news along the pike

Center for Drug Evaluation and Research

June 1998

Volume 4, Issue 6

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Pike's Corners . . .

Spring Awards Ceremony

New Awards, Categories Highlighted

By Jackie Barber

The presentation of a Hammer Award and the first awards of the Center Director's Special Citation as well as two new categories of Peer Honor Awards—information technology and project management—marked the Center's Spring Honor Awards ceremony held June 5 in the Gaithersburg Hilton. The Division of Anti-Viral Drug Products received the National Partnership for Reinventing Government Hammer Award as a result of a nomination from 3M Pharmaceuticals. The company was impressed by the division's use of an interactive communications plan that resulted in the approval of imiquimod in seven months rather than the required 12.

"While it's always rewarding to have our successes recognized outside the organization, it is perhaps more important to share our successes internally and recognize one another's efforts," said Center Director **Janet Woodcock, M.D.**

The awards presented were:

(Continued on page 6)

Off-Label Information Dissemination

Proposed Rule Calls for Current or Planned Studies

The FDA on June 5 published proposed rules to implement Section 401 of the Food and Drug Administration Modernization Act of 1997 that allows manufacturers to disseminate published information—such as studies published in scientific journals or reference texts—about the safety, effectiveness or benefits of "off-label" uses for marketed drugs, biologics and medical devices. The proposed rule has a 45-day comment period ending July 23. The effective date of this section of the new law is Nov. 21 or upon publication of final regulations, whichever comes first.

Off-label use information can only be disseminated for uses that have been, or will be, studied and submitted for FDA approval. The information disseminated must be both scientifically sound and balanced. According to the statute, manufacturers will be allowed to impart this information to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans and Federal and State agencies.

(Continued on page 12)

Former FDA Deputy Nominated for Commissioner

Jane E. Henney, M.D., who worked as Deputy Commissioner for Operations from January 1992 to March 1994, has been nominated by President Clinton to become Commissioner of Food and Drugs. Henney, who specialized in cancer research and is currently vice president for health sciences at the University of New Mexico, attended Manchester College and graduated from Indiana University School of Medicine.

She spent nine years at the National Cancer Institute. While at the FDA, Henney helped draft the Prescription Drug User Fee Act.

"The position of FDA Commissioner is vital to the nation's health and safety, and Dr. Jane E. Henney is the person to lead the FDA into the next millenium," said Secretary of Health and Human Services **Donna E. Shalala.** "From the safety of our foods to the effectiveness of our pharmaceutical and other medical products, Americans rely heavily on the processes, resources and judgement of the Food and Drug Administration.

"Dr. Henney has a proven track record at FDA, and if confirmed by the Senate, she will

(Continued on page 12)

Joe's Notebook

5 R's: Revere, Review, Report, Russ, Ride

Revere: I had the great thrill of taking CDER's exhibit display to Boston—site of Paul Revere's midnight ride—for the annual Drug Information Association meeting earlier this month. The display, which included a stripped-down version of the Center's Web site, attracted hundreds of visitors. For the few who were unfamiliar with the Center's transformation, it was easy to show how transparent CDER has become by clicking around the Web site's store of guidances. The majority of visitors were intimately familiar with the site, and many said they consult it daily.

Review: To help all of us stay abreast of that rapidly growing electronic resource, **Carol Assouad** is inaugurating a new column, tentatively titled Cyber Corner (page 5). Let her know of your suggestions for titles. Carol is familiar to most of you as the Director of the Medical Library, but she is also the Center's Web sites program manager.

Report: A popular item that disappeared rapidly from our display in Boston was the *CDER 1997 Report to the Nation: Improving Public Health Through Human Drugs.* The book's charts speak volumes for the improvements the Center has achieved in drug review times. You can find the electronic version of the report on our Web site at: http://www.fda.gov/cder/reports/rptntn97.pdf. You can also find the report, the covers and PowerPoint slides of the charts on the X:drive in the folder cdernews.

The printed copies of the book are primarily intended for visitors and guests. If you're having a meeting with industry and would like extra copies, please contact **Joan Powers** by phone (7-3473) or e-mail (POWERSJ). We don't have enough copies to provide everyone in CDER with a copy. If you need one for reference, contact Joan or look for extra copies in the Medical Library and its branches.

More folks than I can mention had a hand in creating the report. Special thanks, however, are due to those that did some of the heavy lifting for gathering information from their corners of the Center, including: **Nancy Derr, Linda Katz, Lowell Lima, Mac Lumpkin, Bob O'Neill, Nancy Maizel, Jim MacGregor, Justina Molzon, Melissa Moncavage** and **Ted Sherwood.** Division of Communications colleagues who pitched in with editing included **Lori Frederick** and **Tony Sims.** Finally, DCM's **Wendy Stanfield** created the spectacular cover and layout that display our performance at its best.

Russ: whoops! *Pike* correspondent **Russ Rutledge** reports that we inadvertently omitted his name from last month's *Pike* story on the FDA Honor Awards Ceremony. Russ received the Commendable Service Award as a member of the Laboratory FDA/Industry Discussion Team put together by the Office of Regulatory Affairs. Next month Russ promises a full report on the "exciting" day-long meeting held June 23 to share ideas and gain input from industry on the First Party Audit Program.

Ride: Before leaving on her 350-mile AIDS Ride from Raleigh, N.C., to Washington, **Cathie Schumaker** wrote to say: "I did an 80-mile training ride with 100 riders who will be participating in the AIDS ride. The training ride itself was very inspirational and the group was wonderful. There was a feeling of great support and care. Thanks to everyone for their support and generosity." I hear Cathie successfully completed the ride June 21. Next month look for a report on Cathie's ride from **Jason Walther,** an English major at the University of Maryland, doing a summer internship with DCM.

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).

Views and opinions expressed are those of the authors and do not necessarily reflect official FDA or CDER policies. All material in the Pike is in the public domain and may be freely copied or printed.

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

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Ombudsman's Corner

Avoiding Conflicts of Intellectual Interest

By Jim Morrison

Anyone who has been in the Center for more than a few days has been made aware of rules and regulations regarding standards of conduct and conflict of interest. Over the years, the FDA has placed great emphasis on financial conflicts, ethics and bribery awareness. To be sure, such an emphasis is warranted. Nothing is quite so damaging to the Agency as having one or more employees convicted of exchanging regulatory decisions for monetary or other favors.

However, in our zeal to protect our good name against financial misfeasance, we should not neglect potential conflicts of interest where financial gain is not involved. For example, if a reviewer of a drug belongs to an organization that publicly espouses a point of view for or against that particular drug or its therapeutic class, most people would question the reviewer's ability to perform an unbiased evaluation of that drug.

CDER MAPP 4641.3 covers outside activities and addresses active participation in an organization as evidenced by holding an office or otherwise prominently representing that organization. But is it reasonable to draw a distinction between the levels of participation in an organization? Or what about a reviewer with strongly held views that pose a conflict who does not belong to any outside organization? While the issue may be raised in the context of an outside activity, the problem really stems from an appearance of an intellectual conflict of interest.

In Title 45 of the Code of Federal Regulations, a section is devoted to standards of conduct specifically for the FDA. Section 735-101(a) states in part:

"Because of FDA's special regulatory responsibilities to the consumer and industry, its employees must be especially alert to avoid any real or appearance of conflict of their private interests with their public duties. Their actions must be unquestionable and free from suspicion of partiality, favoritism, or any hint of conflicting interests."

Conflicts arise when we, as private citizens, exercise our right to espouse causes that we believe but which also impact our work. In our public lives, we are commissioned by the American people through Congress to be unbiased evaluators of the safety and effectiveness of drugs.

