news along the pike

Center for Drug Evaluation and Research

May 1998

Volume 4, Issue 5

Inside . . .

Pike's Corners . . .

National Treasury Employees Union

FDA Workers Vote for Union Representation

A large block of FDA employees from around the country has selected the National Treasury Employees Union as their exclusive collective bargaining representative.

NTEU President Robert M. Tobias said the decision of FDA employees, some 3,000 of whom are professionals, including doctors, lawyers and scientists, "reflects an understanding of the reality that Federal employees are better off speaking with a unified voice."

The mail ballots, tallied by the Federal Labor Relations Authority, cover some 5,000 FDA employees. About 80 percent of them work in and around the Agency's headquarters, with the remainder in field offices around the country. More than 60 percent of those taking part in the FDA election voted for union representation.

The total vote count in the election was 1,084 votes for the union and 703 against. The nearly 4,000 employees at FDA's headquarters will be represented by the union's newest

(Continued on page 10)

FDA Honor Awards Ceremony

CDER Individuals, Teams Recognized

By Jackie Barber

A large contingent of CDER employees received awards during the FDA ceremony held May 8 at the DoubleTree Hotel in Rockville. Lead Deputy Commissioner **Michael Friedman, M.D.,** and Agency senior managers presented the awards during the 1998 annual ceremony. The awards and CDER employees receiving them follow:

40-Year Career Service Recognition

Elsworth Dory
Clarence Gilkes
Kathleen Jongedyk
Stanley Koch
Mary Kreienbaum
Clyde Wells

Commissioner's Special Citation

Steven R. Gitterman, M.D., Ph.D.

Gelatin Capsule Working Group: **Nicholas Buhay, Florence Fang, M.S., Charles Hoiberg, Ph.D., Lawrence Lesko, Ph.D., Henry Malinowski, Ph.D., Hioanhon Nguyen, M.S., Carol Noory, Robert Rippere,**

(Continued on page 6)

A 'Hare-Raising' Race

CDER Runner 'Energizes' Parklawn Classic

By Bronwyn Collier

April 24 brought perfect weather and a pink bunny for the 23rd Parklawn Classic walk and run. Runners were surprised when the bunny, carrying a large drum marked "energizer," lined up at the start of the tough 5-mile run course. CDER's **Paul Loebach** admitted to dressing in pink fake fur for the event, dispelling rumors that the Classic had a new corporate sponsor. Although Paul was unable to repeat past medal performances, he was the first bunny to cross the finish line and deserves congratulations for sweating it through to the end.

The annual event commemorated HHS' commitment to health and fitness for its employees and the 200th anniversary of the Public Health Service. Although neither Secretary Donna Shalala nor Surgeon General David Satcher could attend, they both sent their support and well wishes for the participants.

(Continued on page 10)

Joe's Notebook

Abbrvs., Round Holes, Square Pegs

On the opposite page, **Jim Morrison** tells us that the "A" in ADR can stand for "appropriate" or "alternate," depending on who you talk to or what's called for in a particular situation. I'll bet if your business is drugs rather than dispute resolution, what pops into mind is probably: "ADR = adverse drug reaction." Certainly abbreviations and acronyms can make our communications briefer. Because they can be confusing, however, I try to keep them to a minimum in the *Pike* .

My disenchantment with the bureaucratic penchant for alphabet soup began almost 30 years ago—back when the U.S. Army was unceremoniously gathering up young men like myself. Once they had me in their clutches, they had to figure out what to do with me. Being a bureaucracy, the answer was obvious: have Joe fill out forms. One form had a blank space for my new degree. So, without thinking, I wrote: "BA, Eng."

At the completion of basic training, we received orders sending us to training in the job the Army had selected for us, identified by indecipherable number and letter combinations. Most of my buddies were off to be 11Bs—infantry, as our drill sergeant so proudly announced. I was the only one in the platoon sent off to be a 12B. "What's that?" I asked.

"You've received basic infantry training," the drill sergeant explained. "Your buddies are going to do more of the same. Now what do you suppose we infantry do when we come to a river we can't cross and enemy are on the other side shooting back?"

"Swim?" I muttered.

"No, we don't do anything," he replied. "We call on the combat engineers to take care of it. They're 12B." I learned how to build—and blow up—bridges, but never did get to be a real 12B. When I arrived at my first unit, someone who had graduated from my university a year ahead of me was working in what we would call personnel but the Army calls G-1. He recognized my name as a familiar by-line from our college newspaper and sent me off to work on the unit's newspaper. That's how I got into the government information business. Only years later, did I realize that someone had interpreted my "Eng" abbreviation as engineering rather than English.

Reviewer Affairs Committee correspondent **Russ Rutledge** is also project manager for the First Party Audit Program. He promises details about this program in a future issue. In the meantime, Russ wants everyone to know that an industry exchange meeting is scheduled for June 23 from 9 a.m. to 4 p.m. at the Hyatt Regency Bethesda. "Basically, we are going to discuss the concept of First Party Audit Program and solicit comments from regulated industry and the public." Stay tuned . . .

If you're in Metro Park North 1 in the next couple of weeks, Russ, who works in the Division of Manufacturing and Product Quality, says to stop by and give a big CDER welcome to his acting branch chief, **Deborah Grelle,** who is on a 30-day detail from the FDA's Cincinnati field office.

