news along the pike

SUMMER 2003

CENTER FOR DRUG EVALUATION AND RESEARCH

VOLUME 9, ISSUE 3

INSIDE . . .

PIKE'S CORNERS . . .

Center recognizes 52 individuals, 32 teams

FDA, Science Forum honor 10 CDER employees, 7 teams

BY JACKIE BARBER

At the Center's Spring Honor Awards Ceremony held May 30 in Gaithersburg, 52 individuals and 32 teams were recognized. An additional nine individuals and two teams were recognized at the Agency-level ceremony held May 9 in Rockville (page 8). FDA's 2003 scientific achievement awards were presented to one CDER scientist and five teams with CDER scientists at the annual Science Forum held April 24 and 25 in Washington's new convention center (page 8).

"You have continued to meet the challenges and surpass expectations with your innovation and dedication to serving the American people," Center Director **Janet Woodcock, M.D.,** told the awardees at the CDER ceremony. "Your superior leadership, scientific expertise and technical skills demonstrated are second to none. You should feel extremely proud of your accomplishments and even prouder that your efforts have such a profound and positive impact on health care for so many individuals in our country."

Kevin Barber sang the national anthem. **John L. Emelio,** who is the director of the Division of Management Services in the Office of Management, was master of ceremonies. Dr. Woodcock, Deputy Center Director **Steven Galson, M.D.,** and members of the Center's senior management presented the awards.

The awards were:

FDA Outstanding Service Award

Richard C. Adams

(Continued on page 6)

eNDA or eCTD? The story behind e-abbreviations

BY NANCY DERR

If you are as confused as I was about the differences among NDA, eNDA, CTD, eCTD, and the like, you may find the following helpful:

- *NDA, ANDA* and *BLA* refer to the ***type*** of application (new drug application, abbreviated new drug application and biologic license application).
- *eNDA, eANDA* and *eBLA* refer to those applications submitted electronically according to 1999 and 2002 guidances.
- *CTD* refers to the common technical document, a new international format for applications that can be submitted in paper or electronically.
- *eCTD* refers to new electronic specifications for applications submitted in the CTD format—a guidance on this will be issued soon.

We have the capability to receive fully electronic submissions in the CTD format using the new eCTD specifications.

(Continued on page 12)

Woodcock, Galson State of Center address set for Sept. 10

BY KAREN ZAWALICK

The Committee for Advanced Scientific Education kicks off the fall semester with the State of the Center address and a rousing game of CDER Jeopardy.

Janet Woodcock, M.D., and **Steven Galson, M.D.,** the Center's director and deputy director respectively, will give the annual talk, restricted to an internal audience, in Parklawn Conference Rooms D and E on Sept. 10 from 1:30 p.m. to 3:30 p.m. Continuing education credit will not be offered.

The address will be videoconferenced to CORP2; MM2; WOC2; MPN2, Conference Room B; MPN1, Room 227; Park, Room 314; St. Louis, Market Street Room 1006; MOD1 Room 2004; and Building 29B on the NIH campus, Conference Rooms A and B.

At CDER Jeopardy on Sept. 24, watch office directors and review staff match wits.

Follow the weekly calendar of events for upcoming programs.

Karen Zawalick is an educational specialist in OTCOM and CASE executive secretary.

JOE'S NOTEBOOK

Vital statistics—measures of progress

Americans' life expectancies hit an all-time high in 2001, while age-adjusted death rates hit an all-time low.

The Centers for Disease Control and Prevention notes that life expectancy was 77.2 years in 2001, up from 77 in 2000, and increased for both men and women as well as whites and blacks. For men, life expectancy increased from 74.3 years in 2000 to 74.4 years in 2001. For women, life expectancy increased from 79.7 years to 79.8 years. Record high life expectancies were observed for white men and for both black men and women.

Meanwhile, the national age-adjusted death rate decreased slightly from 869 deaths per 100,000 population in 2000 to 855 deaths per 100,000 in 2001. There were declines in mortality among most racial, ethnic and gender groups. Unfortunately, racial disparities in health persist. For example, the age-adjusted death rate for the non-Hispanic black population was 32 percent higher than that for the non-Hispanic white population. Also, mortality for races other than white and black may be seriously understated due to underreporting for some race groups and Hispanic origin on death certificates from which the CDC collects the data.

For those of us who work in public health, the data show encouraging progress against the nation's three leading killers—heart disease, cancer and stroke. These three disease categories accounted for 1.4 million deaths or 59 percent of the 2.4 million deaths in 2001.

From 2000 to 2001, the age-adjusted death rates declined for heart disease by 3.8 percent, for cancer by 1.9 percent and for stroke by 4.9 percent. While heart disease mortality has trended down since 1950, cancer mortality has declined only since 1990. Influenza and pneumonia exhibited the greatest decline, dropping 7.2 percent. Death rate from unintentional injuries decreased by 1.7 percent.

The age-adjusted death rate from HIV/AIDS declined nearly 4 percent between 2000 and 2001, a bigger decline than the year before and continuing a trend that has occurred since 1995 when FDA approved the first protease inhibitor on Dec. 7 of that year. In the subsequent six years, mortality from HIV declined nearly 70 percent after increasing more than 191 percent between 1987 and 1994. Although HIV/AIDS no longer ranks in the top 15 leading causes of death, it remains the sixth leading cause of death for people ages 25-44 and a leading cause of death among African-Americans in this age group.

Increases in age-adjusted death rates occurred for Alzheimer's disease (5.0 percent); nephritis, nephrotic syndrome and nephrosis (3.7 percent); essential (primary) hypertension and hypertensive renal disease (3.1 percent); and homicide (16.9 percent). The dramatic increase in the age-adjusted rate for homicide includes 2,953 certified deaths that resulted from the September 11, 2001, terrorist attacks. Excluding deaths from the terrorist attacks, the age-adjusted death rate for homicide would have declined by 1.7 percent; although, this decline would not have been statistically significant. Homicide had been on a downward trend since 1991.

The infant mortality rate for 2001 was 6.9 infant deaths per 1,000 live births, representing no change from the rate in 2000. The Hispanic as well as the non-Hispanic white population experienced no change in the infant mortality rate, while the black population experienced a slight, but not statistically significant, increase of 0.7 percent.

More data are available in the report, *Deaths: Preliminary Data for 2001,* prepared by CDC's National Center for Health Statistics. Statistics are based on the data recorded on more than 97 percent of state death certificates issued in 2001. The full report is available at http://www.cdc.gov/nchs/data/nvsr/nvsr51/nvsr51_05.pdf.

news along the pike

The Pike is published electronically approximately monthly on the World Wide Web at:

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

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

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

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ORGANIZATIONAL DEVELOPMENT CORNER

Implementing change for higher performance

BY KEN WRIGHT

Change is a given. Adapting and making change a positive process is up to us.

In this column, I would like to introduce you to the Organizational Development Program in the Office of Executive Programs and begin to explain how the process will work. In periodic issues of the *Pike,* I will explain more about the organizational development process as well as provide you with progress reports.

Currently I make up the program with contractor assistance. My goals are to ensure that CDER's community is functioning well within a context of higher performance:

- What can we do better?
- What is higher performance for us?
- How would we know if we were performing at a higher level?

Organizational development

Organizational development consists of strategically designed interventions that help organizations and their employees become more effective and proficient in dealing with change and the unexpected. The process is successful if individuals and their organization are more:

- Informed and competent (higher performing).
- Committed to achieving vision, mission and goals.
- Valued for their contributions.
- Prepared for the next wave of change.