The real or apparent intellectual conflicts cannot be dismissed by an assertion that scientific principles outweigh reviewers' subjective opinions or that the data speak for themselves. The plain fact is that the data do not speak for themselves. If they did, we would not need statisticians. No matter how much objectivity is built into the review process, the judgment of primary reviewers still weighs heavily.

When an advisory committee member has an apparent intellectual or financial conflict of interest, for example, when the member has pioneered the drug being discussed, we ask him to recuse himself or herself from the deliberations on the drug. We should demand no less intellectual honesty from ourselves.

There are many issues in our society that evoke strong feelings on both sides. Some of those issues involve drugs that we are asked to evaluate and to monitor. Abortion and contraception come immediately to mind. There are also many controversial issues related to treatment of drug and alcohol abuse, AIDS and animal testing. If we believe strongly in one or another side of an issue that may bias us with respect to a particular drug, class of drugs or methodology, we have an obligation to discuss the matter with our supervisor and to refrain from participating in any regulatory activity in which we might seem to have a conflict. Supervisors also have an obligation to assure that the work products coming from their areas of responsibility are free from bias or the appearance of bias.

Ultimately we are the only ones who can say for certain whether we hold views that, if known, may appear to bias us in performing our work on a project. There is a natural reluctance to raise such issues with our supervisor for fear that we might be viewed as less valuable to the Agency. But raising such issues strengthens the ethics of the Agency and actually makes those who come forward more valuable. An intellectually honest scientist is the most valuable asset the Agency can have.

Jim Morrison is the Center's Ombudsman.

Post-Marketing Surveillance Leads to Two Drug Withdrawals

The non-steroidal anti-inflammatory bromfenac and the calcium-channel blocker mibefradil, both approved last year, were voluntarily withdrawn from the market by their manufacturers in June. The actions followed postmarketing reports of rare, severe liver failure when brofenac was used for extended periods beyond the 10 days use specified in the labeling, and new information about mibefradil's potentially harmful interactions with more than two dozen other drugs.

"We know that we are going to continue to learn new things about drugs when they are used in a wider patient population after marketing. When that new information turns the benefit-risk ratio negative, products have to come off the market," said **Murray Lumpkin, M.D.,** Deputy Director (Review Management), "Our post-marketing system is designed to detect these rare, serious, unexpected side effects if they occur. This is the way drug development, drug approval and post-marketing surveillance are supposed to work."

The FDA approved bromfenac in July l997 for management of acute pain for 10 days or less. Mibefradil, approved in August 1997 and used to treat hypertension and chronic stable angina, was found in post-marketing reports and an on-going clinical trial to be potentially dangerous with more than 25 drugs. Bromfenac was marketed under the trade name Duract by Wyeth-Ayerst Laboratories of St. Davids, Pa., and withdrawn June 22. Mibefradil, marketed under the trade name Posicor, was withdrawn June 8 by Roche Laboratories of Nutley, N.J.

More information about the two drug withdrawals can be found on CDER's Web at:http://www.fda.gov/cder/drug.htm.

Reviewer Affairs Corner

RAC Subcommittees Tackle Host of Worklife Issues

By Melissa Maust

If you are asking yourself the question, "What has the Reviewer Affairs Committee done for me lately?" then please read on. The RAC provides a forum for all CDER primary reviewers to present their concerns directly to the Center director with the goal of improving the working environment for reviewers.

Work performed by RAC members is recognized as part of their official duties and is acknowledged in performance ratings. Below are summaries of some of the works in progress from the various subcommittees and task forces of the RAC. If you are interested in participating on a subcommittee or a task force, please contact the chair of that group.

The more input and participation that is received, the more accurately the primary reviewers' concerns are represented to the Senior Management Team.

- The *Reviewer's Handbook Subcommittee,* chaired by **Russ Rutledge,** has finalized the CDER Reviewer's Handbook. Every primary reviewer in CDER should have a copy. In addition, the handbook was distributed at the New Reviewer's Workshop. The document will undergo regular updates. The latest version can be found on the X:drive at: X:\coorcomm\rac\subcmte\handbook\revhnd10.f98.
- The *Quality of Worklife Group,* represented by **Terri Rumble,** is working to identify issues that affect the quality of the CDER primary reviewer's daily worklife and to provide a more supportive and satisfying work environment. The group is currently identifying key issues to work on.
- The *Communications and Training Subcommittee,* chaired by **Melissa Maust,** is currently in the process of developing the RAC homepage for incorporation onto the CDER intranet.
- The *Team Model Task Force,* chaired by **Raj Uppoor,** has just finalized a memo of comments that were sent to **Jean Yager** regarding the Reviewer Affairs Committee's response to the "Proposal for the Enhancement of Multidisciplinary Team Approach to Review of Submissions" of Jan. 26. As the Reviewer Affairs Committee represents all primary reviewers in CDER, the comments made on the proposal represent the consensus of RAC members after thoughtful, intense discussions of comments brought before the RAC. In general, the primary reviewers support the concept of a team review process, but have concerns about the proposal as it is currently written. The RAC will continue to provide assistance and support to the Project Management group in the mutual endeavor of improving all aspects of the team review processes in CDER.
- A new task force has been developed to work with **Nancy Smith** on the *CDER Reviewer Career Path.* This task force will offer comments and suggestions for improvement for the promotional path. If you are interested in participating on this task force, please e-mail me (MAUSTM) or **Fred Marsik** (MARSIKF).

Melissa Maust, a chemist in the Office of Generic Drugs, is chair of the RAC.

Temple-Merrill 'Debate,' Pregnancy Labeling Issues Featured

By Joe Oliver

A new edition of the Center's *virtual Journal* is up and running on CDERnet, *http://cdsmlweb1/vj/secondedition/index.htm.* Don't be the last in CDER to see the interesting line-up of pertinent articles. As promised, the *vJ* is home to **Bob Temple's** fascinating piece, "The Architecture of Government Regulation of Medical Products." This article provides an overview of the great debate on this topic between Bob Temple and former chief FDA general counsel Professor Richard Merrill that was featured at the June 17 CDER Seminar. Bob Temple's article was written in rebuttal to an article authored by Professor Merrill. Electronic links between the two articles provide for an electronic debate. If you missed the seminar, you can check out a video of the debate from the Medical Library or its branches.

Take a gander at the results of **Grant Williams'** Reviewer Diagram Project featured in the *vJ* Workroom. The approaches to drug evaluation used by some of CDER's master reviewers are detailed in compelling graphical displays. Next, you can check out **Sandy Kweder's** editorial summarizing the current situation concerning FDA's pregnancy labeling and **Jon Wilkins'** thoughtful proposal on this subject.

Don't just read these articles—send in your comments and critiques to be published. And, if you haven't already, write your own article for publication in finished form or as a preliminary draft for the *vJ* Workroom. Case studies are also welcome and can be accomplished readily within one or two pages.

This long-awaited second edition of the *vJ* is the last "edition" that will be published. From now on, *vJ* articles will be put up individually on CDERnet immediately following the peer review and editorial processes. This means that articles may appear within as few as two or three weeks following submission. Many articles are already in the pipeline and will be featured in the *vJ* over the next several weeks.

We acknowledge the tireless contributions to the CDER scientific community by the *vJ* authors, editors and peer reviewers. Many thanks to **Zan Fleming, Nancy Smith** and OTCOM staff **Carol Assouad, Gail Chotoff, Lori Frederick, Jack Pevenstein, Paul Stauffer** and **Bill Woodard.**

Cyber Corner

CDER's Exploding Web Site to Get New Look

By Carol Assouad

So many exciting places to see, exciting things to do, exciting things to learn. Just never enough time to do it all. I propose to help a little bit by using this new column to highlight some of the Web activities that are going on in CDER, in FDA and in the whole wide world of cyber space.