Cathie Schumaker files this report on her training for the 350-mile AIDS Ride: **"**I have logged over 700 miles in the last 10 weeks of training, including a 90-mile ride to Mount Vernon May 2. I have finally learned to like the taste of Gatorade and appreciate the effect it has in keeping me less tired. I'd like to invite everyone to the closing ceremonies in Washington on Sunday, June 21." Cathie hopes to have the time and location for the next *Pike.* The *Pike's* sports reporter, **Bronwyn Collier,** promises coverage.

news along the pike

The Pike is published electronically on the X:drive in Cdernews and on the World Wide Web at:

http://www.fda.gov/cder/pike.htm

Photocopies are available in the Medical Library (Parklawn 11B-40) and its branches (Corporate Boulevard S-121, Woodmont I 200-S, and Woodmont II 3001).

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Have ideas, news or comments to contribute? Please contact a member of the Editorial Board or:

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Ombudsman's Corner

Alternative or Appropriate Dispute Resolution Gathers Steam

By Jim Morrison

I was privileged to participate in the HHS ADR Forum held April 30 at NIH's Natcher Auditorium. The growing interest in ADR, which stands for alternative dispute resolution or appropriate dispute resolution, depending on who you talk to, is evidenced by the turnout for this conference.

Planners originally anticipated that perhaps 200 people would attend this forum for employees of the Department. Registration quickly grew to 500, the capacity of the auditorium, and more than 250 others had to be turned away. This is truly remarkable, considering that most people were unaware of what ADR stood for just a couple of years ago.

The program began with a plenary session. Among the speakers was Kevin Thurm, deputy secretary of HHS and the Department's chief operating officer, who observed that litigation, with its adversarial nature, frequently destroys relationships. In contrast, the purpose of ADR—whether it is conciliation, mediation or negotiation—is to seek a consensus that repairs and strengthens relationships.

John Settle (what an appropriate name!), who recently left government after 18 years at the helm of the Departmental Appeals Board, noted that ADR represents a new paradigm in how disputes are handled. He urged managers everywhere to adopt new approaches to avoid becoming obsolete. He used the analogy of the Swiss watch industry, which, when given the opportunity to adopt the quartz technology that was developed in Switzerland, chose to rest on its laurels as the world's best clock makers. Instead the technology was snapped up by Texas Instruments and Seiko.

The forum then broke up into a series of concurrent sessions, including:

- *ADR 101,* a discussion of the basics of dispute resolution.
- *Negotiated Rulemaking,* a briefing on how the Health Care Financing Administration used this relatively new process.
- *ADR in the Workplace,* a look at how ADR is being used at FDA and Government Accounting Office (with FDA's **Kathy Vengazo** discussing how the Division of Employee Relations uses ADR instead of formal disciplinary actions).
- *Mediate Instead of Litigate,* a demonstration of how ADR can be used as an alternative to litigation by the Federal Government (with **Kay Cook** from FDA's Office of Chief Counsel presenting).
- *Role of Ombuds in Federal Agencies,* with yours truly and **Suzanne O'Shea** talking about ombuds in FDA, along with ombuds from U.S. Information Agency and NIH in a highly interactive session.
- *Real Life Experiences,* ADR in the Medicare, Medicaid and Head Start Programs.
- *New Directions in Federal ADR Initiatives,* a discussion of the ADR and Negotiated Rulemaking Acts of 1996.
- *Partnering: Exploring the Use of ADR in the Labor-Management Arena,* a session that should be useful to FDA management in the coming months.

Finally, the forum concluded with a general question-and-answer session with the speakers.

I left the forum with a renewed sense of optimism that as the word spreads that conflicts in all arenas can be solved through ADR, we will see a more harmonious and productive atmosphere emerge. When we are willing to see that other people in whatever capacity they operate are not enemies but are just other people with different interests that have an equal right to be heard and respected, we will adopt the principles of ADR in all facets of our work and private lives. As John Settle said in his remarks: "I urge you all to bring ADR from the workplace into your homes and into your communities. You won't hear that said about GPRA or TQM."

If you are involved in a dispute with internal or external customers, consider ADR. Contact me by phone (4-5443) or e-mail (MORRISONJ), and I'll help or find the expert who can. *Jim Morrison is the Center's Ombudsman.*

Communications Corner

Visual Aids Effective Tools for Shorter Meetings, Reaching Agreement

Presenting with visual aids can make you more persuasive, credible and interesting. Communications research show that:

- Combining visual aids with what you say makes you 40 percent more persuasive than talking alone.
- Viewing visual aids boosts audience retention rates by 50 percent.
- Using visual aids in a meeting reduces meeting time by almost 30 percent.
- Including overheads in a meeting presentation spurs 80 percent of participants to agree more quickly to a proposal. Without overheads, the agreement rate drops to 60 percent.
- Restricting a group to a maximum of 10 people yields the best results when you use posters, flip charts and "white" boards. An audience will endure viewing posters and flip charts slightly longer than slides or overheads.

Source: Simple Steps to a Powerful Presentation, Quill Corp., 100 Schelter Road, Lincolnshire, Ill.. 60069, in *communication briefings* 17(5).

HHS Consumer Web Site Improved

HHS unveiled new features for healthfinder, the government's health information Web site launched a year ago. The healthfinder site, at www.healthfinder.gov, serves as a gateway, helping people find reliable health information throughout the World Wide Web, including: how to get healthy, stay healthy and deal with chronic disease; how to locate good doctors and hospitals; how to report fraud and complaints; and how to find reliable health information on the Internet.

EEO Corner

Asian Pacific American Heritage Spotlights Yuan-Yuan Chiu

By Gloria Marquez Sundaresan

May is Asian Pacific American Heritage Month. To observe this event, the Center, FDA's EEO and Civil Rights Office and the Program Support Center will sponsor a display in the Parklawn Building, 5th Floor, B Wing, on Asian Pacific Americans in FDA and PSC. In addition, several Asian Pacific American employees will be attending training conferences in the Washington area. As part of this observance, I interviewed **Yuan-Yuan Chiu, Ph.D,** an accomplished member of the CDER community.