My role is to facilitate the organizational development process, which will be carried out by CDER's management.

Culture survey

We are beginning the organization development/higher performance quality process with an assessment of where we are now through a Centerwide culture survey. This will be carried out with contractor expertise.

The survey will take approximately seven to nine months to complete and collate. The higher the participation level in the survey, the stronger our results will be. We will have the survey ready for response in early September.

The up-coming survey will be compared to one done in 1996, but it alone will be used for benchmarking for purposes of higher performance/quality change.

The survey's focus will allow us to discover what areas in our working environment are considered barriers to everyone's full participation at CDER.

The results of the Center's culture survey will allow us to make more informed decisions for the future of our organization. With this information, we will better understand and be able to manage those human resource issues central to performing our mission and delivering our services. It is an active process—not a one-time event. It will also help us carry out and support CDER long-term planning efforts.

Fundamentally, any change requires the total engagement of and a continuing dialogue at all levels of the organization to be successful.

I'm excited about this opportunity, because I know that planned change done well does work. I did three years of organization development with the Super-Fund team at the Environmental Protection Agency. Originally, the team had 11 goals. In the last year, I helped the team focus on three goals, and they quadrupled the number of site clean-ups thanks to that focus.

I found that organizational development, strategic interventions and conflict resolution were just a few of the tools that could be used to help EPA employees do things more efficiently and effectively.

Ken Wright is director of the Organizational Development and Strategic Planning Staff. In addition to having two master's degrees, one in education and the other in applied behavioral science and organizational development from Johns Hopkins University, he has numerous other professional certifications. During his 25-year career at EPA, he won two silver medals for superior service and three bronze medals.

Pike's Puzzler: Scrambler

BY TONY CHITE

Unscramble the letters to form the name of these very common elements.

1. M L I I H U T
2. I U S M D O
3. O O B N R
4. U E H M I L
5. S A P T O M S U I
6. G S A M N A E E N
7. U H P S O O R S H P

Key: 1. lithium; 2. sodium; 3. boron; 4. helium; 5.potassium; 6. manganese; 7. phosphorus

Tony Chite is a pharmacist and consumer safety officer for the Division of Information Disclosure Policy.

FDA issues white paper on enforcement

FDA noted in a white paper issued June 30 that the Agency is vigorously and aggressively pursuing violations of the Federal Food, Drug and Cosmetic Act. Enforcement activities include warning and untitled letters, injunctions, recalls, arrests and convictions. Overall, these activities point to "dramatically increased enforcement, particularly in areas related to the most serious threats to public health."

Enforcement actions include arrests and convictions on criminal charges involving potentially dangerous activities and actions against manufacturers making misleading claims about product risks and benefits.

FDA's most decisive actions, those that remove products from the market and that bring criminal charges against people who would harm the public, have increased the most.

FDA has enhanced the legal foundation of the letters to product manufacturers whose products are not inherently unsafe, but who engage in promotional activities that are misleading or not truthful.

Record-breaking penalties against medical product manufacturers, including one for $355 million against a drug company in June, have resulted from FDA enforcement actions.

The white paper is at http://www.fda.gov/oc/whitepapers/enforce.html.

Broadband access begins; Office XP, other training available

BY CHERI MARSHALL

In July, OIT began implementing broadband access to the CDER network for SRAS users who currently have a DSL or cable Internet connection to their homes. In order to use your DSL or cable connection to access the CDER network you must:

- Be able to establish a connection to a VPN—virtual private network—through your broadband provider.
- Attend one of the training demonstrations.
- Have a network card (also referred to as a NIC or Ethernet card) in your PC or laptop. If you do not have a network card, OIT can provide one for you. Please email the Broadband Team: BROADBAND@cder.fda.gov if you need a network card.
- Have a government-issued Linksys EtherFast Cable/DSL Router, Ethernet cables and installation CD.
- Have a completed offsite work agreement.
- Have all the SRAS supporting software installed (Cisco Systems VPN Client, Pointsec, ZoneAlarm and Citrix).

You must confirm with your DSL or cable provider their policy regarding connections to VPNs. The Cisco Systems VPN client provides the backbone for the SRAS connection. If your provider prohibits VPN connections, then you won't be able to connect to the CDER network using your current broadband provider. You can continue to connect through dial-up, or you can investigate the possibility of switching to an alternate provider.

If you currently have a wireless network, you won't be permitted to connect to the CDER network at this time. The Agency is currently in the process of assessing and addressing the security issues and vulnerabilities associated with wireless networking.

You will receive your router, cables, installation CD and documentation when you attend one of the training sessions.

Only those who completed the broadband questionnaire will receive an e-mail containing registration information.

Please review the Broadband Policy http://oitweb/Broadband/broadband_policy.htm and Broadband FAQ http://oitweb/Broadband/BroadbandPrimer.htm for additional information.

Office XP hands-on training

BY HEATHER CHAFIN

Office XP offers many new features, and OIT has developed a hands-on approach to learning them.

This new course covers the key points of working with many of the new components that each application has to offer in the Microsoft suite (Word, PowerPoint, Excel and Outlook).

The Office XP environment includes a less cluttered workspace and can interface with consistency among all applications. It uses adaptive menus and toolbars with task panes replacing dialog boxes for common tasks. There are context-sensitive smart tags to override automatic actions and an enhanced document repair and recovery.

Overall Office XP offers applications that are reliable and stable.

The Office XP Hands-On Training is being offered throughout the summer at both OIT training sites: the Park and Corporate buildings. Please see the training schedule for class times.

OIT training this summer

BY HEATHER CHAFIN

The dog days of summer are now upon us, so take advantage of attending one of OIT summers computer classes. While the heat rages outside you can learn a new application in a relaxingly cool training room. Registrations for classes in August and September are now available. The training calendar can be previewed by clicking on http://MyPortal and selecting training from the menu bar.

Here is just a sampling of courses being offered this summer:

- NEST—NDA Electronic Submissions Training.
- NEDAT—NDA Electronic Data Analysis Training.
- File Management.
- DFS—Division Files System.
- DSS—Decision Support System.
- The much-sought-after Microsoft Office XP training.

Aug. 25 to Sept. 12 OIT Training

Monday	Tuesday	Wednesday	Thursday	Friday
25	26 Office XP Hands-On Course 9:00-4:00 (C)	27 Office XP Hands-On Course 9:00-4:00 (C)	28	29
1 JMP-Intro Part 1 1:00-4:00 (P)	2	3 Frontpage XP 9:00-4:00 (C) Office XP Hands-On Course 9:00-4:00 (P)	4 Office XP Hands-On Course 9:00-4:00 (P)	5 Frontpage XP 9:00-4:00 (P)
8 Frontpage XP 9:00-4:00 (P)	9 Office XP 9:00-4:00 (C) File Mngt. & Desktop Supt. Tools 9:00-12:00 (P) JMP-Intro Part 1 1:00-4:00 (P)	10 Office XP 9:00-4:00 (P) Broadband Training 9:00-11:00 (P)	11 Office XP 9:00-4:00 (C) File Mngt. & Desktop Supt. Tools 9:00-12:00 (P) JMP-Intro Part 1 1:00-4:00 (P)	12 Office XP 9:00-4:00 (P) Broadband Training 9:00-11:00 (P)

Key: Corporate Blvd (C), Park Building (P)
Go to http://MyPortal to access training registration and resources.

