigations:
Mr. Charles Edwards
Mr. David Pulham

"Recent Advances in the Analysis of Pharmaceutical Inhalation Products for Process Control and Quality Assessment"
April 4-6, 1994, St. Louis, MO.

WORKSHOP ON CASCADE IMPACTION

"Basic Characteristics and Theory of Cascade Impaction" (Jim Norton, Graseby-Andersen Instruments, Atlanta, GA)

"General Principles of Operation" (Dr. Anthony Cutie, ATI, Inc., Bridgewater, NJ)

"Design Considerations re Performance" (William Chiang, California Measurements, Inc., Sierra Madre, CA)

"Calibration Techniques" (Dr. Nick Miller, MSP Corporation, Minneapolis, MN)

TECHNICAL PROGRAM:

"Particle Size of MDI Aerosols: Methods, Measurement and Meaning" (Dr. David Swift, Johns Hopkins University, School of Hygiene and Public Health, Baltimore, MD)

"In Vitro Testing of MDI's: Progress and Unresolved Issues" (Charles Thiel, 3M Pharmaceuticals, St. Paul, MN)

"Practical Aspects of Inertial Particle Size Analysis of Aerosols" (Dr. Anthony Hickey, University of North Carolina School of Pharmacy, Chapel Hill, NC)

"Characterization of the Effects of the Dynamics of MDI's on Aerosol Distribution" (Dr. Andy Clark, Genentech, Inc., South San Francisco, CA)

"Special Considerations in the Testing of Nebulizers and Pump Sprays" (Dr. Richard Dalby, University of Maryland-Baltimore School of Pharmacy, Department of Pharmaceutics, Baltimore, MD)

"Aerodynamic Particle Sizing for Inhalation Aerosols" (Dr. Rajni Patel, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT)

"Single-Puff Particle Size Analysis of Albuterol MDI's" (Dr. Moheb Nasr, FDA Division of Drug Analysis, St. Louis, MO)

"Comparison of Entry Ports to Cascade Impaction" (Dr. Joel Sequeira, Schering Corporation, Kenilworth, NJ)

"Delivery Characteristics of Solution vs. Suspension Type MDI Aerosols: In Vitro Methods to Document Bioequivalence" (Dr. Chong Kim, Human Studies Division, Health Effects Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC)

"Analysis of Rubber Extractives in MDI Drug Products and Elastomeric Materials" (Dr. Dan Norwood, Glaxo, Inc., Research Triangle Park, NC)

"Effect of Particle Shape on Forward Light Scattering Particle Size Determinations" (Dr. Dan McNamara, Boehringer Ingelheim Pharmaceuticals, Ridgefield, CT)

FDA REACTION PANEL:

Division of Oncology and Pulmonary Drugs/CDER/FDA
Guirag Poochikian
Alan Schroeder
Division of Bioequivalence/OGD/CDER/FDA
Wallace Adams
Division of Chemistry I/OGD/CDER/FDA
Kenneth Furnkranz
Division of Drug Analysis/CDER/FDA
James Allgire