I first met Dr. Chiu when she was a panelist on "CDER Women Share their Success Stories," part of the women's program sponsored by the CDER EEO Information Sharing and Training Satellites. I was impressed with the balance that she has achieved between her personal and professional life. Despite her hectic schedule, she managed to tackle a challenging and successful project of setting up an accredited Chinese school in the community. She attributes her success to the role models that have guided her along the way. This experience allows her to help others in their struggle for career development and advancement.

Dr. Chiu, deputy director of the Office of New Drug Chemistry, joined CDER in 1980 when it was known as the Bureau of Drugs. Previously, she worked at The John Hopkins University from 1976 to 1980, where she was involved with the chemical and genetic studies of immunoglobulin. Dr. Chiu and her group determined the primary, secondary and tertiary structure and the genetic code of human immunoglobulin Hil.

In spite of being in the middle of these exciting scientific studies, she was fascinated about the FDA's role in monitoring and approving drugs for public use. In addition, she was also greatly impressed with the important contributions that the Agency makes to public health through the scientific evaluation of new drugs.

After joining the Agency, she had the opportunity to review the IND and later the NDA for the first biotechnology drug—human insulin—which was approved in 1982. *Time* magazine, in a special issue in the fall of 1996, identified this FDA accomplishment as one of the 10 milestones of the century in medicine. "I am especially thrilled about this work and being a part of history that's really important," Dr. Chiu said. "I'm very proud that our work and the FDA were recognized in such a manner."

In commenting on working in the Agency, Dr. Chiu remarked: "FDA is a fun place to work—a place to have personal and professional growth." She said that one can get involved in many issues and grow personally. Professionally, one can improve, due to an environment rich with multiple disciplines, new scientific data, challenging legal issues and people that interact well at work.

She said CDER is changing and hopes that, in the future, Center employees will be even more responsive to the public's expectations for the safety and efficacy of the drugs they take and to the pharmaceutical industry. "We need to be open-minded," Dr. Chiu said, "not patronizing and arrogant. Most importantly, we need to listen to the people whom we serve and be worthy of their trust."

Dr. Chiu has a bachelor's degree in chemical engineering from National Cheng Kung University in Taiwan and a Ph.D. in chemistry from Harvard University. She has published about 30 scientific articles and co-edited the book, *Drug Biotechnology Regulations, Scientific Basis and Practices.*

Gloria Marquez Sundaresan is an equal employment specialist on the EEO Staff.

Training and Development

How CDER Develops Core Competencies Focused on Mission

By Steve Hayleck, Maria deCarvalho, See Lam, Deb McKemey, Dee Rhodes and Leslie Wheelock

Many of you have heard of or helped with the assessment of "core competencies." However, the purpose and intent of this project may not be clear. The purpose is to determine the skills or tasks needed by high-performing employees to do their jobs effectively. The intent is to develop and deliver training focused on improving your ability to do your job.

The first step in developing core competencies for a particular job starts with researching available background material, primarily position descriptions, job announcements and other studies that may have been performed on that job series or title. From this initial research, a list of tasks pertaining to the job is developed. A focus group of subject matter experts is formed to evaluate and modify this task list for a particular job.

Next, the focus group uses the final task list to determine the knowledge and skills needed to do a particular task. A common example of a task is the entry of data into a computer. The required skill is using a computer or a particular software program.

Finally, the focus group, together with the Center's coordinating committees, determines the training courses needed to meet the knowledge and skills requirements. Using the computer example, a course in a particular statistical software program may be needed.

The Division of Training and Development in the Office of Training and Communications is facilitating the collection of information for the development of core competencies. From information obtained, the division will work with CDER staff to revise or develop courses to meet the core competencies. The end result will be training more clearly focused on the job needs of the individual to accomplish CDER's mission.

The authors are members of the Division of Training and Development.

Information Technology Corner

Division Files System Rollout in Full Swing

By Sue Makoff

In October's *Pike,* we discussed the successful completion of the Division Files System pilot and the start of the DFS rollout to the Center. We are pleased to report that the rollout of DFS is now in full swing. Currently, we have rolled out DFS to eight divisions. By the end of the year, DFS will be implemented in all divisions of the Office of Review Management. Staff in the Office of Clinical Pharmacology and Biopharmaceutics who are co-located with the review divisions also will receive DFS. Those of you who have received DFS are using it. At this time, over 10,600 review document s have been checked in to the system.

For those of you who haven't received DFS yet, DFS is a key component of the Administrative Management of Files initiative. DFS allows CDER staff to route final review documents for signature, automatically store the documents in an electronic repository, search for documents stored in the repository and view the documents online.

Although we are presently rolling out the first phase of DFS to the Center, we are continually updating and refining DFS. During the first weekend in May, we upgraded DFS to a version that supports file formats in Microsoft Office Professional '97.

We are also upgrading the server that converts documents into Adobe portable document format—PDF. With this enhancement, the appearance of documents converted into PDF by DFS will improve, and you will be able to check PDF files into DFS. In addition, you will be able to cut and paste material from the PDF files in DFS into your current work.

In the near future, the CDER DFS working group will be reactivated to begin working on phase two. Plans include e-mail distribution of final documents, the ability to print documents with signatures and automatic updates to COMIS—the Centerwide ORACLE Management Information System.

Sue Makoff is a member of the DFS Team.

