

Food and Drug Administration
Alumni Association
Annual Report/Membership Directory
2007-2008

Keeping FDA Alumni and Employees Connected



6th
Edition

Acknowledgements

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NOTE TO READER

In preparing this publication, every effort has been made to ensure that the information is as up to date as possible and its accuracy verified. However, due to the ever-changing nature of some portions, especially the membership listing, there may be instances where the information as presented is incorrect. Readers are encouraged to report incomplete, inaccurate or new information to Dr. Alan Andersen (andersena@cir-safety.org).

FDAAA Annual Report/Membership Directory 6th Edition

January 2007 - January 2008

FDAAA Officers and Board of Directors

Officers

Chairman, Board of Directors – Elizabeth D. Krell, Ph.D.
Vice Chairman – Robert W. Sauer
President – Anthony C. Celeste
Secretary – Jeffrey B. Springer, J.D.
Treasurer – F. Alan Andersen, Ph.D.
General Counsel – Richard A. Merrill, Esq./Erika Leitzan, Esq.

Board of Directors

F. Alan Andersen, Ph.D.	Gerald F. Meyer
James S. Benson	Wayne L. Pines
Ballard H. Graham	Robert W. Sauer
Jerome A. Halperin	Gail H. Sherman
Elizabeth D. Krell, Ph.D.	John C. Villforth
Burton I. Love	Paul T. Wiener

Associate Member Liaisons

Vanee Komolprasert, Ph.D.
Debra Y. Lewis, O.D.

Table of Contents

The Commissioner’s Corner	1
Message from the President	2
Chairman’s Report	3
Pictorial Year in Review - 2007.....	4
FDAAA Officers	9
FDAAA Board of Directors.....	13
FDAAA Committees & Project Groups	19
FDAAA & FDA Alumni Award Recipients.....	22
FDAAA Mission & History.....	23
Membership Statistics & Demographics	24
New Member Listing	27
Alphabetical Listing of FDAAA Members.....	28
In Memoriam	79
Member Listing By Residence.....	80

Membership

Membership in the FDAAA is open to all former and current employees of the Food and Drug Administration, in addition to persons or entities lending support to the FDA’s mission. Individuals, organizations and institutions supporting the goals of FDAAA are recognized as Friends.

Appreciation

Special thanks go to the many people who volunteered their time in support of FDAAA programs and operations over the past year. The FDAAA also appreciates the support of the following organizations.

Consumer Healthcare Products Association (www.chpa-info.org)

Covington & Burling (www.cov.com)

Food and Drug Administration (www.fda.gov)

Food and Drug Law Institute (www.fdpi.org)

Kendle International, Inc. (www.aacgroup.com)

Parenteral Drug Association (www.pda.org)

PhRMA Foundation (www.pharmafoundation.org)

Pfizer, Inc. (www.pfizer.com)

Raffa and Associates (www.raffa.com)

Temple University School of Pharmacy (www.temple.edu/pharmacy)

Personal Care Products Council (formerly The Cosmetic, Toiletry, and Fragrance Association)
(www.personalcarecouncil.org)



The Commissioner's Corner

This past October, I once again had the pleasure of joining FDA alumni and employees at an event sponsored by your Association. As with previous occasions, it was an honor for me to be among so many wonderful people who've given – and continue to give – greatly of themselves to improve public health throughout the world community.

I told those gathered for the FDAAA annual dinner how quickly my two years at FDA have passed. In that time, I'm proud to say that the agency has made significant progress on a number of fronts. In the area of drug safety, for example, we are focusing more intensely on the total life cycle of medical products. We have renewed our commitment to better communication about drug safety issues. And we're making process improvements for our advisory committees.

Anyone who's been watching the news over the past year knows how much public attention is being paid to food safety and security. Under the direction of Dr. David Acheson, our Assistant Commissioner for Food Protection, we have worked diligently to develop a comprehensive and strategic **Food Protection Plan** based on prevention, intervention and response to food contamination. We've also played a major role in the work of the President's Interagency Working Group on Import Safety headed by HHS Secretary Leavitt.

FDA's environment is changing rapidly and radically. Now, more than ever, FDA must be science-based and science-led. Thanks to the visionary leadership of Dr. Janet Woodcock, we have formed many innovative partnerships under the Critical Path Initiative, including the **C-Path Institute** and **Biomarkers Consortium**. The goal is to modernize the product development process.

As all of you know well, FDA must always seek new and more efficient ways to carry out its public health mission. Mandates expand, and priorities change. Scientific breakthroughs and technological innovation lead to a steady stream of cutting-edge medical products. That's why the Congress and President Bush endorsed **The FDA Amendments Act of 2007**. This critical legislation reauthorizes our drug and device user fee programs which account for roughly 25 percent of our total budget. The law includes important provisions dealing with pediatric pharmaceuticals and research, and establishes a new, separate entity, the **Reagan-Udall Foundation**, to advance our mission of promoting and protecting the public health.

Despite these important gains, we still face many challenges. Some are unforeseeable, as was the case with the pet food containing melamine and toothpaste contaminated with diethylene glycol. But whether expected or not, public health hazards require FDA to be ever vigilant and use the best science to identify and correct problems, as it has done for more than a century. To be effective, we need the help of organizations like yours, so I encourage you to keep informed, stay engaged, and continue to serve as a great national resource!