Electronic Records

BY SCOTT E. ZEISS

Earlier this year, CDER participated in several National Archives activities.

Per the President's Management Agenda, NARA—with the assistance of other Federal agencies including CDER—was tasked under the Electronic Government Initiative to expand the number and types of electronic records formats NARA will accept into its custody.

This assists the Archives in its mission of preserving and making available his-

(Continued on page 5)

Electronic records initiatives; Palm m500 series HotSync problem

(Continued from page 4)

torically significant records that exist in electronic format. To do so, guidance to agencies needed to be developed on how to transfer such records to NARA. Among the formats covered were scanned images of textual records and PDF.

Representatives from OIT aided this effort by attending working groups that reviewed and commented on the draft guidance. As a result, interim guidance now exists for these formats as a supplement to electronic records transfer policies of the Archives.

Additionally, CDER participated in a pilot program with the Federal Records Center in Suitland—the storage facility where many of our drug applications are stored. The process of sending them to FRC utilizes a paper form called the SF-135. FRC wanted the form converted into an electronic format that could be sent as an e-mail attachment. OIT and Central Document Room contract staff complied by merging two separate documents—a coversheet that existed in Microsoft Word and the actual listing of applications to be transferred located in the CDR's Access database—into a PDF version of the SF-135. Appropriate fields were added that allow FDA Records Management and FRC staff to electronically sign and annotate the form, showing the dates of transfer and shelf location of the records. This is the first time the SF-135 has been converted into an electronic format and has greatly reduced the amount of time and paperwork necessary to send and retrieve drug applications.

The FDA Records Office has published a semi-annual newsletter covering records and information issues of concern to Agency staff. Among the topics covered are employee records management and recordkeeping responsibilities, Agency reorganization and what a records control schedule is.

Employees are urged to read the newsletter to familiarize themselves with these matters. To view a copy click on http://intranet.fda.gov/oirm/records/RMnews_103.doc.

To learn more about these initiatives or CDER's records and information management program, please e-mail me (ZEISSS).

Palm m500 series HotSync problem

BY PAUL SECKLER AND PAUL HAUSTEIN

Has your Palm m500, m505 or m515 stopped synchronizing with your PC or laptop when using the USB connection? First, make sure there have been no changes in the configuration of either your PDA unit or your computer that could have caused the problem.

If no configuration changes have been made, check for the following message on your PDA unit when you try to HotSync: "The connection between your handheld computer and the desktop could not be established. Please check your setup and try again."

If you see this message, reboot the computer and try to HotSync again. If it still does not work, the problem may not be with the computer but the PDA. There is a known problem with electrostatic discharge disrupting the USB port on the Palm m500, m505 and m515 PDAs.

According to the Palm support line, an electrostatic discharge can disrupt the Palm m500's USB chip, making it impossible to HotSync the handheld via USB. To help prevent this from happening, Palm has been providing free replacements for the original cradles that shipped with the m500 series to provide better immunity from electrostatic discharge.

The replacement policy applies to original USB cradles that do not have a sticker on the bottom with the letter E or H. Please contact the CDER Help Desk if you do not have an E or H sticker on the cradle. We will make the necessary arrangements to have your cradle replaced.

The replacement cradle provides better protection against electrostatic discharge in the future, but it won't fix handhelds already affected. We have a work-around to correct this problem.

Please contact the CDER Help Desk to have a technician come by to apply this work-around. This work-around is not the complete cure, and it might not work for everyone. Palm is currently working on a more permanent solution. As of yet, no one knows what actually causes this to happen in the first place and there might even be several different causes.

FDA task force explores improvements in fight against counterfeit drugs

FDA has launched an aggressive initiative to protect American consumers from drugs that have been counterfeited. An internal task force is exploring the use of modern technologies and other measures, such as stronger enforcement, that will make it more difficult for counterfeit drugs to be distributed with—or deliberately substituted for—safe and effective drugs.

The task force will submit its initial findings and recommendations shortly and will issue a final report in about half a year after opportunities to hear from the public.

The FDA initiative is designed to:

- Better identify the risks and threats from counterfeit drugs.
- Establish a public and private coalition to fight drug counterfeiting and distribution.
- Develop new tools to aid in identifying, deterring and combating counterfeiting.

In the United States, drug counterfeiting is a relatively rare event. Although FDA believes domestic counterfeiting is not widespread, the Agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug distribution channels.

FDA has also seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about 5 per year through the late 1990s.

CDER representatives on the task force's steering committee are **David Horowitz,** director of the Office of Compliance, and **Deb Autor,** a regulatory counsel in Compliance. Four working groups are concerned with technology, legislative/regulatory issues, industry/health professional liaison and education.

More information and a background paper are available at http://www.fda.gov/oc/initiatives/counterfeit/.

CDER awards ceremony recognizes 52 individuals, 32 teams

(Continued from page 1)

Sarah J. Singer, R.Ph.

Judy A. Staffa, Ph.D., R.Ph.

Audrey A. Thomas

Postmenopausal Estrogen Labeling and Guidance Group: **Mark I. Avigan, M.D., Julie G. Beitz, M.D., Jeanine A. Best, Sandra L. Birdsong, Debra E. Boxwell, Pharm.D., Eric Colman, M.D., Bronwyn E. Collier, BSN, Susan M. Cruzan, Daniel Davis, M.D., Lisa M. Davis, Nancy E. Derr, Evelyn R. Farinas, Richard J. Friedman, Lesleyanne Furlong, M.D., Audrey L. Gassman, M.D., Brenda S. Gierhart, M.D., Maureen A. Hess, Susan L. Honig, M.D., Florence Houn, M.D., MPH, John K. Jenkins, M.D., Brenda J. Kiliany, Margaret M. Kober, Carrie L. Lemley, Markham C. Luke, M.D., Norman S. Marks, M.D., Katherine B. Meaker, Ph.D., Robert J. Meyer, M.D., Scott E. Monroe, M.D., S. Edward Nevius, Ronald J. Orleans, M.D., Jayne E. Peterson, JD, Phill H. Price, M.D., Victor F. Raczkowski, M.D., Lisa D. Rarick, M.D., Crystal L. Rice, Leah W. Ripper, Daniel A. Shames, M.D., Shelley R. Slaughter, M.D., Dornette D. Spell-LeSane, Bruce V. Stadel, M.D., Paul K. Stauffer, Lisa L. Stockbridge, Theresa H. Van Der Vlugt, M.D., Barbara D. Wesley, M.D., Gerald D. Willett, M.D., Sally Winthrop, Susan F. Wood, Ph.D,** and **Diane K. Wysowski, Ph.D.** PHS Unit Commendation: **LCDR Gregory S. Davis, CAPT Rita R. Hassall, CDR David A. Konigstein, CAPT Mary J. Kozmo-Fornaro, LCDR Mary E. Kremzner, CAPT Sandra L. Kweder, CDR George A. Lyght, LCDR Lisa L. Mathis, CAPT David G. Orloff, LT Sandeep S. Saini, CDR Kassandra C. Sherrod,** and **LCDR Samuel Y. Wu.**