Administrative Management Corner

Information Technology Subcommittee Facilitates IT Changes

By Wayne Amchin

The Information Technology Subcommittee of the Administrative Management Coordinating Committee is focusing its efforts on ASAP—the Administrative Systems Automation Project. The subcommittee will facilitate and monitor the piloting and rollout of this important system into CDER and is especially interested in the roll-out of EASE—the Enterprise Administrative Support Environment. EASE is the automated time-keeping module of ASAP.

The subcommittee has received two ASAP status update presentations, and it organized an ASAP briefing for the quarterly Administrative Management Team meeting.

Last year, the subcommittee established a supplies task force to facilitate the transition from centralized funding and purchase of computer-related supplies to decentralized funding and purchase. This effort provided CDER offices the opportunity to express their concerns over decentralization, enabled the Office of Information Technology to facilitate the transition, and freed up OIT resources to provide computer support to CDER staff.

The next issue for the subcommittee to address is the roll-out of new computers and the trickle-down policy for computers being replaced. The subcommittee will be working with OIT and CDER offices to facilitate a smooth transition.

The subcommittee was organized last year and held its first meeting with **Bill Oswald** as chair on April 15, 1997.The current membership includes **Ted Sherwood** (co-chair), **Wayne Amchin** (executive secretary), **Tom Cunningham, Angela Davis, Denise Rahmoeller Dorsie, Roxana Fay, Jennifer Gianan, Brenda Harmon, Bobbi Jones, Dan Luckabaugh, Toni McCannon, Susan O'Malley, Anna Rubino, Paul Stauffer, Michelle Walling** and **Matt Zell.** New members are welcome, as is your input to any of the current members.

Wayne Amchin is a management and program analyst in the Office of Review Management.

Leadership Fellows Applications Due

The Division of Training and Development has set a May 28 deadline for applications for the 1998-'99 CDER Leadership Fellows Program. A maximum of 12 fellows in grades GS-13 to 15 will be selected. The Office of Training and Communications manages the program in partnership with the Council for Excellence in Government. Applications are available in all CDER libraries or by calling DTD's **Bibi Jakrali** (7-3488) who must receive the completed applications by May 28.

This year's program will involve CDER fellows with fellows from other government agencies. The program officially begins in September. Because of the limited number of positions CDER can fund this year, those selected must be able to participate in the program to the fullest extent. Successful completion requires at least two to three days per month as well as time for working on projects. Applicants and their supervisors must agree to participate in all requirements of the program.

CDER Employees Earn Many Honors at FDA Ceremony

(Continued from page 1)

David Scarpetti, Ph.D., Norman Schmuff, Ph.D., Vinod Shah, Ph.D., Gerald Shiu, Ph.D., Bradford Williams, Roger Williams, Ph.D., and **Rebecca Wood.** Former FDA employees: **Gregory Guyer, Michael Ganey, Charles Kumkumian, Ph.D., Lloyd Tillman, Ph.D.,** and **Ramakant Mhatre, Ph.D.**

FDA Award of Merit

Lana Ogram
Rosemary Roberts, M.D.

HIV-RNA Working Group: **Rachel Behrman, M.D., Therese Cvetkovich, M.D., Michael Elashoff, Ph.D., Paul Flyer, Ph.D., Steven Gitterman, Ph.D.,** and **Jeffrey Murray, M.D.**

Nelfinavir Review Team: **Shukal Bala, Ph.D., Michael Elashoff, Ph.D., Paul Flyer, Ph.D., Steven Gitterman,M.D., Ph.D., Kenneth Hastingsm, Pharm,D,, Sheryl Lard Whiteford, Ph.D., Paul Lui, Ph.D., Samuel Maldonado, M.D., James Ramsey, Ph.D.,** and **Kellie Schoolar Reynolds, Pharm.D.**

OTC Labeling Rule Team: **Kathryn Aikin, Ph.D., Debra Bowen, M.D., Kevin Budich, Gloria Chang, Marina Chang, Ling Chin, M.D.,M.P.H., Maria Rosanna Cook, M.B.A., Helen Cothran, Robert Eshelman, Katharine Freeman, Linda Fujiwara, William Gilbertson, Pharm.D., Robert Heller, Diana Hernandez, Linda Hu, M.D., Linda Katz, M.D.,M.P.H., Michael Kennedy, Karen Lechter, Ph.D., Debbie Lumpkins, Cazemiro Martin, Babette Merritt, Louis Morris, Ph.D., Anne Mustafa, Rosemarie Neuner, M.D.,M.P.H., Delores Pinkey, Gerald Rachanow, J.D., Elizabeth Ryland, Ellen Shapiro, Robert Sherman, Brenda Sturdivant, Michael Weintraub, M.D.,** and **Bradford Williams.**

Ritonavir and Indinavir Review Teams: **Narayana Battula, Ph.D., Rachel Berhman, M.D.,M.P.H., Barbara Davit ,Ph.D., Paul Flyer, Ph.D., Steven Gitterman, M.D.,Ph.D., Thomas Hammerstrom, Ph.D., Janice Jenkins, Ph.D., Deborah Kallgren, Lisa Kammerman, Ph.D., Kofi Kumi, Pharm.D., Stanka Kukich, M.D., Sheryl Lard Whiteford, Ph.D., John Lazor,Pharm.D., Paul Liu, Ph.D., Stephen Miller, Ph.D., Jeffrey Murray, M.D.,M.P.H., Kellie Schoolar Reynolds, Pharm.D., Pritam Verma, Ph.D., Ita Yuen, Ph.D.,** and **Joyce Korvick, M.D.**