I wish you continued success in the year ahead. As a Philadelphia native, I also congratulate your Association for its ongoing work with the Temple University School of Pharmacy to sponsor a scholarship program to aid academically deserving students enrolled in graduate studies in quality assurance and regulatory affairs. Keep up the great work!

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs



Message from the President

In my new role, I have reached out to our Board of Directors, committee chairs and many of you to set forth a guiding vision for our future. Early in 2008, the Board will hold a strategy meeting to begin work on a plan to identify the direction the Association should take during its second five years. We hope to identify several key goals and to establish a mechanism to achieve these goals. We are already working to more clearly define the key functions and responsibilities of the Association's various committees, in order to avoid duplication of effort and get the most "bang for the buck" in carrying out organizational responsibilities. Also, we have taken the initiative to more firmly establish a relationship between the FDAAA and FDA at the Office of Commissioner level. This will, we hope, give the Association even more visibility within FDA and enhance the working relationship between our two organizations.



Chairman's Report

Reflecting on the events of the past year provides a great opportunity to express appreciation for the activities and services that so many members in the FDA Alumni Association have worked hard to provide. Making an organization like FDAAA successful and meaningful takes the dedication and efforts of many volunteers. The reward, of course, is deriving a sense of satisfaction similar to that which we all take from our years of service to FDA: the Alumni Association allows us the opportunity to extend that experience, and perhaps to branch out in some novel directions!

Listing just a few of our events and services this year serves to illustrate my point:

- Alan Andersen continues his regular e-mails that are full of news about members, about FDA, about upcoming events, about retirements, about job opportunities and volunteer opportunities – the list is almost endless.
- We have responded to requests from foreign governments this year for speakers and instructors on a variety of topics.
- Wayne Pines and the members of his Activities Committee organized the 2007 FDAAA lunches, complete with superb luncheon speakers. These speakers, consisting of a veritable “who’s who” in FDA, briefed us on current “hot button” issues, on management issues and challenges at FDA, and on emerging problems faced by the Agency. The Committee also arranged for Commissioner von Eschenbach to speak at our annual dinner in October. At the dinner, Dr. von Eschenbach caught the spirit of our Association perfectly when he discarded his prepared remarks in order to “engage in a dialogue” with his “family”.
- Our scholarship program for Temple University’s Pharmacy QA/RA Program is going strong, with the second scholarship in the program awarded this year.
- Our Communications Committee started a Facebook site for members as a way to allow members to interact with each other in this social networking site.

We have seen some important changes this year as well. Dick Merrill, who served as our general counsel for more than five years, decided that it was time to step down from that position. We were fortunate to have had Dick’s wise guidance during our development, and our fortune has continued with our newly appointed GC from Covington and Burling, Erika Lietzan. Best wishes to Dick on his retirement, and welcome aboard, Erika!

Of course, you can read about these and many other newsworthy items on our website, kept up to date and interesting, by Bill Rados’ Communications Committee and webmaster Ken Krell. The point is made, I think, that the time, energy and talent our members contribute to FDAAA keep it fresh and vibrant.

We face a number of new opportunities and issues in 2008, and some continuing ones as well. One of these is the challenge of how to serve, how to include, and how to involve our members who do not live in the greater Washington, DC area. Another is the need to reach out to our FDA colleagues and recruit them to join as Associate Members and to continue as full members once they retire.

I am confident that in this new year of 2008, FDAAA will continue to thrive, and serve the needs of its members and the FDA.

Pictorial Year In Review – 2007

Annual Meeting - April



Association members gather at the Bethesda Marriott North on April ___ for a stimulating afternoon discussion of the adequacy of FDA resources.

A distinguished panel discusses FDA's dire financial straits. (From left to right: Wayne Pines, moderator; Stephen Ubl, President & CEO - AdvaMed; Cal Dooley, President & CEO - Grocery Manufacturers Association & Food Products Association; Dr. Linda Suydam, President - Consumer Healthcare Products Association; and John Bailey, Executive Vice President - Cosmetic, Toiletry & Fragrance Association.



Wayne Pines introduces special speakers from separate organizations advocating greater resources for FDA: William Hubbard (seated left), from the Coalition for a Stronger FDA; and Steven Grossman (right), with The FDA Alliance.



With outgoing Board Chairman, John Villforth, on hand, new FDAAA Board Chairman, Liz Krell, presents a plaque to Peter Barton Hutt (left) in appreciation for his presentation of The Harvey W. Wiley Lecture – 2007.

Bob McCleary (left) and colleague, Glenn Scimonelli, from CDRH’s Division of Communication Media, accept the FDAAA Volunteer of the Year Award from John Villforth. The award recognized years of video support services by Division staff at Association events.



Members of an Associate Member-based work group gather at the annual meeting. The group is developing strategies for making FDA employees more aware of the FDAAA and opportunities for membership and project participation.