FDA Group Recognition Award

In Vitro Metabolism/Transport-Based Drug Interaction Group: **Sophia S. Abraham, Ph.D., Sayed Al Habet, Ph.D., R.Ph., Sang M. Chung, Ph.D., Philip M. Colangelo, Pharm.D., Ph.D., Jerry M. Collins, Ph.D., Shiew Mei Huang, Ph.D., Ronald E. Kavanagh, Pharm.D., Ph.D., Lawrence J. Lesko, Ph.D., Wei Qiu, Ph.D., N.A.M. Atiqur Rahman, Ph.D., Kellie S. Reynolds, Pharm.D., Sandip K. Roy, Ph.D., Solomon Sobel, M.D., John M. Strong, Ph.D., Xiaoxiong Wei, M.D., Ph.D., Lei K. Zhang, Ph.D.,** and **Jenny H. Zheng, Ph.D.**

Ketamine Neurotoxicity Investigative Group: **William Allaben, Ph.D., Nancy S. Chang, M.D., Hirsch D. Davis, Joseph J. DeGeorge, Ph.D., Patrick J. Faustino, Ph.D., Neil Grunberg, Ph.D., Kathy Haberny, Ph.D., Joseph P. Hanig, Ph.D., David Lester, Ph.D., Thomas Papoian, Ph.D., Merle G. Paule, Ph.D., Patrick S. Pine, Andrea M. Powell, Ph.D., Andrew C. Scallet, Ph.D.,** and **William Slikker Jr., Ph.D.** PHS Officer Nominated for PHS Award: **CAPT Frank D. Sistare.**

OCPB New Reviewers Course Team: **Raman K. Baweja, Ph.D., Brian P. Booth, Ph.D., Jogarao V. Gobburu, Ph.D., Andre J. Jackson, Ph.D., Patrick J. Marroum, Ph.D., Mehul U. Mehta, Ph.D., N.A.M. Atiqur Rahman, Ph.D., Chandrahas G. Sahajwalla, Ph.D., Ramana S. Uppoor, Ph.D.,** and **Gene M. Williams, Ph.D.**

OGD Scientific Symposium Committee: **Raman K. Baweja, Ph.D., Karen A. Bernard, Ph.D., Chandra S. Chaurasia, Ph.D., Rebacca A. Decker, John D. Franolic, Ph.D., Carol Y. Kim, Pharm.D., See Yan Lam, Pharm.D., Ph.D., Melissa A. Lamb, Dominick C. Roselle, Ph.D., Arthur B. Shaw, Ph.D., Neeru B. Takiar** and **Lawrence X. Yu, Ph.D.**

OTCOM Federal Register/Code of Federal Regulations Instructional Services Team: **Muriel N. Cherry, Lois G. Chester** and **Kathryn W. Kruse.**

Review Support Branch, DLPS/OGD: **Mark D. Anderson, Elizabeth T. McNeal** and **Nadine Warren.** PHS Officers Nominated for Companion Award: **CAPT Timothy W. Ames, LT Peter Chen, LCDR Michelle Dillahunt, LT Thomas O. Hinchliffe, LT Sarah H. Ho, LT Craig P. Kiester, LT Soojung S. Kim, LT Jeen S. Min, LT Wanda Pamphile, LT Nicole Park, LT Stanley M. Shepperson** and **LT Chi-Ann Y. Wu.**

Voriconazole NDA Review Team: **Renata Albrecht, M.D., M.R. Alivisatos, M.D., Shukal Bala, Ph.D., Marc W. Cavaille Coll, M.D., Ph.D., Leo Chan, R.Ph., Philip M. Colangelo, Pharm.D., Ph.D., Edward M. Cox, M.D., MPH, Barbara M. Davit, Ph.D., Cheryl A. Dixon, Ph.D., Mark J. Goldberger, M.D., MPH, Linda L. Gosey, Kenneth L. Hastings, DPH, Karen M. Higgins, D.Sc., Gene W. Holbert, Ph.D., Rosemary Johann Liang, M.D., Karin M. Klunk, Owen G. McMaster, Ph.D., John H. Powers, M.D., Rigoberto A. Roca, M.D., David L. Roeder, Norman R. Schmuff, Ph.D.,** and **Rosemary Tiernan, M.D., MPH** PHS Unit Commendation: **LCDR Ellen C. Frank** and **LT Jouhayna S. Saliba.**

FDA Leveraging/Collaboration Award

Ramzi N. Dagher, M.D.

Equal Opportunity Achievement Award

Frances V. LeSane

PHS Commendation Medal

CDR Terri L. Crescenzi

CAPT Lillie D. Golson

LCDR Mitchell V. Mathis

Center Director's Special Citation

Edward M. Cox, M.D., MPH

Rosemary Roberts, M.D.

CDER Special Recognition Award

Cynthia A. Bigger, Ph.D.

Charles R. Bonapace, Pharm.D.

Kuldeep R. Dhariwal, Ph.D.

Jennifer L. DiGiacinto, Pharm.D.

Cheryl A. Dixon, Ph.D.

Joan S. Flaherty

Tapash K. Ghosh, Ph.D.

Thomas S. Hammerstrom, Ph.D.

Linda L. Lewis, M.D.

Patricia P. Harlow, Ph.D.

Thomas A. Marciniak, M.D.

Moheb M. Nasr, Ph.D.

Celia J. Winchell, M.D.

CDER'S Program Management Team: **Tanya L. Abbott, Amy M. Garvin, Jeremy R. Lowery, Jamie M. Metz, Bonita L. Moore, Carol T. Norwood** and **Chris-**

(Continued on page 7)

Innovation, dedication, scientific and technical expertise honored

(Continued from page 6)

tine Shipe.

Hepatitis B Drug Development Working Group: **Russell D. Fleischer, PA-C., MPH, Katherine A. Laessig, M.D., Linda L. Lewis, M.D., Lalji Mishra, Ph.D., Jeffrey S. Murray, M.D., MPH, Julian J. O Rear, Ph.D., Guoxing Soon, Ph.D.,** and **Barbara Styrt, M.D., MPH**

Pharmacy Compounding Database Team: **Kathleen R. Anderson, Pharm.D.,** and **Crystal A. King.**

CDER Administrative/Program Management Excellence

Julie L. Basore

Raya S. McCree

Tammy L. Mueller

Renee V. Redd

CDER Excellence in Communication Award

Ayse N. Hisim

Division of Oncology Drug Products Pediatrics Subcommittee: **Ramzi N. Dagher, M.D.,** and **Alla Shapiro, M.D.** PHS Unit Commendation: **CDR Stephen I. Hirschfeld.**

CDER Information Technology Excellence Award

Paul Haustein (Booze-Allen & Hamilton)

Desktop Management Team: **Wilberforce E. Brooks Jr., Gurminders J. Khalsa, James W. Marshall** and **Rodney K. Smith.**

Office of Drug Safety AERS Quarterly Update Team: **Paul F. Reinstein** and **Lynette Swartz.**

CDER Leadership Excellence Award

Eric G. Colman, M.D.

Julieann DuBeau

Margaret M. Kober

Joyce A. Korvick, M.D.

Brad G. Leissa, M.D.

Timothy J. McGovern, Ph.D.

William W. Oswald

Khyati N. Roberts

Janice M. Soreth, M.D.

Robert L. West

Duu-Gong Wu, Ph.D.

CDER Excellence in Mentoring Award

Marta L. Locklear

Kellie S. Reynolds, Pharm.D.