Wasting Working Group: **Elizabeth Koller, M.D.,** and **Marianne Mann, M.D.**

FDA Group Recognition

CDER Genetic Toxicology Committee: **Chang-Ho Ahn, Ph.D., Aisar Atrakchi, Ph.D., Anita Bigger, Ph.D., Norma Browder, Ph.D., J. Christopher Cordaro, Ph.D., James Farrelly, Ph.D., Edwin Matthews, Ph.D., Robert Osterberg, Ph.D.,** and **Ronald Steigerwalt, Ph.D.**

Electronic CRF/CRT Committee: **Renata Albrecht, M.D., Kaye Fendt, M.S.P.H., Brad Leissa, M.D., Randy Levin, M.D., Lilia Talarico, M.D., Curtis Wright, M.D., M.P.H.,** and *(PHS Unit Commendation)* **CAPT Stephen Wilson, Dr.P.H.**

PHS Meritorious Service Medal

CDR Frank Sistare

PHS Outstanding Service Medal

CAPT Robert Tonelli
CDR Paul Zimmerman

Jackie Barber is the CDER incentive awards officer.

Lesko Honored by Temple University

Larry Lesko, Ph.D., Director of the Office of Clinical Pharmacology and Biopharmaceutics, has received two awards from his *alma mater*, Temple University School of Pharmacy:

- On April 9, Lesko received the Josep B. Sprowls Distinguished Lecturer Award, which involved two seminars. Lesko gave a patient-focused presentation that covered the evaluation of generic drugs and the significance of drug interactions in patient-based pharmaceutical care and one clinical pharmacology in drug development to graduate students. He clarified current standards that the Center uses to evaluate generic drugs as well as the need for careful monitoring of metabolically driven drug interactions. He assured the students that generics with a narrow therapeutic index, such as warfarin, were safe and effective.
- On May 9, Lesko was presented the School of Pharmacy's Certificate of Honor at the University Founder's Dinner.

Lesko received his B.S. and Ph.D. degrees in pharmaceutics from Temple, and university officials said this is the first they can recall that the same individual received both awards in the same year.

Subramaniam Receives Society Award

CDER pharmacist **V. Puri Subramaniam, M.S., P.D., R.Ph.,** has been selected as a Fellow of the American Society of Health-System Pharmacists. Subramaniam, a consumer safety officer in the Division of Prescription Drug Compliance and Surveillance, Office of Compliance, will be the only pharmacist from FDA, along with 32 other pharmacists nationwide and internationally, to be designated a fellow in 1998 at the society's annual meeting next month in Baltimore.

Prior to joining FDA in 1990, Subramaniam held a variety of positions in hospital pharmacy practice as a clinical pharmacist, teaching coordinator and director of pharmacy services. In 1988, he was appointed clinical pharmacist and quality assurance coordinator at the Veterans Affairs Medical Center in Washington. He also established pharmacy externship training programs for students from the University of Maryland School of Pharmacy where he was clinical assistant professor and preceptor in pharmacy practice from 1982 to 1988. He is a former president of the Society of FDA Pharmacists and immediate past president of the Washington Metropolitan Society of Health-System Pharmacists.

New Categories Announced

Center Sets June 5 for Spring Honor Awards Ceremony

By Jackie Barber

CDER will hold its Spring Honor Awards ceremony on Friday, June 5, at 10:30 a.m. at the Gaithersburg Hilton, 620 Perry Parkway.

CDER will recognize the accomplishments of its employees with the following FDA awards: Commendable Service, Outstanding Achievement, Equal Opportunity Achievement and Group Recognition. Commissioned officers will receive Public Health Service Commendation Medals and Unit Commendations.

In addition to FDA Honor Awards, the Center will also be presenting CDER Peer Honor Awards. Two new categories have also been added since the Fall ceremony:

- *Project Management Excellence Award*, recognizing project management staff whose activities demonstrate excellence in support of CDER's program goals and mission.
- *Information Technology Excellence Award*, recognizing individuals or teams whose activities demonstrate excellence in the area of information technology, in support of CDER's program goals and mission.

This year will mark the first time that **Janet Woodcock, M.D.,** will present the Center Director's Special Citation. Another award presentation will include individuals who will be awarded Vice President Al Gore's Hammer Award.

CDER Peer Honor Awards will be given in the following categories:

- *Team Excellence Award*, recognizing teams for extraordinary contributions to CDER's mission.
- *Support Staff Excellence Award*, recognizing clerical, technical, assistant and general support individuals or teams whose activities demonstrate excellence in achieving CDER's mission.
- *Administrative/Program Excellence Award*, recognizing individuals or a team who effectively carry out the program's mission, ensuring excellence, as well as striving to make significant contributions to CDER program goals.
- *Leadership Excellence Award*, recognizing individuals who demonstrate extraordinary effectiveness in directing a program towards the accomplishment of CDER's mission.
- *Excellence in Communication*, recognizing individuals or a team who demonstrate excellence in effectively communicating for CDER to either external or internal constituents.

In addition, the Center will present CDER Special Recognition Awards and program certificates for Leadership Fellows.

CDER is proud to recognize and reward the many accomplishments of its employees throughout the year. A special thanks goes to the members of the CDER Peer Honor Awards Nomination Committee: **Vijaya Tammara** (chair), **Pauline Fogarty, Anita Harrell, Mark Lynch, Linda Roberts** and **Gloria Sundaresan.**

For more information, please call 4-2004.

Jackie Barber is the CDER incentive awards officer.

'Biochip' Technology Workshop Slated for July 14, 15

By Neil Wilcox, D.V.M., M.P.H.