Top photo (left to right): Bonnie Markovitz, Debra Lewis, Ting Eng Ong and group leader, Vanee Komolprasert. Bottom photo (left to right): Gregory Holt, LindaTukenmez and Erica Keys. Work group members not shown in the photos include: William Allaben, Kimberly Holden, Li-Shan Hsieh, Juan Jimenez, Abu Khan, Donald Marlowe, Dano Murphy, Chingju Sheu and Len Valenti.

Luncheon – March



New FDA appointees – John Dyer, Deputy Commissioner for Operations & COO, and Susan Winckler, Chief of Staff – share lunch with FDAAA members and discuss the agency’s budget, IT infrastructure and relations with Congress, the media and stakeholders.

Luncheon – June



CVM Director, Dr. Stephen Sundloff (right), explains a massive pet food recall to a lunch gathering of Association members and conducts a science experiment demonstrating how certain contaminants proved deadly to dogs and cats.



Luncheons - September and November



Murray Lumpkin, M.D. (left photo), FDA's Deputy Commissioner for International and Special Programs, was the featured speaker at November luncheon. Lumpkin discussed new initiatives in international arena, including plans to post investigators abroad to improve FDA's ability to monitor the quality of products intended for import to the United States.

Paul Seligman, M.D., CDER's Associate Director for Safety Policy and Communication, spoke about FDA's ongoing and future drug safety initiatives at September luncheon. (No event photos available.)

2007 Awards



FDAAA Board of Directors Vice Chairman, Bob Sauer (center), receives the FDA Distinguished Alumni Award at the agency's annual awards ceremony this summer. Sauer is flanked by Commissioner von Eschenbach (left) and CVM Director, Stephen Sundlof (right).



Katherine McKinney, Ph.D., a technical writer and biochemical engineer with 11 yrs. of pharmaceutical industry experience, is 2007 recipient of FDAAA Centennial Scholarship Award. McKinney will use the scholarship at Temple U. to enhance her expertise in regulatory issues and strategy.

FDAAA Officers

Chairman



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Elizabeth (Liz) Krell (formerly Jacobson) began her 26-year career at FDA in 1975 as a researcher for the Bureau of Radiological Health, one of the predecessors of the Center for Devices and Radiological Health. She served in a number of scientific management positions in CDRH, including Director of the Office of Science and Technology and Deputy Director and Acting Director of the Center. From 2000-2001, Liz acted as FDA's Senior Advisor for Science and Director of the Office of Science Coordination and Communication in the Office of the Commissioner. Since her retirement in 2001, she has worked as a consultant to FDA and served on the Science Advisory Board to Health Canada. In 2003, she joined the Advanced Medical Technology Association (AdvaMed) as Executive Vice President for Technology and Regulatory Affairs before leaving in 2004 to do consulting work. Liz chaired one of the Association's first standing committees – the Member Services Committee – and, in addition to serving on the Board of Directors, is a member of FDAAA's Editorial Board

Vice-Chairman



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Bob Sauer's career with FDA started in 1972 with the former Bureau of Radiological Health following its transfer to FDA. In 1973, he started a 10-year assignment with the agency's emerging medical device program, working first with the Deputy Commissioner, then as Executive Officer to create the new organization and plan for implementation of the Medical Device Amendments of 1976. He spent the next 11 years as FDA's Personnel Officer and, in 1994, became Executive Officer for the Center for Veterinary Medicine. In 2001, he served as the agency's Associate Commissioner for Planning. Bob retired in 2002 and is presently involved in consulting work for federal and non-federal organizations

President



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Tony Celeste joined Kendle International, Inc. (formerly AAC Consulting Group, Inc.) in 1985 after serving 25 years with the Food and Drug Administration. He assumed the President and CEO position of AAC in 1986. He currently holds the position of Senior Vice President. The last position he held with FDA was Director of the Office of Regional Operations, the unit responsible for managing and directing the Agency's field force of investigators, analysts, compliance officers and administrative staff. Prior to transferring to FDA headquarters in 1976, Celeste held a series of positions of increasing responsibility with the Agency. He entered government service as a chemist in the New York District in 1960. Successively, he had assignments as Supervisory Chemist, Kansas City District; Food and Drug Officer, developing general compliance policy, Washington, DC; Chief Chemist, Detroit District; Director, Boston District; and Director, Cincinnati District. Prior to his appointment as FDAAA President, Tony chaired the Communications Committee, served as Editor-In-Chief and was responsible for initiating the Association's newsletter.

Secretary



Jeffrey B. Springer, J.D.
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Jeff Springer was an attorney in the Office of the Chief Counsel from 1968 until he retired in 2001. During his three decade legal career with FDA, he held a variety of management, supervisory, and staff positions, and served as the FDA Deputy Chief Counsel for 20 years. He has been employed as a consultant since 2002. Jeff was appointed FDAAA Secretary in April 2005.