Diana M. Willard

CDER Project Management Excellence

Christy L. Cottrell

Lorene M. Kimzey

DACCADP's Project Management Team: **Lisa E. Basham-Cruz, Kimberly A. Compton, Parinda Jani, Victoria Kao, Lisa M. Malandro** and **Sara E. Stradley.**

DAVDP Project Managers: **Marsha S. Holloman, Christine K. Lincoln, Jeff D. O'Neill, Virginia L. Yoerg** and **Karen A. Young.** PHS Officers Nominated for Companion Award: **LT Sean J. Belouin, CAPT Anthony W. DeCicco, LCDR Sylvia D. Lynche, LCDR Nitin K. Patel, LT Vasavi T. Reddy** and **LT Destry M. Sillivan.**

Project Managers in the Division of Anti-Viral Drug Products: **Grace N. Carmouse, Susan Cobb, Joean E. James, Marsha S. Holloman, Christine K. Lincoln, Jeff D. O'Neill, Khai M. Phi, Melissa M. Truffa, Virginia L. Yoerg** and **Karen A. Young.** PHS Officers Nominated for Companion Award: **LT Sean J. Belouin, LTJG Sean R. Byrd, CAPT Anthony W. DeCicco, LCDR Sylvia D. Lynche, LCDR Nitin K. Patel, LT Vasavi T. Reddy, LT Destry M. Sillivan** and **LCDR Leslie A. Stephens.**

CDER Support Staff Excellence Award

Martha A. Carter

Rebacca A. Decker

Darlene T. Johnson

Kelly S. Phelan

Kim J. Robertson

Rose M. Smith

Barbara J. Townsend

CDER Team Excellence Award

Antibiotic Resistance RFP Working Group: **Leo Chan, R.Ph., Charles K. Cooper, M.D., Edward M. Cox, M.D., MPH, David L. Roeder, Albert T. Sheldon, Ph.D.,** and **Matthew A. Zell.** PHS Unit Commendation: **CAPT Hamilton L. Brown.**

Buprenorphine Review Team: **Ali Al Hakim, Ph.D., Silvia N. Calderon, Ph.D., Tien Mien Chen, Ph.D., Gerald Dalpan, M.D., Suresh Doddapaneni, Ph.D., Jarilyn Dupont, J.D., Michael Klein, Ph.D., Dale L. Koble, Ph.D., Deborah B. Leiderman, M.D., Timothy J. McGovern, Ph.D., Thomas J. Permutt, Ph.D., Sara E. Stradley, Ana Szarfman, Ph.D., Lynn A. Whipkey, J.D.,** and **Celia J. Winchell, M.D.**

Cancer Drug Development Patient Consultant Program Team: **Brenda J. Atkins, Amy C. Baird, Christy L. Cottrell, Ramzi N. Dagher, M.D., Patricia Delaney, Clare Gneeco, Ph.D., David J. Graham, M.D., Donna J. Griebel, M.D., Patricia Keegan, M.D., Richard T. Lostritto, Ph.D., Joann Minor, Richard Pazdur, M.D., Dorothy W. Pease, Maureen A. Pelosi, Lilliam A. Rosario, Ph.D., Daniel Schultz, M.D., Alla Shapiro, M.D., Dianne P. Spillman, Grant A. Williams, M.D.,** and **Alexandra Worobec, M.D.** PHS Unit Commendation: **LCDR Sean K. Bradley, LCDR Patricia N. Garvey, CDR Steven I. Hirschfeld, LCDR Ann M. Staten** and **CAPT Paul F. Zimmerman.**

CDER Barcode Working Team: **Jane A. Axelrad, Virginia G. Beakes, Phillip L. Chao, Mary C. Gross, Diane M. Maloney, Melodi J. McNeil, R.Ph., Olivia A. Pritzlaff** and **Steven A. Tucker.** PHS Unit Commendation: **CAPT Steven K. Galson, CDR Carol A. Holquist, CAPT Thomas J. McGinnis, CAPT Thomas G. Phillips** and **CAPT Paul J. Seligman.**

Ciprofloxacin Team: **James F. Brower** and **Duckhee Y. Toler.**

Claritin OTC Review Team: **Marina Y. Chang, Emmanuel O. Fadiran, Ph.D., Matthew R. Holman, Ph.D., Linda S. Hu, M.D., Chong-Ho Kim, Ph.D., Shinja Kim, Ph.D., Cazemiro R. Martin, Ph.D., Timothy J. McGovern, Ph.D., Luqi Pei, Ph.D.,** and **Guiragos K. Poochikian, Ph.D.** PHS Unit Commendation: **CAPT Elaine G. Abraham, LCDR Charles E. Lee, CDR Houda Mahayni, CAPT Mary E. Purucker, CAPT Ching-Long Sun** and **LCDR Anthony**

(Continued on page 8)

CDER employees recognized at FDA ceremony, Science Forum

(Continued from page 7)

M. Zeccola.

Division of Pharmaceutical Evaluation II Metabolic and Endocrine Review Team: **Hae Young Ahn, Ph.D., Sang M. Chung, Ph.D., Steven B. Johnson, Pharm.D., Sze W. Lau, Ph.D., Wei Qiu, Ph.D.,** and **Xiaoxiong Wei, Ph.D.**

DMETS Medication Error News and Resources Team: **Tia Harper-Velazquez, R.Ph.** PHS Unit Commendation: **CAPT Kevin R. Dermanoski, CDR Charles V. Hoppes** and **LCDR Marci A. Lee.**

DNA Microarray Team: **Patrick S. Pine, Barry A. Rosenzweig, CAPT Frank D. Sistare** and **Karol L. Thompson, Ph.D.**

Lindane Team: **James F. Brower, Larry K. Revelle, Ph.D., Nakissa Sadrieh, Ph.D.,** and **Benjamin J. Westenberger.**

MedWatch Process Improvement Team: **Norman S. Marks, M.D.,** and **Toni Piazza-Hepp, Pharm.D.** PHS Unit Commendation: **CAPT Roger A. Goetsch, CDR David A. Konigstein** and **CDR James W. Wilson, III.**

Network Team: **Tony T. Chuo** and **Richard J. Johnson.**

Neuropharmacology Review Team: **Raman K. Baweja, Ph.D., Wen Hwei Chou, Ph.D., Ronald E. Kavanagh, Ph.D.,** and **Ramana S. Uppoor, Ph.D.**

Potassium Iodide 65-milligram Tablet Review Team: **Shirley Berryman, Shirley S. Brown, Ph.D., LT Peter Chen, John F. Grace, CAPT Harvey A. Greenberg, LT Sarah H. Ho, Shing Hou Liu, Ph.D., LT Wanda Pamphile, Parul Patel, LCDR Angel M. Payne, Paul Schwartz, Ph.D.,** and **Michael Smela, Jr., Ph.D.**

Searching PubMed Instructional Services Team: **Nichelle Cherry, Lois G. Chester, Nancy L. Muir** and **Colleen A. Pritchard.**

White Oak Laboratory Research Building Planning Team: **Almetia L. Hoskins, Patricia E. Long-Bradley, Robbe C. Lyon, Ph.D., Edward B. Radden, CAPT Frank D. Sistare, John M. Strong, Ph.D.,** and **James L. Weaver, Ph.D.**

FDA awards ceremony

These awards were presented to CDER employees May 30 at the FDA ceremony in Rockville:

FDA Award of Merit

Raymond F. Anthracite, M.D.