The ability to produce high-density arrays of DNA on computer microprocessors—called "microarrays," "genechips" or "biochips"—promises to revolutionize medical diagnosis, drug discovery, disease management and infectious agent identification. An FDA workshop, "DNA Microarray: Current Technology and Future Applications," will be held July 14 and 15 at the NIH's Natcher Conference Center in Bethesda.

The two-day workshop, exclusively for FDA employees, will feature a number of invited speakers from industry and academia who will discuss various microarray technologies and the instrumentation used. Applications and opportunities for use in the pharmaceutical, biologics and food industries, as well as in disease diagnostics and veterinary medical settings will be presented.

These applications will impact many Agency review activities and regulated products, and it is important that FDA research and review staff be informed about the current scientific and technical issues in microarray development and application.

Registration through the FDA-only intranet is now available at: http://first.fda.gov/scisem/microarr.htm. There will be no fee for registration. For more information, contact **Donna Mentch** by e-mail (dmentch@oc.fda.gov) or phone (7-3038).

Neil Wilcox, D.V.M, M.P.H., is a senior science policy officer in the Office of Science.

Project Management Corner

Go-Away Set for June 1

By Jean Yager

Reserve June 1 for the all-Center project management go-away. Hosted by the Project Management Coordinating Committee, the all-day event will be held at the Gaithersburg Hilton. The morning session will feature short seminars from the Office of Compliance, Office of Information Technology and Office of Generic Drugs as well as updates from several PMCC subcommittees.

In the afternoon, breakout discussion groups will work to identify best practices on key topics and share this information with their colleagues. The meeting will close with a presentation from **Murray Lumpkin, M.D.,** Deputy Center Director (Review Management), on the future direction for project management and teams in CDER.

Jean Yager is director of project management.

Reviewer Affairs Corner

Your 1998 Representatives, Alternates Elected

By C. Russ Rutledge

In January's *Pike,* I outlined the organization of the Reviewer Affairs Committee, showed where to find information and introduced the newly elected officers. This month features the 1998 RAC representatives roster. Each division should have both a primary representative and an alternate. RAC members are non-supervisory professionals in the physical, life and social sciences who perform such duties as reviewing drug applications and communication about drugs.

There are a few alternate positions still available. If your division is lacking representation and you would like to participate with this dynamic and interactive group, please contact **Melissa Maust, Fred Marsik** or **Tanya Abbott** for more information.

In other matters, the RAC distribution list has been modified to include only the current representatives and their alternates. Previously, the RAC distribution list was composed of former reps and other interested reviewers. Because it is sometimes necessary to send draft information to the RAC representatives for comments, the committee found it necessary to modify this distribution list so that this preliminary information wouldn't be misinterpreted and cause confusion.

The X:drive (X:\coorcomm\rac*) contains all the RAC information, including meeting minutes, subcommittee reports, works in progress, finalized documents and history. This should be sufficient information to keep those interested in following the activities of the committee up to date.

C. Russ Rutledge is a compliance officer in the Division of

- **Tanya Abbott** (executive secretary), Office of the Center Director, 4-6779.
- **Jo Ann Spearmon, Janet Norden** (A), Division of Drug Marketing, Advertising & Communications, 7-2831.
- **Aisar Atrakchi, Andrea Powell** (A), Division of Neuropharmacologic Drug Products, 4-2850.
- **Karen Johnson, Judy Chiao** (A), Division of Oncologic Drug Products, 4-2565/7-1538.
- **Adebayo Laniyonu, Robert Yaes** (A), Division of Medical Imaging & Radiopharmaceutical Drug Products, 3-1560/3-3560.
- **Harry Geyer, Monte Scheinbaum** (A), Division of Anesthetic, Critical Care & Addiction Drug Products, 3-4250/3-3741.
- **Robert Prizont**, Division of Gastrointestinal & Coagulation Drug Products, 3-0479.
- **Kevin Budich**, Division of Labeling and Nonprescription Drug Compliance, 4-1065
- **Russ Rutledge,** Division of Manufacturing and Product Quality, 4-2455.
- **Ada Irizarry, Melvin Szymanski** (A), Division of Prescription Drug Compliance & Surveillance, 4-0101
- **Gurston Turner, Jose Carreras** (A), Office of Compliance Clinical Investigations Branch, 4-1032.
- **Gemma Kuijprs,** Division of Metabolic & Endocrine Drug Products, 3-3510.
- **Fred Marsik** (vice chair), **Harold Silver** (A), Division of Anti-Infective Drug Products, 7-2120/2188.
- **Ita Yuen, Russell Fleischer** (A), Division of Anti-Viral Drug Products, 7-2330/7-2331
- **Lynnda Reid, Javier Avalos** (A), Division of Dermatologic & Ophthalmologic Drug Products, 7-2072/7-2044.
- **Elizabeth Ludwig, Asoke Mukherjee** (A), Division of Anti-Inflammatory, Analgesic, & Dental Drug Products, 7-2080/7-2516
- **Linda Hu,** Division of Over-the-Counter Drug Products, 7-2222.
- **Anne Trontell, Luqi Pei** (A), Division of Pulmonary Drug Products, 7-4260.
- **Terri Rumble, Diane Moore** (A), Division of Reproductive & Urologic Drug Products, 7-4260.
- **Steve Kunder,** Division of Special Pathogen & Immunologic Drug Products, 7-2334.
- **Chan Park, Jacqueline White** (A), Division of Labeling & Program Support, 7-5827/4-0365.
- **Melissa Maust** (chair), **Naiqui Ya** (A), Division of Chemistry I, 7-5763/7-5760.
- **Abraham Croitoru, Tracey Rogers** (A), Division of Chemistry II, 7-5849.
- **Nhan Tran, Zakaria Wahba** (A), Division of Bioequivalence, 7-5733/4-0345.
- **Japobrata Choudhury,** Division of Biometrics I, 4-5582.
- **Barbara Elashoff, Kate Meaker** (A), Division of Biometrics II, 7-1054/7-4257.
- **Mohamed Al-Osh, Mahboob Sobhan** (A), Division of Biometrics III, 7-3029/3120.
- **Alaka Chakravarty, Shahla Farr** (A), Division of Biometrics IV, 7-2171/7-2037
- **Beverly Friedman,** Division of Pharmacovigilance and Epidemiology, 7-0903.
- **Patricia Hughes, Brenda Uratani** (A), Office of New Drug Chemistry, 3-5818/7-1605.
- **Kathleen Jongedyk,** Division of New Drug Chemistry I, 7-5349.
- **Maria Ysern, Ali Al-Hakim** (A), Division of New Drug Chemistry II, 3-0483.
- **Milton Sloan, Rajendra Uppoor** (A), Division of New Drug Chemistry III, 7-2182/7-2526.
- **Sayed Al-Habet, Lydia Kieffer** (A), Division of Pharmaceutical Evaluation I, 4-6650/4-2564.
- **K. Gary Barnette, Robert Shore** (A)**,** Division of Pharmaceutical Evaluation II, 7-4254/7-6412.
- **Sue-Chih Lee, Houda Mahayni** (A), Division of Pharmaceutical Evaluation III, 7-2052/7-2010.