Treasurer



F. Alan Andersen, Ph.D.

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After completing his Ph.D. in Biophysics from Penn State, Alan Andersen joined the Food and Drug Administration in 1971 as a researcher studying the genotoxic effects of ionizing, microwave, ultraviolet and ultrasound radiation at the Bureau of Radiological Health. In 1981, he joined the Bureau of Medical Devices as Associate Director for Standards. After the merger of the radiological health and medical device programs in 1982, he joined and later headed the Office of Science and Technology. In 1992, Alan was appointed to head the Office of Device Evaluation. He is a Past President of CLSI, an international, interdisciplinary, non-profit and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. He is on Board of Directors of the Penn State Graduate School Alumni Association. Since 1993, Alan has been the Director and Scientific Coordinator of the Cosmetic Ingredient Review (CIR), an independent endeavor to review and assess the safety of ingredients used in cosmetics and publishes findings in peer-reviewed scientific literature. In addition to serving as FDAAA Treasurer, Alan chairs the Member Services Committee.

General Counsel



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Dick Merrill served as FDA's Chief Counsel from 1975-1977 during which he was instrumental in the drafting and enactment of the 1976 Medical Device Amendments. In 1977, he returned to the University of Virginia Law school where he had been teaching since 1969. From 1980-1988, Merrill was Dean of the Law School. In 1991, he joined the Washington, DC law firm of Covington & Burling as Of Counsel. In addition to his duties as Professor of Law at UVA and legal work related to FDA matters, Merrill is a member of the National Academy of Sciences Institute of Medicine for which he has chaired or co-chaired many study committees (including two commissioned by FDA). Dick currently serves as co-chair with Dr. Donald Kennedy (former FDA Commissioner) on the Academy's program of Science, Technology and Law. Dick stepped down as FDAAA General Counsel in the Fall 2007.

General Counsel



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Erika Lietzan is a partner in the food and drug group of Covington & Burling LLP. She focuses on FDA regulation of prescription and OTC drugs, biologics, and medical devices, and she has also advised clients in the food, dietary supplement, and cosmetic industries. Her work includes advocacy at FDA, advisory work and strategic advice relating to FDA matters, and assistance with related legislative strategies on Capitol Hill and related legislative and litigation strategies in the states. She is an active member of the Food & Drug Law Institute, serving on the editorial advisory board for its Journal, and she was recently elected a member of the American Law Institute. Erika also chairs the American Bar Association's committee on Biotechnology Law, and she is a frequent speaker and writer on FDA issues.

FDAAA Board of Directors

Elizabeth D. Krell, Ph.D.

Robert W. Sauer

See **Officers** section for bios

F. Alan Andersen, Ph.D.

Director



James S. Benson
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Jim Benson was employed by FDA for 20 years during which time he held a number of senior positions. Jim began his career as head of the Division of Training and Medical Applications in the former Bureau of Radiological Health (now CDRH). In this post, he led a number of successful nationwide programs to reduce unnecessary radiation exposure. He was later promoted to BRH Deputy Director and remained in the position following the 1982 merger of FDA's radiological health and medical devices programs. From July 1988-July 1991, he served as FDA Deputy Commissioner and later as Acting Commissioner. He returned to CDRH in 1991 as Director and retired from FDA in 1992. From early 1993 through mid-2002, Benson was Executive Vice President for Technical and Regulatory Affairs at Advamed. While there, he had a significant role in the enactment of The Food and Drug Modernization Act of 1997, the Biomaterials Access Act of 1998 and the Medical Device User Fee and Modernization Act of 2002. Jim now is a private consultant to medical device companies and serves on the Board of several organizations. He headed the Association's Awards Subcommittee.

Director



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Ballard Graham began his 32-year career at FDA as an inspector technician for the Detroit District office in the Indianapolis, Indiana resident post. He was a graduate of the Stride Intern Program. Ballard served in a number of FDA field offices, in addition, to numerous detail assignments to FDA headquarters and HHS headquarters. His field assignments included resident-in-charge, Sioux Falls, South Dakota; Supervisory Investigator, New Jersey District; Director, Investigations Branch, Philadelphia District; and Director, Atlanta District. He is a graduate of OPM's Executive Potential Program and the Federal Executive Institute. Since his retirement in from FDA 2002, he has worked as Divisional Vice President Global Compliance for Abbott Laboratories, a North Chicago health care company.

Director



Jerome A. Halperin

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Jerry Halperin began his public health career in 1958. During 25 years with the U.S. Public Health Service and FDA, he held assignments in hospital pharmacy; radiological, environmental and occupational health, including the head of FDA's radiological health laboratory and the agency's drug regulatory program. Jerry served as Deputy Director of the former Bureau of Drugs and later as Acting Director of the Office of Drugs in the former National Center for Drugs and Biologics. In mid-1983, he joined the CIBA-Geigy Corp. as Vice President-Technology for the non-prescription drug division, responsible for product development, clinical development, regulatory affairs and quality assurance. In 1990, he assumed the position of Executive Vice President and Chief Executive Officer of the U.S. Pharmacopeial Convention, Inc. In July 2001, he became President and CEO of the Food and Drug Law Institute; he retired from FDLI in 2006. With his ardent support, FDAAA held its first public exhibit in conjunction with FDLI's annual educational conference in 2003 and returned as an exhibitor at the FDLI conference in 2004. Jerry was appointed FDAAA Treasurer in April 2004 and stepped down in 2006.