I'll take you on behind-the-scenes tours each month where you'll meet people in the Agency involved in Web activities, show you some sites in the creation stage and some brand new ones, let you in on Web planning and research activities and maybe take you on some interesting cyber adventures. I'm also going to ask for plenty of help and feedback from you. How about help naming this column for starters? You can't careen around cyber corners after all, so I'd like something much less staid than this.

Did you know that in just a few weeks, July 1, we'll be celebrating CDER's second Internet Web site anniversary? We've certainly grown and learned a lot in that time. From just a wee baby of about 5 megabytes and 30,000 hits on our pages that first month, we now add more than 75 megabytes of information to the site weekly and get 2.5 million hits monthly. We've obviously outgrown our rather simple organizational structure, so the library's web resources team's big summer project is to redesign the Web site's information architecture and look. In the meantime, we added an interim design for all the new drug information we now post to the site (http://www.fda.gov/cder/approval/index.htm), including the final labeling text and approval letters for both new and generic drugs and supplements.

During June, you'll see the piloting of pages with frames, similar to a multipaned window, to allow easier navigation through voluminous materials. Earlier this month, we introduced the Adverse Events Reporting System's Electronic Submissions Page (http://www.fda.gov/cder/aerssub/), by the AERS pilot project coordinator, **Debbie Yaplee.** This page supplies guidance and forms for industry to participate in a pilot program to submit electronic drug periodic reports; its Trading Partner Agreement Form is also our first use of template forms in HTML, PDF and Microsoft Word formats. The new AERS submission page will be quickly followed by a CDER FDA Modernization Act Page, coordinated by **Nancy Derr** of CDER's Policy Staff. This page will form a Table of Contents or triage page to all CDER's FDAMA-related work, including time lines, guidances and other documents.

And later this month, you'll see a brand new service, consumer drug information—a brief, consumer-friendly rewrite of the label for all new molecular entities. This page is **Ellen Shapiro's** fellows project for the CDER Directors Leadership Fellows Program. Ellen is OTCOM's Director, Division of Communications Management.

While these frames make it much easier for many of our users to navigate individual pages, we will also be providing non-frame and text-only access to these pages in order to remain accessible to all our users and to comply with the requirements of the Americans with Disabilities Act.

All FDA Web program managers are working hard at coordinating and communicating so we don't design and post duplicate information or waste scarce resources. Various FDA units take leads on projects, and the other units link to the unique material. This gives all our users multiple access points to information and makes us all seem more responsive and superhumanly productive. One downside is the difficulty in keeping up with all that's there. So, I'd like to highlight a very significant project on which the Office of Public Affairs and FDA's overall Web Site Program Manager, **Bill Rados,** took the lead—a very rich page of nearly all FDA laws and regulations. At http://www.fda.gov/opacom/laws/lawtoc.htm, this page includes the Food Drug and Cosmetic Act, the Fair Packaging and Labeling Act, the Tea Importation Act and many other laws we enforce.

I promised you a behind-the-scenes peak at a page in development. Here's one that only CDER viewers will have access to until it's finished, the CDER History Page at http://cdernet/history/default.htm. This page is a joint project of FDA Historian, **Donna Hamilton,** and our graphics director, **Bill Woodard.** I think you'll find this project interesting from many aspects—be sure to follow the link to photos of all the FDA Commissioners.

Please let me know of anything you'd like me discuss. I'll be happy to hear from you.

Carol Assouad is Division Director, Medical Library, and program manager, CDER Web sites.

Isom's Position as OIT Director Made Permanent Appointment

Center Director **Janet Woodcock, M.D.,** announced that **David Isom** has been chosen to be permanent Director of the Office of Information Technology after doing "an outstanding job as interim director of the newly formed OIT."

Isom has been instrumental in the development and implementation of CDER's information technology strategy and has fostered a strong partnership with IT colleagues throughout the Agency. "His knowledge of CDER programs, along with his management skills and technical abilities, makes him highly qualified for the position," Woodcock said.

Isom, a frequent contributor to the *Pike*, had been project manager for the Automated Management of Files program before taking the reigns of OIT a year ago.

OIT was formed to provide a more focused approach to Centerwide information technology support, services, investment management and strategic planning. The office is a key player in moving the Center toward the goal of accepting and reviewing electronic regulatory submissions by the year 2002.

Project Management, Information Technology Have Awards

(Continued from page 1)

FDA Awards

FDA Commendable Service Award

Jacquelyn A. Barber

Ruth Clements

Rebecca E. Nalley

Thomas J. Permutt, Ph.D.

Edward M. Sherwood

Melvin F. Szymanski

Gloria J. Troendle, M.D.

Duu Gong Wu, Ph.D.

Alcohol-Analgesic Warning Team: **Debra L. Bowen, M.D., Maria Rosanna Cook, M.B.A., Diana M. Hernandez, Debbie L. Lumpkins, Stephanie A. Mason, Anne J. Mustafa** and **Ida Yoder.**

Evaluating Clinical Studies of Antimicrobial Drug Products Team: **Oluwarde M. Adeyemo, Ph.D., Renata Albrecht, M.D., Mercedes S. Albuerne, M.D., John J. Alexander, M.D., Sousan S. Altaie, Ph.D., David C. Bostwick, David W. Feigal, Jr., M.D., Luigi S. Girardi, M.D., Ralph D. Harkins, Ph.D., Robert J. Hopkins, M.D., David B. Katague, Ph.D., Brad G. Leissa, M.D., Daphne Lin, Ph.D., Cheryl L. McDonald, M.D., Nasim R. Moledina, M.D., Robert E. Osterberg, Ph.D., Francis R. Pelsor, Ph.D., Alexander T. Rakowsky, M.D., Rosemary Roberts, M.D., Albert T. Sheldon, Ph.D., Janice M. Soreth, M.D., Susan D. Thompson, M.D., Joseph K. Winfield, M.D., and** *(PHS Unit Commendation)* **CDR Carmen L. DeBellas** and **CAPT Lillian Gavrilovich.**

Nicotine Patch Research and Review Working Group: **Harry M. Geyer III, Ph.D., E. Douglas Kramer, M.D., Robert J. Parker, Ph.D., John M. Strong, Ph.D., James A. Vick, Ph.D., M.S., and** *(PHS Unit Commendation)* **CAPT Eugene H. Herman** and **CDR Frank D. Sistare.**

Postmarketing Safety Evaluation Team: **Janos T. Bacsanyi, M.D., Debra E. Boxwell, Pharm.D., Evelyn R. Farinas, R.Ph., M.G.A., Lanh A. Green, R.Ph., M.P.H., Carol A. Pamer, R.Ph., Toni Piazza-Hepp, Pharm.D., and Sarah J. Singer, R.Ph.**

PQRI Implementation Group: **Karl P. Flora, Ph.D., Ajaz S. Hussain, Ph.D., and Helen N. Winkle**

FDA Outstanding Achievement Award

John J. Alexander, M.D.

David C. Bostwick

Jon E. Clark, M.S.

Elizabeth A. Duvall-Miller

Martha R. Heimann, Ph.D.

Shiew-Mei Huang, Ph.D.

David J. Lee, Ph.D.

Cheng Yi Liang, Ph.D.

Moheb H. Makary, Ph.D.

Brian L. Pendleton, J.D., M.A.

Prabhu Rajagopalan, Ph.D.

Nancy B. Sager

Abdul J. Sankoh, Ph.D.

Roopa Viraraghavan, M.D.