PDUFA I User Fee Goals Met for FY '96, On Track for FY '97

By Murray Lumpkin, M.D.

Congratulations are in order for all CDER staff. The Center exceeded the user-fee deadlines for reviewing and acting on all 109 original new drug applications received in fiscal year 1996 and—for first time—was 100 percent on time. This cohort's goal under the original Prescription Drug User Fee Act was for 80 percent of the NDAs reviewed on time. Greater than 95 percent of all resubmissions, efficacy supplements and manufacturing supplements were also acted on within user fee time frames.

The Center is now working through the fiscal year '97 cohort with a goal of 90 percent of NDAs reviewed within deadline. So far, 88 of 122 original NDAs filed have been acted upon, all on time. The remainder are still within target. In addition, this is the first cohort expected to meet a six-month review time for 90 percent of priority applications. In this cohort, 26, or 21 percent, are priority applications, slightly higher than previous cohorts. To date, the Center has acted on 24 on time—exceeding our user fee goal in this category. The last two are still within goal.

In addition, 10 of the 145 efficacy supplements filed were classified as priority, a comparable percentage to previous cohorts. All 10 have been acted on within the user fee goal—a 100 percent on-time review performance vs. a 90 percent goal.

Murray Lumpkin, M.D., is Deputy Center Director (Review Management).

Review Science Research Grants to be Videoconferenced in June

By Rose Cunningham

Scientific Rounds are extended through June. On Wednesdays from 9:30 a.m. to 11:30, the principal investigators of the fiscal year 1996 grants for Review Science Research will give videoconferenced updates on their results or progress.

June 3—(Videoconferenced from Woodmont II, Conference Room G, to Parklawn Conference Room G and Corporate Boulevard S-100)

- Development of Centerwide shared program for exchange of abuse liability indications for new drugs. **Michael Klein.**
- The need and predictability of photocarcinogenicity testing in animals. **Javier Avalos** and **Abby Jacobs.**
- Analysis of the predictive value of preclinical toxicology studies for anticancer agents. **Julie Beitz.**
- Impact of certain types of changes to clinical trial conduct. **H.M. James Hung.**
- Literature review and annotated bibliography of the statistical literature relevant to active control trials. **Lisa Kammerman** and **S. Edward Nevius.**

June 10—(Videoconferenced from Woodmont II, Conference Room G, to Parklawn 13B-39 and Corporate Boulevard S-100)

- Unadjusted and adjusted survival analysis—a study of dramatic differences in P-values between the logrank test and adjustment using Cox regression in highly censored survival data. David Hoberman.
- Multiple Endpoints Analysis and Bootstrap. Kun Jin.
- Guidelines for the evaluation of anti-aging drugs. Jack Longmire.
- Quality assurance program for non-clinical review data. **Ted Jiy Guo.**
- Development and analysis of a database from clinpharm and biopharm studies in NDAs from 1994-1997. **Mehul Mehta**. Combined with: Past experiences can improve the drug development and drug reviewprocess, a survey of drug interaction studies. **John Balian.**

June 17—(Videoconferenced from Woodmont II, Conference Room G, to Parklawn 13B-39 and Corporate Boulevard S-100)

- A new program for carcinogenicity analysis. **Michael Elashoff.**
- Similarity testing with multiple endpoints. **Yi Tsong.**
- An improved class of tests for category discrimination in the analysis of oncologic tumor response and toxicity data. **Steven Hirschfeld** and **Vance Berger.**
- Meeting PDUFA timelines for chemistry reviews of NDAs and INDs. **Su Tso.**
- The role of pharmacokinetic-pharmacodynamic (PK/PD) modeling in the analysis and review of Phase 3 clinical trials. **Raymond Miller.**

June 24—(Videoconferenced from Parklawn Conference.Room. B to Woodmont II, Conference Room G and Corporate Boulevard S-100)

- Evaluation of the current regulatory practices governing preclinical toxicology studies of a reverser of cancer multidrug resistance in combination with a cytotoxic anti-cancer agent(s). **Chang Ahn.**
- To investigate the effect of age on the PK/PD of approved anti-epilelptic drugs and to optimize dosing regimens for these drugs in various age groups using several PK/PD models. **V.J. Tammara.**
- Evaluation of clinical drug development strategies to achieve subpopulation-specific optimal doses. **Chuanpu Hu** and **Raymond Miller.**
- The safety of nicotine replacement products. **Monte Scheinbaum.**

Rose Cunningham is a regulatory health projects manager on the Executive Operations Staff.