Director



Burton I. Love

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Burton Love spent 30 years with FDA's field organization, starting in 1966 as an investigator in Dallas. He steadily rose through the field ranks, becoming a Resident Investigator, Supervisory Investigator, Director of Investigations and Director of Field Investigations. He served eight years as Regional Director of the Midwest Region before retiring in 1996. Since his retirement, Burton has worked as a consultant to FDA, for both CFSAN and ORA, has been active in his local church as well as serving as the Treasurer for the local affiliate of Habitat for Humanity. He initiated the "FDA Alumni Network", an e-mail-based network used to keep over 300 former employees abreast of major events inside FDA and the lives of alumni. He is a co-founder of FDAAA and has served as President and Chairman of the Board. Burton was actively involved in the Association's efforts in support of the FDA centennial observance in 2006.

Director



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Gerry Meyer's career at FDA spanned 23 years, from 1972-1994, during which he held senior positions, including Associate Commissioner for Management and Operations and Director of the Office of Legislative Services. He also served as Deputy Director and Acting Director of the agency's Center for Drug Evaluation and Research. Since leaving FDA, Meyer has held senior regulatory affairs positions for several pharmaceutical firms. He has also served as a member of the Board of Directors of the Pharmaceutical Education and Research Institute and as a member of the Editorial Board of Pharmaceutical Technology. Gerry is currently a Senior Consultant with Kendle International, Inc. (formerly AAC Consulting Group, Inc.).

Director



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Wayne Pines served 10 years at FDA, from 1972-1982. He was FDA's Director of Consumer Education and Information, Founding Editor of FDA Consumer magazine, chief spokesman from 1975-82 and Associate Commissioner for Public Affairs from 1978-82. He is currently a media and regulatory consultant, and is president of regulatory services at APCO Worldwide. He has edited several books on FDA-related crisis management and how to work with the FDA. Wayne has also chaired for more than a decade the Drug Information Association and Food and Drug Law Institute educational symposia on advertising and promotion regulation.

Director



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Before coming to FDA in 1992, Gail Sherman worked for the National Center for Health Statistics, the Centers for Disease Control and Prevention, and the Office of the Assistant Secretary for Health. Once in FDA, she joined CBER as Director of the Division of Manufacturers Assistance and Training. In this capacity, she provided management oversight and leadership of the Center's internal training programs, industry outreach activities and, in 2002, CBER's centennial observance. As Vice President of the Montgomery County Club of the University of Maryland Alumni Association, Gail brought useful insights and experience to her role as an employee Associate Member Liaison to the Board of Directors, and was elected to the FDAAA Board of Directors in April 2005. She was also a member of the Ad Hoc Committee on the FDA Centennial. In August 2004, Gail retired from FDA service and joined the Parenteral Drug Association as Vice President of Education and Director of PDA's Training and Research Institute.

Director



John C. Villforth
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John Villforth transferred into FDA in 1971 along with 500 members of the U.S. Public Health Service's Bureau of Radiological Health after the Environmental Protection Agency was formed. He served as BRH Director from 1969-1982 when FDA's radiological health and medical devices programs were combined into the Center for Devices and Radiological Health. He served as the Director of CDRH from 1982 until his retirement from government in 1990. John was also the Chief Engineer of the USPHS and served in the Commissioned Corps with the rank of Rear Admiral and Assistant Surgeon General. Following his time in government, he joined the Food and Drug Law Institute as its President until 2001. He presently serves on two corporate boards and several non-profit boards. John lives in the Gaithersburg area and is enjoying retirement with his wife, three daughters and six grandchildren. John is an FDAAA co-founder and former President and Chairman of the Board of Directors.

Director



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Paul Wiener joined FDA in 1962 as an Investigator in the New York District and retired from the Agency in 1999 as an Assistant to the District Director in New Jersey District. He served as a Supervisory Investigator for 16 years in New Jersey. Immediately following his retirement Paul joined two global pharmaceutical manufacturers and worked for close to five years as a Compliance Director in areas of internal and external global audits, GMP training and other compliance areas. In 2005 he opened his own compliance consultancy firm -- GxP Associates. Paul has co-authored IPEC's excipient auditing guideline and has served as President of the Central Atlantic States Association of Food and Drug Officials. He lives in New Jersey with his wife of 40 years. His son and daughter have given him five grandchildren to spoil. Paul is an avid metal detectorist and spends his free time searching for treasures of the past.

Associate Member Liaison



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Debra Lewis is the Director, Orphan Products Development Grants Program in FDA's Office of the Commissioner. She manages the \$14 million OPD extramural clinical research program to advance new products for rare diseases such as Huntington's Disease and Cystic Fibrosis. Prior to joining the OPD, Debra served as Deputy Director for the Office of Health and Industry Programs in the Center for Devices and Radiological Health. She has also served as the Director of the CDRH Staff College; Branch Chief in the Office of Device Evaluation's Division of Ophthalmic Devices (Diagnostic and Surgical Devices and Contact Lens Product Branches); Acting Director of the Premarket Approval Staff; and Clinical/Scientific Reviewer. Debra is a Captain in the USPHS Commissioned Corps and a fellow of the American Academy of Optometry.