Russell J. Abbott

Debra L. Birenbaum, M.D.

Paula G. Bourkland

Rita J. Thompson

Artesunate Review Team: **Renata Albrecht, M.D., Matthew A. Bacho, Shukal Bala, Ph.D., David J. Cummings, Ph.D., Ruthanna C. Davi, Barbara M. Davit, Ph.D., Antoine N. El Hage, Ph.D., Mark J. Goldberger, M.D., MPH, Kenneth L. Hastings, Dr.P.H., Karen M. Higgins, Sc.D., Rosemary Johann Liang, M.D., Karin M. Klunk, Steven C. Kunder, Ph.D., Joette M. Meyer, Pharm.D., Sumathi Nambiar, M.D., Rigoberto A. Roca, M.D., David L. Roeder, Leonard V. Sacks, M.D., Norman R. Schmuff, Ph.D., Robert B. Shibuya, M.D., Ramesh K. Sood, Ph.D.,** and **Kalavati C. Suvarna, Ph.D.** PHS Unit Commendation: **LCDR Ellen C. Frank.**

Nitazoxanide Review Team: **Renata Albrecht, M.D., Shukal Bala, Ph.D., Leo Chan, R.Ph., Dakshina Chilikuri, Ph.D., Barbara M. Davit, Ph.D., Antoine N. El Hage, Ph.D., Mark J. Goldberger, M.D., MPH, Kenneth L. Hastings, Dr.P.H., Karen M. Higgins, Sc.D., Gene W. Holbert, Ph.D., Rosemary Johann Liang, M.D., Steven C. Kunder, Ph.D., Rigoberto A. Roca, M.D., David L. Roeder, Norman R. Schmuff, Ph.D., Robert B. Shibuya, M.D., Kalavati C. Suvarna, Ph.D.,** and **Jyoti Zalkikar, Ph.D.** PHS Unit Commendation: **LCDR Ellen C. Frank** and **LT Kristen Miller.**

PHS Outstanding Service Medal

CAPT Tan T. Nguyen

40 Years of Career Service

Don C. Cox

Robert Heller

Larence Sturghill

Scientific achievement

These CDER scientists were honored for scientific achievement at the FDA Science Forum held April 24 and 25 in Washington:

Excellence in Analytical Science

Noninferiority Clinical Trial Statistics Development Group: **Sue-Jane Wang, Ph.D., Hsien-Ming James Hung, Ph.D.,** and **Yi Tsong, Ph.D.**

Excellence in Laboratory Science

CDER Vasculitis Research Unit: **Jun Zhang, M.D., Eugene H. Herman, Ph.D., Alan D. Knapton** and **Frank D. Sistare, Ph.D.**

Excellence in Review Science

Zili Li, M.D., MPH

Outstanding Intercenter Scientific Collaboration

Chromatography Media Decay Evaluation Team: **Janice Brown, M.S.**

OP-1 Implant HDE Review Team: **James G. Farrelly, Ph.D.**

Coronary Drug-Eluting Stent Regulatory Review Team: **Xiao-Hong Chen, Ph.D., Nallaperumal Chidambaram, Ph.D., Patrick John Marroum, Ph.D., Kasturi Srinivasachar, Ph.D., Belay Tesfamariam, Ph.D.,** and **Douglas C. Throckmorton, M.D.**

Jackie Barber is CDER's incentive awards officer.

FDA's McGinnis receives pharmacy group's award

The Pharmacists Planning Service Inc., a non-profit organization that promotes consumer public health education and pharmaceutical information, presented its Distinguished Person of the Year Award to **CAPT Thomas J. McGinnis** at the American Pharmaceutical Association Annual Meeting in April 2003.

McGinnis, director of pharmacy affairs in FDA's Office of Policy, joins the ranks other distinguished federal employees who have received the group's award, including former FDA Commissioner Frank E. Young and former Surgeon General C. Everett Coop.

PUBLIC MEETING

Status of useful written Rx information for consumers assessed

BY ELLEN SHAPIRO

FDA held a public meeting July 31 to assess the current status of the private sector's efforts to provide useful written prescription drug information to consumers.

A 1996 law specifies a goal for 2006 that 95 percent of individuals filling new prescriptions should receive useful written information along with their medicine. The law says useful information must be easily understood, scientifically accurate and nonpromotional in tone and content.

"The FDA is confident the goals can be met by 2006 if a serious coordinated effort can occur," said **Tom McGinnis,** FDA's director of pharmacy affairs, at the conclusion of the day-long series of presentations from industry, consumer groups and industry associations. There were 114 people attending the meeting.

The participants attending the meeting and presenting included representatives from AARP, Public Citizen, Center for Medical Consumers, National Council for Patient Information and Education, National Association of Chain Drug Stores, American Society of Health System Pharmacists, Pharmaceutical Research and Manufacturers Association, Pharmaceutical Printed Literature Association, Thomson Healthcare, Inc., Cerner Multum and Scriptchek.

Several participants expressed concerns about the "usefulness" of the current information. Some questioned whether currently dispensed information is:

- Understandable and legible.
- Accurate, timely and up-to-date.
- Presented in a consistent way.
- Well-written or written at too high an education level.
- Balanced about risks and benefits.

Other issues discussed included whether more space is needed on the leaflets; mail-order pharmacies; new technologies; barriers to and costs associated with meeting the 2006 goals; how to get patients to read the information; and what should be done for non-English speaking patients

The National Council of Patient Information and Education presented its plans for education, implementation and ensuring that the criteria for useful information will be met. The group said it will continue to work closely with FDA to meet timelines and ensure all audiences are involved in the process, including doctors, pharmacist, nurses and consumers.

Several participants expressed their frustration over how much time has gone by since the criteria for useful patient information were established in a 1997 report and their hope that things move along at a faster pace.

More information about this meeting, previous public meetings, the 1997 report and FDA commissioned surveys of patient information can be found on the CDER Office of Drug Safety's Patient Labeling and Risk Communication Web site under the heading "Useful Private Sector Written Prescription Drug Information for Patients" at http://www.fda.gov/cder/Offices/ODS/writtenPrescripInfo.htm. Slides and transcripts will be posted as they become available.

Ellen Shapiro is director of the Center's Division of Public Affairs.

GOVERNMENT CUSTOMER SUPPORT EXCELLENCE

OTCOM's Division of Drug Information is runner-up in teamwork category

A focus on professionalism and sharing were key elements leading the Division of Drug Information to a runner-up finish in the 2003 Government Customer Support Excellence Awards. The division competed in teamwork, one of four categories in the competition.

The award was presented in June at a conference for government help desk and call center operations sponsored by DCI, a professional development company.

All members of the division, which has about 20 pharmacists and consumer safety officers, were present for the award ceremony held in Arlington, Va.

The division is the Center's focal point for inquiries from consumers, health care professionals, insurance companies, regulated industry, academia, law enforcement, attorneys, other parts of the FDA and other government agencies. It provides timely and accurate information on the full range of CDER's activities. The division works with other Center organizations to create consistent messages to the public. Among the services the division offers are:

- Identification of drugs.
- Information about new approvals and other "hot topics."
- Recall and shortage information, as well as liaison with the Office of New Drugs and the Office of Compliance to identify and resolve issues of drug availability.
- Overviews of Center responsibilities presented to visiting foreign government officials from the division's international visitors team.
- Database research using computerized information resources for regulations, guidances and general information about human drugs and their use.
- A repository for all CDER publications, such as regulatory guidances, Federal Register notices, FDA Consumer articles and other drug-related information.
- Consumer Drug Information Web page, which provides summary educational information on newly approved prescription drugs written in plain language.
- Preceptor program for pharmacy students and drug development fellows.