CDER's Sildenafil Web Site Popular

By Carol Assouad

Sildenafil (Viagra) was the first drug for which CDER on the day of approval simultaneously published on the World Wide Web the approval letter, the labeling text, consumer information and the joint review (April *Pike).* From the approval day March 27 through April 30, this information was accessed more than 200,000 times. The sildenafil home page had about 75,000 hits, followed by the consumer information and question-and-answer pages with about 36,000 hits each. The labeling was accessed about 10,000 times. The implications of posting this extensive information for new drug products are significant for accurate and reliable communications. Three of five Freedom of Information requests were withdrawn as a result.

Carol Assouad is the Medical Library Director.

National Treasury Employees Union Wins FDA Election

(Continued from page 1)

chapter—Chapter 282. The nearly 1,000 employees in the field included in this election will be part of the union's already existing HHS regional chapters.

NTEU, the largest independent Federal sector union, represents 150,000 Federal employees in 18 agencies and departments, including about 500 FDA employees in Atlanta and Kansas City, Kan.

During the organizing campaign, FDA employees voiced their concerns about a variety of issues dealing with their work lives, including evaluations and promotional opportunities, conflict resolution and matters relating to continued government downsizing and attempts to reduce Federal pay and benefits.

The union has appointed interim officers to serve until there is enough membership to vote on bylaws and a permanent executive board. Picked as interim president of Chapter 282 is CDER's **Robert Young, M.D.,** a medical officer in the Office of Compliance's Division of Scientific Investigations. Interim vice presidents named for CDER are: **Mariana Chang,** Division of Over the Counter Drug Products; **Josephine Jee,** Division of New Drug Chemistry I; and **Charles Dieter,** Division of Testing and Applied Analytical Development.

Young said that the union presence in the FDA would help improve working conditions for employees and provide "a real opportunity for the Agency, as an agency, to work better—and that will result, hopefully, in greater consumer protection."

To ensure that all FDA managers and supervisors understand the impact of the election, the FDA's Office of Human Resources and Management Services is sponsoring a four-hour workshop for managers, supervisors and management officers. This training is mandatory for all managers and supervisors in FDA. During the workshop, an expert in labor and management relations will cover:

- The basic concept of the bargaining unit.
- Representation rights of the union with emphasis on formal discussions and employee rights to union representation in meetings held in connection with an investigation .
- Responsibilities of the first-line supervisor.
- Basics of the negotiated grievance procedure.
- Unfair labor practice procedures.

CDER managers and supervisors should register for one of the following sessions by sending an e-mail to Sonya Armstrong in the Division of Training and Development (ARMSTRONGS) with the date and time of the session they will be attending:

- *Parklawn*, Rm. 13B-39, May 18, 8 a.m. to noon and 1 p.m. to 5 p.m.; June 1, 1 p.m. to 5 p.m.
- *Woodmont II*, Conference Room G, May 19, 1 p.m. to 5 p.m.
- *Corporate Boulevard*, Room S-400, May 21, 8 a.m. to noon and 1 p.m. to 5 p.m.
- *Metro Park North I*, Room 259, May 22, 8 a.m. to noon.

7 CDER Runners Place in Age Categories for Parklawn Classic

(Continued from page 1)

Lead Deputy Commissioner **Michael Friedman, M.D.,** enthusiastically stepped in as master of ceremonies and official starter for this year's walk.

"Drill sergeants" from the Sergeants' Program, an adult fitness regimen, led walkers through a vigorous warm-up prior to starting the walk. Their motto is: "No milk, no cookies, no mercy—be all you used to be!" After the warm-up, safety marshals had an easy job overseeing the walker safety as more than 700 representatives from virtually every HHS agency briskly tackled the 2.5-mile course. Walkers completing the course received ribbons declaring their accomplishments.

Disaster threatened the run when buses hired to transport participants to the event from outlying buildings and take runners to the starting line failed to arrive. Classic committee volunteers swiftly stepped in and sent messages to participants to take Metro to the Parklawn Building. They then secured any type of transportation they could get their hands on to get the runners to the starting line. Runners must have wondered if they were being taken to the border as they were crammed into delivery trucks, pick-ups, flat-bed trucks and vans. The start was delayed 10 minutes to accommodate the late arrivals.

Medals were awarded to **Jeffrey Merkowitz** (Office of the Secretary; gold), **Melissa Starinsky** (FDA; gold), **Lorenz Studer** (NIH; silver), **Pamela Boteler** (NIH; silver), **Matthew Myers** (FDA; bronze), and **Amy Subar** (NIH; bronze).

Seven CDER runners were among the FDAers who figured prominently in their age categories: **David Hilfiker** (CDER), **John Baxley, Ray Frankewich** (CDER), **Peter Martineau, Nick Reuter, William Roth, Mark Gonitzke** (CDER), **Steve Sherman** (CDER), **Louis Pribyl, Walt Brown, Bruce Drum, Gerry Shipps, Russ Abbott** (CDER), **Arthur Hass, Butch Bosin, Bill Price, Mandy Eisemann, Erica Sugar** (CDER), **Kyle Myers** and **Linda Carter** (CDER).

Race results will be found at: http://classic.dhhs.gov/classic.

Congratulations to all participants and special thanks to all the volunteers who made the Classic possible. See you next year.

Bronwyn Collier is Associate Director for Regulatory affairs in ODE III.