Associate Member Liaison



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Vanee Komolprasert earned a B.S. degree in Food Technology from Chulalongkorn University in Thailand, a M.S. degree in Packaging and a Ph.D. degree in Agricultural Engineering, both from Michigan State University. She is also a licensed professional engineer. She came to FDA's Moffett Center in 1991 as a packaging researcher for Division of Food Processing and Packaging, Office of Plant and Dairy Food, Center for Food Safety and Applied Nutrition. For over 14 years, she led a number of food packaging safety projects at the Moffett Center in collaboration with Illinois Institute of Technology and industry, and two major projects are plastics recycling for food contact use and packaging irradiation incidental with food. Komolprasert is presently a consumer safety officer, Division of Food Contact Substance Notification Review, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition. She coordinates a review team for food contact notification submissions that are required for new substances intended for single and repeated use food contact surfaces. She joined FDAAA in 2004.

FDAAA Committees & Project Groups

BOARD COMMITTEES

Executive Committee

The Executive Committee consists of FDAAA Officers and manages the operational affairs of the Association. The Committee is accountable to, and regularly consults with, the Board of Directors. In developing organizational policy, steering and coordinating activities, and providing management oversight of all fiscal matters, the Committee also seeks advice and assistance from committee chairs and Associate Member Liaisons.

Elizabeth Krell (Chair)

Anthony Celeste
Alan Andersen
Richard Merrill
Robert Sauer
Jeffrey Springer

Nominating Committee

One of the Association's standing committees, the Nominating Committee recruits, screens and recommends to the Board of Directors alumni member candidates for leadership positions, on both the Board and in various Officer positions, in addition to identifying persons to serve as Associate Member Liaisons. The Committee is also in charge of FDAAA's awards program. (*At its Fall 2007 meeting, the Board of Directors decided to establish a freestanding Awards Committee – see next page for Committee membership.)

Michael Beatrice (Chair)

James Benson (Chair, Awards Subcommittee*)

Jerome Halperin
Arvin Shroff
Anthony Celeste (Ex Officio)

Awards Subcommittee*

James Benson (Chair)

Alan Andersen
Kay Holcombe
Mark Novitch
Tony Celeste

SUPPORTING COMMITTEES & PROJECT GROUPS

Activities Committee

The Activities Committee coordinates all educational and special events, including the Association's annual meeting. It also oversees the start-up of cooperative projects with FDA in the areas of counterterrorism and international affairs consulting.

Wayne Pines (Chair)

Andrea Chamblee
Minna Golden
Rita Hoffman
Linda Horton
Jean-Ah Kang
Nancy Myers
Adam Trujillo

Awards Committee

The Committee was established as a freestanding committee in 2007 to manage the Association's awards program.

Robert Eccleston (Chair)

LaJuana Caldwell
Anthony Celeste
Carrie Smith Hanley
Donald Marlowe

Communications Committee

The Committee keeps the membership informed on major news of the organization through an Association newsletter, website and annual directory. It also oversees the development and operation of member databases and the Association's Editorial Board.

William Rados (Chair)

Joseph Arcarese
Anthony Celeste
Robert Eccleston
Kenneth Krell
Robert Mazzaferro

Editorial Board

William Rados (Editor In Chief)

Anthony Celeste
Mark Barnett
Elizabeth Krell
Burton Love
Wayne Pines
John Villforth

Member Services Committee

Formed in 2004, this Committee (successor to Membership Committee) identifies the desires and expectations of Association members and translating them into tangible programs, benefits and services. The Committee also develops strategies for expanding FDAAA membership (including exhibits), production of new member materials and formation of local-area chapters.

Alan Andersen (Chair)

Jake Barkdoll
Robert Bell
Patricia Bianchi
Rosemary Cook
Rita Hoffman
Vanee Komolprasert
Debra Lewis

FDAAA & FDA Alumni Award Recipients

FDA Distinguished Alumni Award – 2007 (*Nominated by FDAAA)

2007 – Michael Blackwell, Robert Sauer

Previous Recipients

2006 - Alan Andersen*, Fred Hooten

2005 - Douglas Archer, Anthony Celeste*, Peter Barton Hutt*

2004 - Sherwin Gardner*, Richard Merrill*, Wayne Pines*

2003 - James Benson*, J. Richard Crout*

2002 - Jerome Halperin, Michael Taylor

2001 - Gerald Barkdoll, Joseph Hile, Gerald Meyer, John Taylor

2000 - Charles Edwards, Sanford Miller, Mark Novitch, John Villforth

1999 - Bruce Burlington, Ronald Chesemore, Gerald Guest, Richard Geyer, Carolyn Hardegree,
Burton Love, Arthur Norris, Carl Peck, John Turner, John Vanderveen

FDAAA Volunteer of the Year Award – 2007

2007 – Division of Communication Media, Center for Devices and Radiological Health

Previous Recipients

2006 - Andrea Chamblee, Jean-Ah Kang, George (Bert) Mitchell

2005 - Kelly Sauer

2004 - Joseph Arcarese

The Harvey W. Wiley Lecture (Special Recognition) – 2007

2007 – Peter Barton Hutt, Covington & Burling

Previous Lecturers

2006 - Donald Kennedy, Bing Professor of Environmental Sciences, Stanford University,
and former Stanford President and FDA Commissioner