In an average month the division answers about 3,500 e-mails, 3,500 telephone calls and 600 letters.

The award noted that the division conducts weekly staff meetings devoted to sharing the previous week's events, debriefing, solving unanswered queries and communicating information among each other.

Inquires about CDER can be referred to the division by e-mail or phone at:

- Druginfo@cder.fda.gov.
- 1-888-INFO FDA (toll-free).

Spring retreat focuses on pharmacogenomics, microarray studies

BY WAFA HARROUK, PH.D.

The pharm/tox semi-annual scientific retreat held on May 21 gathered P/T reviewers within CDER and highlighted the theme of pharmacogenomic and toxicogenomics as scientists in the Agency try to understand the "crossword puzzle" of genomics.

The remainder of the retreat was devoted to an overview of the P/T evaluation in the Center for Biologics Evaluation and Research and updates from regulatory working groups.

The keynote address, "The impact of gene expression profiling in toxicity and drug development," was presented by Cynthia Afshari, Ph.D. from Amgen Inc. Dr. Afshari walked the reviewers through the basic steps involved in conducting a microarray experiment and a brief review of commonly used data analysis approaches. Dr. Afshari offered four types of application for microarrays: biomarker discovery, drug class prediction, early screening in the drug pipeline and determination of no adverse effect levels. She illustrated the concepts with data from the International Life Sciences Institute Nephrotoxicity Working Group.

Highlights of other presentations included:

Update on Nonclinical Pharmacogenomics Subcommittee. **Pat Harlow, Ph.D.**, from the Division of Cardio-Renal Drug Products, shared a brief overview of the goals, functions and activities completed by the subcommittee since its inception in August last year.

"Chemogenomics in drug innovation and approval." Leslie Browne, Ph.D., from Iconix Pharmaceuticals, introduced the concept of predictive chemogenomics which aims at producing safer compounds for clinical use with a more cost-effective research and development process. Iconix has created the DrugMatrix database, which bridges genomics and chemistry to investigate a compound's toxicity profile and possible mechanism of action. The database uses microarray data linked to traditional toxicology endpoints including pharmacological, blood chemistry and histopathological data for individual animals in a searchable format. Dr. Browne illustrated the concept by showing expression profiles of a group of agents that cause liver and kidney toxicity.

Nonclinical regulatory issues. **John Leighton, Ph.D., DABT**, from the Office of New Drugs and co-chair of the Nonclinical Pharmacogenomics Subcommittee, discussed the active role undertaken by the Agency in concert with industry and academia on pharmacogenomics issues. This interaction will ensure CDER's active dialog with the industry as it strives to embrace the new technology and to keep the P/T community abreast of the state-of-the-art developments in the field.

Regulatory research initiatives. **Frank Sistare, Ph.D.,** Director of the Division of Applied Pharmacology Research and the other co-chair of the Nonclinical Pharmacogenomics Subcommittee, emphasized the importance of the research his division undertakes as it relates to the incorporation of emerging technologies into the regulatory process.

Regulatory research projects. **Karol Thompson, Ph.D.,** from the Division of Applied Pharmacology Research, provided a brief description of regulatory research lab-based initiatives which include the effort to evaluate the performance of RNA standards for assessing platform and experimental consistency.

Preclinical development of biotechnology-derived products. **Andrea Weir, Ph.D., DABT,** from CBER, gave an overview of CBER review divisions and the types of products regulated by each division. Dr. Weir outlined concepts that are unique to reviewing biologics drug products including species relevance, tissue cross-reactivity and immunogenicity. She also detailed the preclinical studies indicated to support the safety of biotechnology-derived products.

Update on the Cardiotoxicity Expert Committee. **Elisabeth Hausner, DVM,** from the Division of Cardio-Renal Drug Products, shared a brief overview of the current understanding of biomarkers for cardiac toxicity and provided the history, objectives and accomplishments of the expert working group. Current efforts are focused on assessing the use of cardiac troponins as cardiotoxic biomarkers.

Update on the Expert Working Group for Vascular Injury. **Tom Papoian, Ph.D.,** also from the Division of Cardio-Renal Drug Products, briefed the audience on the group's objectives and opportunities for collaboration between public and private partners in order to better assess and eventually prevent human risk to drug-induced vascular injury.

The revised pharm/tox review template. was by **Jeri El Hage, Ph.D.,** from theDivision of Metabolic and Endocrine Drug Products, discussed revisions to this template by the Good Review Practice Working Group to improve functionality of the GRP template and to remove irrelevant data entries.

The retreat was organized by P/T reviewers from various divisions at CDER including **Mamata De, Ph.D., Hanan Ghantous, Ph.D., Anwar Goheer, Ph.D., Thomas Papoian, Ph.D., Lilliam Rosario, Ph.D., Wendy Schmidt, Ph.D., Andrea Weir, Ph.D., Adele Seifried, M.S.,** and myself.

Following opening remarks by Dr. Rosario, from the Division of Oncologic Drug Products, **Robert Osterberg, Ph.D.,** from the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, welcomed **David Jacobson-Kram, Ph.D., DABT,** to his new position as an associate director for P/T in the Office of New Drugs.

Dr. Jacobson-Kram brings to the FDA a vast experience in the field of genetic toxicology including work at the National Institute on Aging, George Washington University School of Medicine and Johns Hopkins University Oncology Center, the Environmental Protection Agency and culminating with 15 years of experience at BioReliance Corp. where he was vice president of the Toxicology and Laboratory Animal Health Division until April, 2003. Dr. Jacobson-Kram shared his vision and plans with the P/T community and addressed some reviewers' questions.

Wafa Harrouk is a visiting scientist in the Division of Metabolic and Endocrine Drug Products.

New pharm/tox head stresses professional development

BY PATRICK E. CLARKE

Providing people the opportunity to learn is one of the goals of **David Jacobson-Kram, Ph.D., DABT,** chosen as the associate director of pharmacology and toxicology in the Office of New Drugs, after a nationwide search.

"I think professional development is critical, since advances in the field are moving so quickly," Jacobson-Kram said. "And the people I've been dealing with in the pharmacological/toxicological field at CDER are certainly on a par with industry people."

He comes to the Center after 15 years of running the toxicology division of BioReliance Corp. in Rockville. The division, with more than 100 employees, holds contracts and performs a wide variety of toxicology testing for the pharmaceutical and environmental industries as well as government agencies. "Because of my former position I have an objective view of the process. I see the sponsor perspective and the FDA perspective," he said.

"Ultimately, much of the work we did for the pharmaceutical industry was submitted to the FDA," he said.

He has three main scientific interests:

- The use of transgenic animals for carcinogenicity testing.
- Toxicogenomics, or understanding how changes in gene expression mediate toxicological responses.
- Genotoxicity, or the assessment of exogenously induced genetic alterations.

All drug applications submitted to CDER have genotoxicity data. "There is some lack of consistency among divisions on how to deal with positive genotoxicity data," Dr. Jacobson-Kram said. "Each division, based on its indications and history, may react to data differently. For me, one of my biggest challenges will be ensuring there is consistency among the divisions in OND."