FDA Group Recognition Award

CDER Genetic Toxicology Committee: **Chang-Ho Ahn, Ph.D., Aisar H. Atrakchi, Ph.D., R. Daniel Benz, Ph.D., Anita C. Bigger, Ph.D., Norma J. Browder, Ph.D., Daniel Casciano, Ph.D., J. Christopher Cordaro, Ph.D., Rosalie K. Elespuru, Ph.D., James G. Farrelly, Ph.D., Edwin J. Matthews, Ph.D., Robert E. Osterberg, Ph.D., Michael J. Prival, Ph.D., Leonard M. Schechtman, Ph.D., Chingju W. Sheu, Ph.D., and Ronald W. Steigerwalt, Ph.D.**

Electronic CRF/CRT Committee: **Renata Albrecht, M.D., Mary A. Buesing, M.D., Kaye H. Fendt, M.S.P.H., Robin L. Jones, Peter A. Lachenbruch, Ph.D., Brad G. Leissa, M.D., Randy Levin, M.D., Linda A. Sigg, M.S., Jeffrey Keith Smith, Lilia Talarico, M.D., Curtis Wright, M.D., M.P.H., and** *(PHS Unit Commendation)***CDR Frederick W. Miller** and **CAPT Stephen E. Wilson.**

Ephedrine Monograph Review Team: **Debra L. Bowen, M.D., Marina Y. Chang, Ling Chin, M.D., M.P.H., Linda P. Fujiwara, Linda M. Katz, M.D., M.P.H., Michael D. Kennedy, Cazemiro R. Martin, Babette A. Merritt, Anne J. Mustafa** and **Gerald M. Rachanow, J.D., and** *(PHS Unit Commendation)* **CAPT Roger A. Goetsch.**

PHS Outstanding Service Medal

CDR David J. Hussong

PHS Commendation Medal

CDR Linda S. Brophy, CDR Philip E. Coyne, Jr., CDR Mary B. Forbes, CDR Rita R. Hassall, CDR Mary Ann Holovac, LT Duane M. Kilgus, CDR Armando Oliva, CDR David G. Orloff, CDR Sheila M. O'Keefe, CAPT Alan C. Schroeder, CDR Richard M. Tresley and **CDR Marilyn A. Welschenbach.**

National Partnership for Reinventing Government Hammer Award

Imiquimod Review Team: **Narayana Battula, Ph.D, Rachel E. Berhman, M.D., M.P.H., Barbara M. Davit, Ph.D., Anthony W. DeCicco, R.Ph., James G. Farrelly, Ph.D., David W. Feigal, Jr., M.D., M.P.H., Paul A. Flyer, Ph.D., Kenneth L. Hastings, Pharm.D., Mary Ann Jarski, Janice B. Jenkins, Ph.D., Stanka Kukich, M.D., Yulan Li, Ph.D., Stephen Miller, Ph.D., James C. Ramsey, Ph.D., and Anthony M. Zeccola.**

CDER Awards

CDER Special Recognition Award

Richard C. Adams

Janet G. Higgins

Lawrence J. Lesko, Ph.D.

Frederic J. Richman

Sharon M. Sheehan

Joseph Sieczkowski, Ph.D.

Extended-Release Dissolution Working Group: **Hae-Young Ahn, Ph.D., Raman K. Baweja, Angelica Dorantes, Ph.D., William K. Gillispie, Ph.D., Ting Eng Ong-Chen, M.S. , Nicholas M. Fleischer, Ph.D., Ajaz S. Hussain, Ph.D., Kofi A. Kumi, Ph.D., Stella G. Machado, Ph.D., Houda Mahayni, Ph.D., Henry J. Malinowski, Ph.D., Patrick J. Marroum, Ph.D., Vinod P. Shah, Ph.D., He Sun, Ph.D., Vijaya K. Tammara, Ph.D., and Venkata R.S. Uppoor.**

Food-Effect Bioavailability and

(Continued on page 7)

New Center Director's Special Citation Presented for 1st Time

(Continued from page 6)

Bioequivalence Studies Working Group: **June S. Cory, M.S., M.P.A., Nancy E. Derr, M.A., Yih-Chen Huang, Ph.D., Ajaz S. Hussain, Ph.D., Lydia C. Kaus, Ph.D., Jenny Lee, M.S., Lawrence J. Lesko, Ph.D., Henry J. Malinowski, Ph.D., Moheb H. Makary, Ph.D., Ameeta Parekh, Ph.D., Kellie Schoolar Reynolds, Pharm.D., and Roger L. Williams, M.D.**

Immediate-Release Dissolution Working Group: **James M. Fan, M.S., Nicholas M. Fleischer, Ph.D., James D. Henderson, Ph.D., Lawrence J. Lesko, Ph.D., Moheb J. Makary, Ph.D., Henry J. Malinowski, Ph.D., Larry A. Ouderkirk, Suva Roy, Ph.D., Pradeep M. Sathe, Ph.D., Vinod P. Shah, Ph.D., Gur J.P. Singh, Ph.D., Lloyd Tillman, Ph.D., and Yi Tsong, Ph.D.**

1998 CDER Fellowship Program Certificate

John J. Alexander, M.D.

Center Director's Special Citation

G. Alexander Fleming, M.D.

Innovations Recognition Committee: **Tracy L. Acker, CAPT Timothy W. Ames, Carol S. Assouad, Audrey T. Borja, Celeste F. Bové, M.A., CCC-A, CDR Linda S. Brophy, Elaine C. Frost, Nancy Haggard, Rhyonda M. Jackson, Lisa A. Kammerman, Ph.D., Lisa Kellerman, Chin C. Koerner, Joyce A. Korvick, Patricia L. Leonard, Mary T. Meyer, Corrine P. Moody, Stacey L. Nichols, Lana L. Pauls, Marsha L. Pincus, Ellen Shapiro, Gail H. Sherman, Nancy D. Smith, Ph.D., Carrie Smith-Hanley, Paul K. Stauffer, Marie A. Urban, Paul T. Wiener, CAPT Stephen E. Wilson** and **William B. Woodard, Jr.**

Regulatory Research and Analysis Staff: **Joseph F. Contrera, Ph.D., and Edwin J. Matthews, Ph.D.**

CDER Peer Honor Awards

CDER Adminstrative/Program Management Excellence Award

Anita G. Harrell, Barbara M. Jones, Sally J. Lewis and **Juandy S. Walston**.

CDER Time Reporting Team: **J. Richard Allen, Ph.D., Charlene C. Cherry, Kristin P. Crown, Anne M. Henig, Dong K. Kim, Victoria G. Levi, Daniel F. Luckabaugh** and **Sandra Valencia-Gonzalez**

CDER Excellence in Communication Award

Fluoroquinolones and Pediatrics Group: **Renata Albrecht, M.D., John J. Alexander, M.D., Philip M. Colangelo, Pharm.D., Ph.D., Amy Lenore Ellis, Ph.D., Pauline Fogarty, Brad G. Leissa, M.D., Carolyn A. McCloskey, M.D., and Robert J. Hopkins, M.D.**

Office of Testing and Research Web Page Coordinators: **Celeste F. Bové, M.A., CCC-A, William H. Doub, Ph.D., Sandra J. Logan, Gerald K. Shiu, Ph.D., and James L. Weaver, Ph.D.**

OGD/DCI Chemists: **Devinder S. Gill, Ph.D., and Robert W. Trimmer, Ph.D.**

Protease Inhibitor Post-Marketing Safety Evaluation Team: **Debra E. Boxwell, Pharm.D., Jeffrey S. Murray, M.D., M.P.H., Toni Piazza-Hepp, Pharm.D., Theresa A. Toigo, R.Ph. M.B.A, LT Kimberly A. Struble** and **Kimberly M. Thornton**

CDER Information Technology Excellence Award

Jonathan D. Cook

Howard S. Spungen

Office of New Drug Chemistry Focal Point Team: **Raymond P. Frankewich, Ph.D., J. Steven Hathaway, Ph.D., Theresa J. Monaco, Tammy L. Mueller, Dianne V. Woods** and **Duu Gong Wu, Ph.D.**

CDER Leadership Excellence Award

Debra B. Birnkrant, M.D.