2005 - Abbey S. Meyers, President, National Organization for Rare Disorders

2004 - Paul G. Rogers, Hogan & Hartson, and former U.S. Congressman

FDAAA Service Recognition Award (None Presented in 2007)

Previous Recipients

2006 - Ron Chesemore, Jerry Halperin, Burton Love, Paul Parkman

2005 - Sharon Smith Holston, Arthur Norris, Mark Novitch

FDAAA Certificate of Appreciation (None Presented In 2007)

Previous Recipients

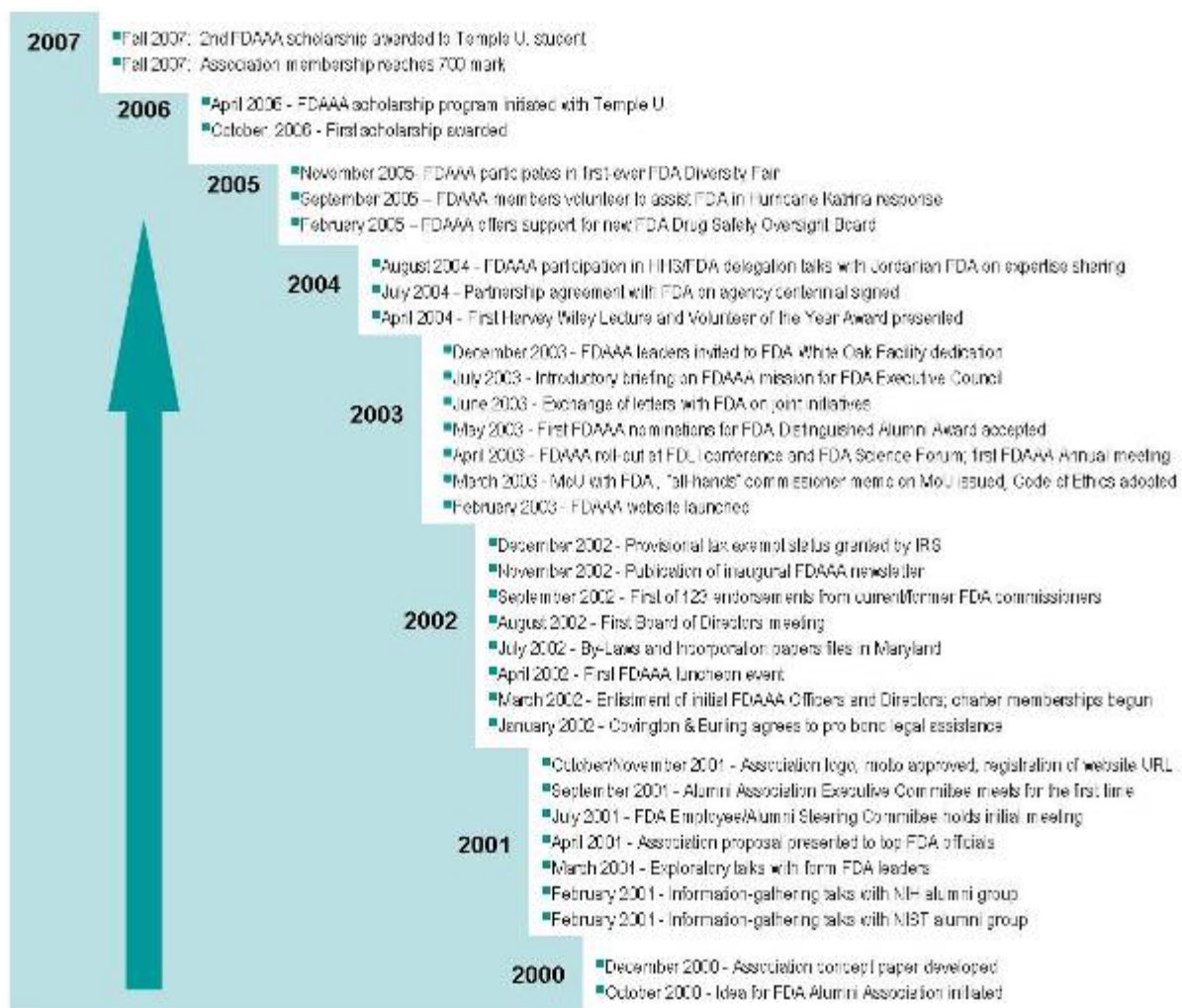
2004 - Kenneth Krell, Edith Seligson

2003 - Eric Greenberg, Bruce Kuhlik, Heather Nevin

FDAAA Mission & History

The Food and Drug Administration Alumni Association, Inc. is a non-profit volunteer service organization that:

- ▶ promotes the public health mission of the FDA by providing the assistance of alumni experts with specialized technical, scientific and institutional knowledge;
- ▶ provides educational and professional development opportunities to enable FDA alumni to stay abreast of current, challenging issues facing the agency;
- ▶ assists FDA in its ongoing capacity-building efforts by making students and professionals aware of public service opportunities at the agency;
- ▶ educates the public about the ever-expanding mission of the FDA and the importance of its work;
- ▶ sponsors outreach programs to educate and guide health authorities throughout the world in their efforts to establish and improve national regulatory systems relating to food, drugs, biologics, medical devices, and other health care and consumer products; and
- ▶ honors exceptional contributions to FDA's public health mission by former FDA employees and other individuals.