These issues will be addressed through the Pharmacological/Toxicological Coordinating Committee, which has representatives from every division in OND. He anticipates that the committee will come up with guidances on uniform ways to interpret data and make recommendations for additional testing.

Dr. Jacobson-Kram also anticipates that the group of pharmacologist/toxicologists will grow significantly in the coming years, in part due to PDUFA III funding.

"It will be a challenge to identify and hire qualified pharmacologists and toxicologists ," Dr. Jacobson-Kram said.

The evaluation of biologic therapeutics will also present a challenge, according to Dr. Jacobson-Kram.

"Folks here haven't seen the types of products that are routinely evaluated at CBER, they have different characteristics and different manufacturing processes," Dr. Jacobson-Kram said. "As a result, there's a learning curve."

His management philosophy is that one size doesn't fit all.

"You need to understand individuals' needs to help make them better performers," he said.

Patrick Clarke is a public affairs specialist in the Office of Training and Communications.

CBER transferees welcomed to CDER during orientation program

About 150 members of the Center for Biologics Evaluation and Research were joined by a "who's who" of CDER's leadership at an all-day welcome and orientation program.

Most are members of CBER's Office of Therapeutics Research and Review currently detailed to CDER and to be officially integrated beginning Oct. 1.

Center Director **Janet Woodcock, M.D.,** and Deputy Director **Stephen Galson, M.D.,** kicked off the proceedings with a warm welcome and a CDER overview.

Debbie Henderson, director of the Office of Executive Programs, and OTRR acting head **Sharon Risso,** now a senior advisor to Dr. Woodcock, spoke next about the similarities and differences between the two centers.

The remainder of the program was divided into three sections, each of which included a panel discussion and a question-and-answer period:

- *Review Matters* included orientations to the Office of New Drugs (**Sandra Kweder, M.D.**), the Office of Pharmaceutical Science (**Ted Sherwood**) and the Office of Pharmacoepidemiology and Statistical Science (**Melodi McNeil**).
- *Policy and Regulatory Matters* featured presentations by the Office of Medical Policy (**Tom Abrams**), the Office of Counter-Terrorism and Pediatric Drug Development (**Dianne Murphy, M.D.**), the Office of Compliance (**Edwin Rivera Martinez**), the Office of Regulatory Policy (**Jane Axelrad**) and the Office of Executive Programs (**Debbie Henderson**).
- *Practical Matters* featured orientations to the Office of Information Management (**Anne Myers**), the Office of Information Technology (**Linda Burek**), the Office of Management (**Doug Hamilton**) and the Office of Training and Communications (**Nancy Smith, Ph.D.**).

Program attendees were given an orientation packet with a compilation of useful information about CDER's organization and its leadership.

The program was organized by OTCOM's Division of Training and Development.

Reviews of the welcome program were enthusiastic. "I think we made our new colleagues feel very welcome indeed," Dr. Woodcock wrote. "More good work from OTCOM!"

OTRR's non-laboratory-based divisions, the Division of Clinical Trial Design and Analysis and the Division of Application Review and Policy, are detailed to the Office of New Drugs. These will form the proposed Office of Drug Evaluation VI and will move into Woodmont II this fall.

OTRR's laboratory-based divisions, the Division of Monoclonal Antibodies and the Division of Therapeutic Proteins, are detailed to the Office of Pharmaceutical Science. They will form the Office of Biotechnology Products.

Traditional submissions in paper

- Based on traditional format.

Traditional submissions in electronic format

(eNDA, eANDA, eBLA)

- Based on traditional format.
- Content in PDF and SAS Transport.
- Table of contents in PDF.
- Explained in 1999 and 2002 guidances.

Submissions in CTD format

(paper or electronic)

- Based on ICH CTD format.
- Recommended beginning July 2003.
- If submitting electronically, use traditional electronic specifications as explained in 1999 and 2002 guidances.

Electronic submissions using e-CTD specifications

(eCTD)

- Based on ICH CTD format and ICH eCTD specifications.
- Use eCTD backbone files instead of traditional PDF table of contents.
- Contents remain in PDF and SAS Transport.
- Draft guidance is under development.
- Pilot under way.

eNDA, eANDA, eBLA or eCTD? The story behind e-abbreviations

(Continued from page 1)

"Traditional" e-submissions

Until fairly recently, we received submissions the old-fashioned way, following the traditional format and submitted in paper, lots of paper. Beginning in 1997, we began to accept case report forms and case report tabulations in electronic format in place of paper.

In 1999, we and our colleagues at the Center for Biologics Evaluation and Research issued a guidance on how to submit electronic versions of traditional NDAs and BLAs. In 2002, we issued a guidance addressing the electronic submission of abbreviated new drug applications for generic drugs.

These "traditional" electronic submissions are sometimes called eNDAs, eANDAs and eBLAs, respectively.

The contents of these types of electronic submissions are in PDF and SAS Transport. Reviewers use the PDF table of contents of an application to move through the application. Applications can be submitted through the mail, on floppy disks, CD-ROM and even digital tapes if the submission is really big. The guidances can be found on our electronic regulatory submissions and review Web site at http://www.fda.gov/cder/regulatory/ersr.

Common technical document

We have been working with the International Conference on Harmonization to develop the common technical document. The CTD allows data in the same format to be submitted to multiple countries. Companies that use the CTD format can submit essentially the same application to the ICH members—the United States, the European Union and Japan—and other countries that adopt the format such as Canada.

We are now encouraging companies to submit their applications using the CTD format. Applications created in the CTD format can be submitted to the Agency in paper or electronically as described in the 1999 and 2002 guidances.

The contents of electronic versions are in PDF and SAS Transport, and a PDF table of contents enables the reviewer to move through the application. Although these applications use the CTD format, they are eNDAs because they used the 1999 and 2002 specifications.

eCTD ready to go

Last year, the ICH partners agreed on new electronic specifications for the CTD called the eCTD specifications. Currently, we are developing guidance that will help industry when they assemble submissions based on the eCTD specifications.

Meanwhile, we have a procedure in place to receive submissions using the eCTD specifications under a very structured pilot program. We are working closely with industry on the first submissions to make sure everything goes smoothly.

Electronic submissions using the eCTD specifications differ from "traditional" electronic submissions in a number of aspects. For example, although the contents of the applications will still be in PDF and SAS Transport, the eCTD includes files called the eCTD backbone files instead of the PDF table of contents. The eCTD backbone files enable us to receive, file and review the submissions. The backbone files are written in XML, or eXtensible Markup Language. XML has more power to display data and information than the PDF table of contents files.

Another important difference is that the eCTD specifications can be used to submit all applications and related submissions, including NDAs, BLAs, ANDAs, INDs, drug master files and promotional material. The eCTD backbone files enable reviewers to navigate through the submission using a special electronic viewer system developed by CDER and CBER reviewers. Among other things, the viewer allows reviewers to:

- Create an up-to-date, cumulative table of contents for the entire application at any time.
- Access any electronic submission from a single screen.
- Download files so submissions can be used even when the reviewer's computer is disconnected from the network.

CDER encourages eCTD specifications

We hope that companies will transition to the eCTD specifications as soon as possible. Because not everyone will be able to transition at the same time, we will continue to receive, file and review applications in all formats. But because this may be confusing for companies and reviewers, we are encouraging companies to contact us before using the eCTD specifications.

Nancy Derr is a policy analyst in the Office of Regulatory Policy.