Karen A. Bernard, Ph.D.

Ajaz S. Hussain, Ph.D.

Andrea N. Meyerhoff, M.D.

Kathy P. Miracco

Michael E. Welch, Ph.D.

Charlotte A. Yaciw

ODEV/DOTCDP Leadership Team: **Debra L. Bowen, M.D., Maria Rosanna Cook, M.B.A., Linda M. Katz, M.D., M.P.H., and Anne J. Mustafa**

OPS/ONDC Leadership Team: **Yuan-yuan Chiu, Ph.D., and Eric B. Sheinin, Ph.D.**

CDER Project Management Excellence Award

Lana J. Ragazinsky

CDER Government Performance and Results Acts (GPRA) Team: **Betty L. Jones, Banks T. Johnson** and **Pamela Slatt Fagelson**

CDER Support Staff Excellence Award

Dorothy E. O'Brien

Lillian V. Riley

Helen R. White

Rosa L. Williams

OGD/DCI Secretaries: **Brooksie M. Cooper** and **Eugenie S. Patrick.**

CDER Team Excellence Award

Active Pharmaceutical Ingredient (API) Working Group: **Patricia M. Beers Block, John M. Dietrick, Richard S. Lev, Paul J. Motise, Edwin Rivera-Martinez** and **Kasturi Srinivasachar, Ph.D.**

Biopharmaceutics Coordinating Committee: **Mei-Ling Chen, Ph.D., June S. Cory, M.S., M.P.A., Yih-Chain Huang, Ph.D., Ajaz S. Hussain, Ph.D., Lawrence J. Lesko, Ph.D., Henry J. Malinowski, Ph.D., Ramakant M. Mhatre, Ph.D., Shriniwas G. Nerurkar, Ph.D. , Rabindra N. Patnaik, Ph.D., Vinod P. Shah, Ph.D., C.T. Viswanathan, Ph.D., and Roger L. Williams, M.D.**

Case Management and Guidance Group, DMPQ: **Sheila M. Banks, Nicholas Buhay, Monica E. Caphart, Brian J. Hasselbalch, Richard S. Lev, Paul J. Motise, Brian Nadel, Luann M. Pallas, Tracy A. Roberts, Barry Rothman, Clyde Rutledge** and **Duanne S. Sylvia.**

CDER Labeling and Nomenclature Committee: **Mark W. Askine, Ph.D., Daniel L. Boring, R.Ph., Ph.D., Maryanne Gallagher, John F. Grace, R.Ph., Durand M. Hedin, R.Ph., CDR Carol A. Holquist, Stanley A. Koch, R.Ph., David B. Lewis, Ph.D., John C.**

(Continued on page 8)

CDER Kicks Off 4-Day New Employee Orientation

By Nancy Smith, Ph.D.

The Office of Training and Communications launched the Center's redesigned four-day CDER New Employee Orientation Program this month. The new program replaces a one-day orientation and aims at imparting a solid foundation in CDER's mission, vision and culture as well as core competencies.

- Day 1 consists of an in-depth look at CDER and the FDA—what our history has been, what we are presently doing and what the future holds. This will help new employees explain the organizational structure of CDER.
- Day 2 of the program covers FDA legislation, regulations and policies as well as the drug approval process. All new employees need to have a good understanding of the basics related to the drug approval process and the regulations and guidances that CDER uses to ensure that drugs are safe and effective.
- Day 3 of the program is devoted to communications, ethics, career development and library skills. These are all basic needs for any new CDER employee to understand the issues related to teamwork, communication and customer service as well as understanding the services available to all employees for education, training and library research.
- Day 4 is devoted to computer skills. The computer skills discussed will help achieve the CDER core competency of demonstrating use of the computer and applications needed in the daily work environment.

OTCOM offers a special thanks to folks throughout CDER who helped develop the program: **Tom Abrams, Susan Carey, Heather Chafin, Stephanie Hungerford, Debbie Kallgren, Karen Koenick, Lana Kostecka, Kathy Kruse, Janice Newcomb, Michael Olson, Ted Sherwood** and **John Simmons.** Members of the Division of Training and Development team who planned the new course are: **Iris Kalaf, Maria de Carvalho and Bibi Jakrali.**

All new employees who have started work in June are strongly encouraged to attend. For more information, please contact **Sonya Armstrong** by e-mail (ARMSTRONGS) or phone at 7-1450.

Nancy Smith is Director, Office of Training and Communication.

Anti-Viral Drug Products Earns Hammer Award for Imiqimod Review

(Continued from page 7)

Markow, CAPT Yana R. Mille, Mary C. Norris, Meade D. North, CAPT Thomas G. Phillips, Vaiyapuri Subramanian, R.Ph., Robert J. Wolters, Ph.D., and Mona R. Zarifa, Ph.D.

CDER Stretch Planning Group: **CDR Linda S. Brophy, Susan H. Carey, Yuan-yuan Chiu, Ph.D., Susan S. Johnson, Ph.D., Pharm.D., Joyce A. Korvick, David A. Lepay, Lori A. Paserchia, Robert H. Seevers, Cynthia M. Tolson** and **CAPT Stephen E. Wilson**

CDER's Regulatory Policy Staff: **Tawni M. Brice, Janet M. Burroughs, Mary E. Catchings, Leanne Cusumano, Nancy E. Derr, M.A., Carol E. Drew, CDR Michael D. Jones, Lee D. Korb, Thomas C. Kuchenberg, Andrea C. Masciale, Wayne H. Mitchell, Howard P. Muller, Jr., Brian L. Pendleton, J.D., M.A., David T. Read, Christine F. Rogers, Audrey A. Thomas** and **Olivia A. Vieira**

Clinical Pharmacology Section (CPS) of the Medical Policy Coordinating Committee: J**ohn D. Balian, M.D., Marc Cavaille Coll, M.D., Ph.D., David M. Green, Ph.D., Peter K. Honig, M.D., M.P.H., Shiew-Mei Huang, Ph.D, Abraham M. Karkowsky, M.D., Ken Kobayashi, M.D., Lawrence J. Lesko, Ph.D., Samuel D. Maldonado, M.D, John R. Senior, M.D., Jonathan K. Wilkin, M.D., and Roger L. Williams, M.D.**

Division of Bioequivalence: **James E. Chaney, Ph.D., Lin-Whei L. Chuang, Kuldeep R. Dhariwal, Ph.D., Yi-Chain Huang, Ph.D., Andre J. Jackson, Ph.D., Jahnavi S. Kharidia, Ph.D., Man M. Kochhar, Ph.D., Jenny Lee, M.S., Moheb H. Makary, Ph.D., Ramakant M. Mhatre, Ph.D., Shriniwas G. Nerurkar, Ph.D., Hoainhon T. Nguyen, M.S., Farahnaz Nouravarsani, Ph.D., Larry A. Ouderkirk, Moo Kwang Park, Ph.D., Amrat P. Patel, Ph.D., Sikta Pradhan, Ph.D. , Surendra P. Shrivastava, Ph.D., Pradeep M. Sathe, Ph.D., Gur J.P. Singh, Ph.D., Nhan L. Tran, Ph.D., and Zakaria Z. Wahba, Ph.D.**