Membership Statistics & Demographics

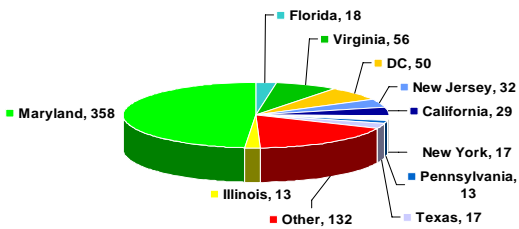


First we were local

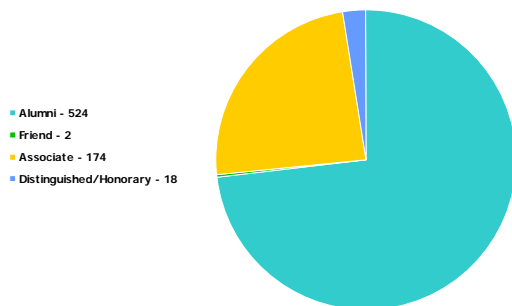
Then we became national

- 39 states & District of Columbia

Membership by State 2007



Distribution by Member Category



Today we are global ...

- Italy
- People's Republic of China
- Puerto Rico
- Singapore
- Switzerland
- Thailand

SPEICAL OFFER!
(*See details below)



KNOW SOMEONE WHO MIGHT JOIN FDAAA?

Share this membership application with a former FDA co-worker or alumni who might be interested in our Association. Copies are also available on the FDAAA website.

Applicant Name:

Last

First

Middle

Check all applicable boxes:

Mr. Ms. M.D. J.D. Ph.D. Sc.D.

Other (specify): _____

Address you want Association materials mailed to:

_____ Apt. ____

City: _____ State: _____ Zip: _____

Home Telephone: _____

Business Telephone: _____

Fax: _____

E-mail: _____

Years Worked at FDA: 19_____ to _____

FDA Center/Office for which you worked: _____

Job Category (e.g., administrative, product reviewer, compliance officer, scientist, investigator, engineer, consumer affairs officer, public affairs officer, educator, writer): _____

* One-year free entry memberships are now being offered to applicants with 10 or more years of service with FDA.

Volunteer Services: If you wish to volunteer your services in support of the Association, please indicate your area(s) of interest:

- Activity/Event Planning
- Administrative Support
- Awards
- Committees
- Fundraising
- Historian
- Member Directory
- Newsletter
- Photography/Videography
- Website
- Other (specify): _____

Annual Dues (check appropriate category):

- Alumni Member
 - ___ \$35/1 yr.
 - ___ \$65/2 yrs.
 - ___ \$90/3 yrs.
 - ___ Free one-year membership
- Associate Member
 - ___ \$20/1 yr.
 - ___ \$35/2 yrs.
 - ___ \$50/3 yrs.

Make checks payable to FDAAA and mail with application to:

FDAAA
c/o Alan Andersen
1101 17th St., NW, Suite 412
Washington, DC 20036

The FDAAA is a tax exempt, non-profit organization under Section 501(c)(3) of the Internal Revenue Code. In general, member dues and other contributions are tax deductible



FDAAA Welcomes New Members!

Ray H. Abraham
Darrell E. Baker
Ronda Balham
Andrew M. Barlow
David B. Batson
Joan M Batson
Brenda J. Bolden
Ricardo Carvajal
Andrew C. Chang
Marjorie F. Dannis
Sinai I. Davis
Edward F. Dawson
Michael P. Divine
Maria E. Donawa
Carl E. Draper
Michael N. Druckman
Gary J. Dykstra
DeVaughn Edwards
Stephen J. Fernbach
Gilbert A. Fleming
Larry E. Glaze
Karen L. Goldenthal
Scott N. Goldie
Brian E. Harvey
Kenneth L. Hastings
David Hilfiker
James E. Hoadley
George J. Jackson
Erika Leitzan
Renita A. Johnson-Levita
Diana J. Kolaitis

Joanna W. Ku
Paul M. Kuznesof
Deborah A. Lavoie
Erika Leitzan
Richard S. Lipov
Marcia Madrigal
Henry F. Maher
John C. Matheson
Lester H. Mathis
Joseph L. McCallion
Carmen Medina
Ken A. Miles
Melisa M.C. Moonan
Onesmo M. Mpanju
Nrapendra Nath
Doug Nelson
Michael C. Olson
Suzanne M. O'Shea
Mary S. Pastel
Guirag Poochikian
Donald L. Powell
Kim A. Rice
Stanley C. Rogers
Jeanne Román
Caesar A. Roy
Brenda C. Seidman
William L. Schwemer
Eric B. Sheinin
Dennis T. Strickland
Voyce P. Whitley
Susan F. Wood