Division of New Drug Chemistry II, Pulmonary Drug Product Chemistry Team: **Craig M. Bertha, Ph.D., Hossein S. Khorshidi, Ph.D., Chong Ho Kim, Ph.D., Dale L. Koble, Ph.D., John C. Leak, Ph.D., Eugenia M. Nashed, Ph.D., Linda L. Ng, Ph.D., Guiragos Poochikian, Ph.D., Brian D. Rogers, Ph.D., CAPT Alan C. Schroeder** and **Vibhakar J. Shah, Ph.D.**

Individual Bioequivalence Working Group: **Mei-Ling Chen, Ph.D., Karen M. Higgins, Ph.D., Lawrence J. Lesko, Ph.D., Stella G. Machado, Ph.D., CAPT Justina A. Molzon, Rabindra N. Patnaik, Ph.D., Donald J. Schuirmann, M.S., and Roger L. Williams, M.D.**

Metered Dose Inhalers and Dermatologicals Training Group: **Wallace P. Adams, Ph.D., Dale P. Conner, Pharm.D., Richard T. Listritto, Ph.D., Donald J. Schuirmann, M.S., Vinod P. Shah, Ph.D., Surendra P. Shrivastava, Ph.D., Gur J.P. Singh, Ph.D., and Michael Smela, Jr.**

Neuropharmacology Clinical Pharmacokinetics Review Team: **Sayed Al-Habet, Ph.D., Raman K. Baweja, Ph.D., Iftekhar Mahmood, Ph.D., Chandrahas Sahajwalla, Ph.D., Vijaya K. Tammara, Ph.D., and Rae Yuan, Ph.D.**

MPCC/CPS Population Pharmacokinetics Working Group: **Ene I. Ette, Ph.D., Emmanuel O. Fadiran, Ph.D., Karen M. Higgins, Ph.D., Mohammad Hossain, Ph.D., Chuanpu Hu, Ph.D., Shiew-Mei**

(Continued on page 9)

Volunteer Instructors Honored for '97-'98 Academic Year

By Chris Nguyen

The Division of Training and Development, Office of Training and Communications, held an Instructors' Awards Ceremony May 29 to honor those in CDER who volunteered their time and expertise to teach courses during the 1997-'98 academic year. There were about 60 people in attendance. In opening remarks that kicked off the ceremony, Center Director **Janet Woodcock, M.D.,** expressed her appreciation and thanks to all the instructors for their effort and involvement. OTCOM Director **Nancy Smith, Ph.D.,** followed by welcoming the group and conveying thanks from the DTD coordinators who presented the awards.

Awardees received a canvas attaché case as a memento. Awards were also presented to the Committee for Advanced Scientific Education chairperson, **Zan Fleming,** and subcommittee chairpersons, **John Senior, Frank Sistare** and **Jim Knoben.** The courses and instructors were:

Topics in Clinical Trials: **Susan Ellenberg, Martin Himmel, Thomas Laughren, Robert O'Neill** and **Robert Temple.**

Introduction to Drug Regulatory Procedures: **Bette Barton, Bronwyn Collier, Norman Drezin, Edwin Dutra, Evelyn Farinas, Donald Hare, Brenda Holmes, Gerald Rachanow** and **Denise Zavagno.**

Overview of FDA Legal Activities: **David Fox.**

Understanding the Drug Review Process—Mini Workshop for Secretarial and Support Staff: **Brenda Kiliany, Mary Kremzner** and **Larry Lim.**

Successful Meetings and Minutes: **Chin Koerner.**

IND Course Development: **Bronwyn Collier, Debbie Kallgren, Corinne Moody, Robbin Nighswander, Leah Ripper** and **Cathie Schumaker.**

Topics in Applied Statistics—Multiple Endpoints and Multiple Comparison in Clinical Trials: **Mohammad Huque** and **Abdul Sankoh.**

Design and Conduct of Clinical Trials: **Aloka Chakravarty, Victor Raczkowski, Kathie Robie-Suh, Grant Williams, Steve Wilson.**

Basic Statistical Methods: **Ruthanna Davi, Barbara Elashoff, Karen Higgins, Katherine Meaker** and **Nancy L.P. Silliman.**

Basic Topics in Statistics—Survival Data Analysis: **Katherine Meaker.**

Basic Topics in Statistics—ANOVA and Regression: **Michael Elashoff.**

Connecting Clinical Trials Data to Information About the Treatments Studied: **Vance Berger:**

Basic Statistical Methods: **Katherine Meaker.**

Presentation Power and More: **Carol Assouad** and **Jack Pevenstein.**

"Workplace Violence" portion of the Conflict Management Seminar: **Renee Davis, Pam Kelley, Cindy Lepson, Sara Sutphin** and **Kathy Vengazo.**

Regulatory Science: **Wallace Adams, Dennis Bashaw, Nilambar Biswal, Albinus D'Sa, Tony El-Hage, Zan Fleming, Paul Goebel, Chuck Hoiberg, Tom Laughren, Robert Osterberg, Nancy Ostrove, Toni Piazza-Hepp, Eric Sheinin, Kasturi Srinivasachar** and **Grant Williams.**

New Reviewers' Workshop: **Thomas Abrams, Tracy Acker, Funmilayo Ajayi, Carol Assouad, Bette Barton, Wendy Cheng, Gail Chotoff, Susan Cobb, Kim Colangelo, Tricia DeSantis, Kay Fendt, Enid Galliers, Roger Goetsch, Steve Goldman, David Graham, Thomas Hassall, Janet Higgins, Barbara Hill, Zei-Pao Huang, Gordon Johnston, Heidi Jolson, Karen Kapust, Carol Knoth, Kathy Kruse, Randy Levin, Mac Lumpkin, Fred Marsik, Melissa Maust, Kathie McConnell, Jim Morrison, Stacey Nichols, Lana Pauls, Lisa Rarick, Kathy Robie-Suh, Linda Ruckel, Sally Singer, Nancy Smith, Douglas Sporn, Paul Stauffer, Brad Stone, Robert Temple, Kimberly Topper, Andrea Weir, Steve Wilson, Janet Woodcock** and **Debbie Yaplee.**

ICH Training Workshop: **Patricia DeSantis.**

DTD coordinators were: **Sonya Armstrong, Steve Hayleck, Iris Khalaf, Nanette McAtee, Debbie McKemey, Chris Nguyen, Sarah Thomas, Leslie Wheelock, See Yan Lam** and **Karen Zawalick.**

Chris Nguyen is an employee development assistant in DTD.

Zan Fleming, Two Groups Honored with Director's Special Citation

(Continued from page 8)

Huang, Ph.D., Carolyn D. Jones, Ph.D., Lawrence J. Lesko, Ph.D., Stella G. Machado, Ph.D., Samuel D. Maldonado, M.D., and He Sun, Ph.D.

Trovafloxacin/Alatrovafloxacin Team: **Funmilayo O. Ajayi, Ph.D., Renata Albrecht, M.D., Regina Alivisatos, M.D., Sousan S. Altaie, Ph.D., Philip M. Colangelo, Pharm.D., Ph.D., CDR Philip E. Coyne, Jr., Daniel Davis, M.D., M.P.H., CDR Carmen L. DeBellas, Amy Lenore Ellis, Ph.D., Pauline Fogarty, Qihao Jiang, Ph.D., David B. Katague, Ph.D., Brad G. Leissa, M.D., Daphne Lin, Ph.D., Mamodikoe K. Makhene, M.D., Robert E. Osterberg, Ph.D., Rigoberto A. Roca, M.D., Albert T. Sheldon, Ph.D., B. Vithal Shetty, Ph.D., Nancy Paul Silliman, Ph.D., and Mathew T. Thomas, M.D.**

Vaginal Drug Product Labeling Team: **Renata Albrecht, M.D., Christina Chi, Ph.D., Daniel Davis, M.D., M.P.H., Brad G. Leissa, M.D., and Joseph K. Winfield, M.D.**

Jackie Barber is the CDER incentive awards officer.

Offices of Drug Evaluation Deputy Directors Named

By Murray Lumpkin, M.D.

The Office of Review Management had selected deputy directors for each of the five offices of drug evaluation: ODE I, **Rachel Behrman, M.D., M.P.H.;** ODE II**, Florence Houn M.D., M.P.H.;** ODE III, **Victor Raczkowski M.D., M.S.;** ODE IV, **Sandra Kweder M.D.;** ODE V **Robert DeLap M.D., Ph.D.**

The ODE deputy directors are responsible for coordinating, developing, writing, gathering consensus and training people on policy issues related to the 1997 FDA Modernization Act and reauthorization of the Prescription Drug User Fee Act. In addition to these Centerwide, cross-cutting issues, they will also have office oversight and policy activities.

ODE I—Rachel Behrman

Dr. Behrman has been at the FDA since 1989 in the Division of Anti-Viral Drug Products and group and team leader since 1993. In addition, she has also chaired two subcommittees of the Medical Policy Coordinating Committee. As chair of the policy drafting subcommittee since 1995, Dr. Behrman has shepherded several new guidances on adverse reactions, clinical trials and the warnings and precautions sections of labeling. She has also chaired the women's health subcommittee of MPCC since 1993.

Dr. Behrman graduated from Washington University in St. Louis with a bachelor's degree in mathematics, from Mount Sinai School of Medicine in 1983 and from The Johns Hopkins University School of Hygiene and Public Health with an M.P.H. in 1989. She trained in internal medicine at Montefiore Hospital and Medical Center and in infectious diseases at Mount Sinai from 1983 to 1988. She is board certified in internal medicine and infectious diseases.

ODE II—Florence Houn

Dr. Houn joined the Agency in 1993 and served as the Director of the Division of Mammography Quality and Radiation Programs in the Center for Devices and Radiological Health. Her skillful implementation of the mammography quality legislation is viewed as one of the major successes of the FDA during the 1990s. Dr. Houn was also acting as the interim branch chief of the microbiology branch of the Division of Clinical Laboratory Devices in CDRH. She concurrently serves as an instructor in oncology at Johns Hopkins.

Prior to joining the FDA, Dr. Houn served as lead physician for Matilda Koval Medical Center, a primary care provider for 2,500 patients. Dr. Houn received a bachelor's degree in biology from Harvard in 1980, earned her M.D. from Albert Einstein College of Medicine in 1984 and her M.P.H. from Johns Hopkins in 1992. She completed her internal medicine training at Columbia. Dr. Houn is board certified in internal medicine and a member of the American College of Physicians, the American Society of Preventive Oncology and the National Asian Women's Health Organization Advisory Board.

ODE III—Victor Raczkowski

A pediatric cardiologist, Dr. Raczkowski has most recently served as the Deputy Director of the Division of Medical Imaging and Radiopharmaceutical Drug Products. He joined the FDA in 1990, working first as a medical officer in the Division of Cardio-Renal Drug Products and then as the acting Deputy Director in the Division of Clinical Trial Design and Analysis in the Center for Biologics Evaluation and Research.

Dr. Raczkowski received a bachelor's degree in chemistry from Swarthmore College in Pennsylvania, a master's degree in pharmacology from the University of Chicago, and an M.D. from Rush Medical College in Chicago. Dr. Raczkowski performed his internship and residency in pediatrics at Children's Hospital National Medical Center and then completed a fellowship in pediatric cardiology at Children's. He is board certified in both pediatrics and in pediatric cardiology.

ODE IV—Sandra Kweder

Dr. Kweder, a commissioned officer in the U.S. Public Health Service, earned her M.D. degree with honors from the Uniformed Services University of the Health Sciences in 1984, where she was named the outstanding Public Health Service graduate. She is board certified in internal medicine, having completed a residency in internal medicine at the Walter Reed Army Medical Center in 1987. Dr. Kweder joined the FDA in 1988 as a medical reviewer in the Division of Anti-Viral Drug Products. She later served as a supervisory medical officer in that division from 1990 to 1993 and then as acting director of the Division of Epidemiology and Surveillance from 1993 to 1995. She earned an exceptional capability promotion to the rank of commander in the commissioned Corp in 1991.

Recently, Dr. Kweder completed a two-year residency at Brown in which her primary field of concentration was pharmacology and use of drugs in pregnant women. After returning to CDER, she served as a special assistant to the director of the Division of Reproductive and Urologic Drug Products. Dr. Kweder is co-chair of the FDA Pregnancy and Labeling Task Force.

ODE V Director—Robert DeLap

Dr. DeLap, who had headed the Division of Oncology Drug Products, will become ODE V Director, temporarily leaving the office without a deputy. He received a B.S. from Michigan State University, a master of science, Ph.D. (biochemistry/molecular biology) and M.D. from New York University. Following a post-doctoral year in biochemistry at NYU, Dr. DeLap completed his internal medicine residency at the University of Michigan and his fellowship in medical oncology at Yale. He is board certified in internal medicine and medical oncology. He joined FDA in 1993 as a reviewing medical officer in the Division of Oncology Drug Products and became division director in 1995. Prior to joining FDA, Dr. DeLap was a faculty member at Georgetown University in medical oncology and pharmacology. Over a seven-year period, Dr. DeLap worked in the pharmaceutical industry. From 1983 to 1986, he was an assistant director of clinical oncology research at Parke Davis and, from 1986 to 1990,a director of clinical development at Lederle Laboratories.

Division of Oncology Drug Products Deputy Director **Dr. Robert Justice** has been named acting director of that division.

Murray Lumpkin is Deputy Center Director (Review Management).

Weintraub Leaves Consumer-Oriented Legacy at ODE V

The Office of Review Management announced that **Michael Weintraub, M.D.,** will be leaving July 3 after five years of service. He will further pursue his many interests, both within the drug development world and in other areas.

In 1992, Dr. Weintraub left a successful academic career to head the part of CDER then responsible for over-the-counter drug products. He brought to the job both a knowledge of drug development research—particularly in the areas of weight control products and human pharmacology—and a passion for consumer health care. The combination revitalized the Center's involvement with over-the-counter products and their manufacturers.

Dr. Weintraub started a trend of science-based studies of consumer involvement with direct access drug products that has increased our understanding of how consumers administer medication to themselves. Under his guidance, consumer access to over-the-counter drug products improved for items such as analgesics, smoking cessation products, hair-growth treatments and H-2 blockers for heartburn.

Nonprescription Drug Manufacturers Association senior vice president and director of science and technology R. William Soller, Ph.D., said: "Dr. Weintraub has left an indelible mark on the industry through his determined approach to defining rigorous standards for Rx-to-OTC switch through joint advisory committee reviews, and the use of label-comprehension and actual-use studies."

When the new Office of Drug Evaluation V was created, Dr. Weintraub's responsibilities expanded to include oversight of the Division of Dermatologic and Dental Drug Products, and the Division of Analgesic, Anti-Inflammatory and Ophthalmologic Drug Products in addition to the Division of Over-the-Counter Drug Products. He was instrumental in formulating and implementing the Center's new procedures for the review and oversight of all over-the-counter drug products.

Newly appointed ODE V Deputy Director **Robert DeLap, M.D., Ph.D.,** (page 10) has been named take over as director.

ORM Names Electronic Review Guru

Randy Levin, M.D., has been named Office of Review Management Associate Director for Electronic Review. In this position, Dr. Levin will be responsible for coordinating, implementing and overseeing the various electronic review initiatives and other information technology initiatives in ORM. He will serve as co-chair of the ORM's IT committee as well as an ORM representative on the Centerwide IT committee.

His office for these responsibilities, which are expected to take about half his time, will be located on the sixth floor of Woodmont II. Because it is important for anyone in this position not to get detached from the drug review environment, Dr. Levin will continue to fulfill his present responsibilities as a team leader in the Division of Neuropharmacological Drug Products and will maintain an office there for this purpose.

Tuberculosis Drug Approved

The Division of Special Pathogens and Immunologic Drug Products on June 22 gave accelerated approval to a new drug for pulmonary tuberculosis, making it the first drug approval for this indication in 25 years and making the United States the first country to approve this new therapy. Rifapentine will be marketed for use in combination with other anti-tuberculosis agents that help treat pulmonary tuberculosis. Rifapentine has been designated as an orphan drug.

In a clinical trial comparing rifapentine and rifampin, a similar pulmonary tuberculosis drug, rifapentine was shown to have a 10 percent relapse rate compared to a 5 percent rate for rifampin. The Antiviral Drugs Advisory Committee recommended approval of this drug in May, despite the higher relapse rate, because the drug regimen is easier to follow, which should improve patient compliance and deter drug resistance.

The review team included: **Funmi Ajayi, Brenda Atkins, Marc Cavaille-Coll, Paul Flyer, Linda Gosey, Ken Hastings, Thomas Hammerstrom, Lisa Hubbard, Kofi Kumi, Joyce Korvick, Sheryl Lard, Marianne Mann, Owen McMaster, Norman Schmuff and John Smith.** Special thanks to **Tom Hassall.**

Hoechst Marion Roussel, Inc., of Kansas City, Mo., will market rifapentine under the trade name Priftin.

Hepatitis C Treatment OK'd

The Division of Anti-Viral Drug Products approved a drug and biologic combination on June 3 to treat chronic hepatitis C in patients who have relapsed following previous treatment with interferon alone. The two therapies that comprise this combination are interferon alfa-2B recombinant for injection (Intron A) and ribavirin (Rebetol) capsules.

Although clinical trials have shown that the combination appears to suppress blood levels of the hepatitis C virus better than retreating patients with interferon alone, the combination is not a cure for chronic hepatitis C. It is unknown if this treatment will delay liver disease progression or how the two agents work together. Serious side effects in some patients may include birth defects, anemia, depression and flu-like symptoms. The clinical trials showed that after six months of therapy followed by six months of follow-up without therapy, approximately 45 percent of patients treated with the combination were able to sustain reduced hepatitis C virus levels compared with 5 percent who were retreated with interferon alone.

The review team was: **Narayana Battula, Rachel Behrman, Terrie Crescenzi, Jim Farrelly, Russell Fleischer, Paul Flyer, Janice Jenkins, Heidi Jolson, Rao Kambhampati, Stanka Kukich, Steve Miller, Dave Morse, Tan Nguyen, Prabhu Rajagopalan, Jim Ramsey** and **Greg Soon.** Special thanks to **Laurie Burke, Bill Schweiterman** and **John Senior.**

Schering Corporation of Kenilworth, N.J., will market the combination as Rebetron and include detailed patient information.

Off-Label Information Dissemination to be Linked to Studies

(Continued from page 1)

The proposed rules, which closely track the FDAMA provisions, specify the type of off-label or unapproved use information that can be disseminated and under what conditions it must occur. Under FDAMA, FDA must study its experience with the provision, and the provision will sunset Sept. 30, 2006, or seven years after the final regulation, whichever comes first.

William B. Schultz, FDA Deputy Commissioner for Policy, noted that in the past the concept of allowing manufacturers to disseminate off-label information raised concerns about diminishing a manufacturer's incentive to develop the safety and efficacy data about these uses that would lead to their approval—concerns addressed by the legislation and implemented in the proposed rules.

"FDAMA and the new proposed rules tie dissemination of this information to a commitment to do the necessary research on the new uses," Schultz said. "These proposed rules are intended to implement the statutory provision, which will allow health care practitioners to receive information about unapproved uses of approved medications and devices and to stimulate the development of new studies or collection of existing evidence about off-label uses for FDA's review."

Under the proposal, firms or sponsors would no longer have to wait until FDA approves their supplemental application before disseminating certain scientific information about unapproved uses of their products, provided the information:

- Concerns a drug or device that has been approved, licensed or cleared for marketing by FDA.
- Is in the form of an unabridged reprint or copy of a peer-reviewed scientific or medical journal article, or an unabridged reference publication, about a clinical investigation that is considered scientifically sound by qualified experts.
- Does not pose a significant risk to the public health.
- Is not false or misleading.
- Is not derived without permission from clinical research conducted by another manufacturer.
- Includes certain disclosures (for example, that the new use has not been approved by FDA), the official labeling and a bibliography of other articles relating to the new use.

The manufacturer also would have to submit to FDA, 60 days prior to dissemination, a copy of the information to be disseminated and other data specified in the proposal. For approved drug products, this submission would be sent to the Division Of Drug Marketing, Advertising and Communications, which will coordinate and track the 60-day review process.

A firm that has not submitted a supplemental application for the new use could begin disseminating information if it meets one of these conditions:

- Certified that it has completed the necessary studies and that a supplemental application will be submitted within six months.
- Provided an adequate protocol and reasonable schedule for the necessary studies and certified that the application will be submitted within 36 months of the initial dissemination.
- Received an exemption from the requirement to submit an application on the grounds that the necessary studies would be unethical or economically prohibitive.

If FDA determines that the information is not objective and balanced, it can require the manufacturer to include additional objective and scientifically sound information or an objective statement prepared by FDA about the safety or effectiveness of the new use.

Manufacturers would have an ongoing responsibility to provide FDA with additional information about the disseminated new uses, and FDA could order the cessation of the dissemination if the additional information indicated that the "off-label" use may not be effective or may pose a significant risk to public health.

Laurie Burke (DDMAC) is the CDER contact person for the proposed rule, and **Peggy Dotzel** (FDA Office of Policy) is the Agency contact.

Former Deputy Commissioner for Operations Nominated for Top Job

(Continued from page 1)

continue to shape the Agency to respond to the changing nature of the industry and the health care marketplace. Dr. Henney will encourage and nurture collaborative relationships with consumers and industry alike—this is crucial to FDA's success in the years ahead. Dr. Henney will work vigorously to carry out the Food and Drug Administration Modernization Act, and as Commissioner she will work closely with Congress to ensure its implementation.

"A talented manager, Dr. Henney has the solid medical and academic credentials that are needed to understand the burgeoning field of biomedical research and development. As FDA Commissioner, Dr. Henney will provide the leadership that is needed to make the 21st century FDA the model agency of consumer protection that it must be.

"In addition to voicing my support for Dr. Henney, I would like to commend **Dr. Michael Friedman** for the outstanding service and dedicated professionalism that he has demonstrated while serving as Acting FDA Commissioner."

Additional Labor-Management Training

The Center has been able to arrange for three additional sessions of labor relations training for team leaders, program specialists and management officers as well as supervisors and managers. You can register to attend a session by sending an e-mail to Sonya Armstrong (ARMSTRONGS) with the date and time of one of the following sessions:

- July 7, 8 a.m. to noon, Woodmont II, Conference Room G.
- July 7, 1 p.m. to 5 p.m., Corporate Boulevard, Room S-400.
- July 8, 8 a.m. to noon, Parklawn, Room 13B-39.