news along the pike

May 1997

Center for Drug Evaluation and Research

Volume 3, Issue 5

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FDA, CDER Spring Award Ceremonies

Individuals Honored for 'Moving Mountains'

By Jackie Barber

"CDER employees have made so many accomplishments that they have literally moved mountains and have been recognized around the world," said Center Director **Janet Woodcock** in her opening remarks at the Center's Spring Honor Awards Ceremony. A highlight of the ceremony on the morning of May 9 was the presentation of the first of CDER's new peer honor awards. To open the ceremony, the Montgomery County Police Color Guard presented the colors, and **Kevin Barber** sang the national anthem. **Ruth Clements** announced each award, and office directors provided an explanation of individual or team contributions. Those honored at the CDER ceremony and at an FDA ceremony held later in the day are as follows:

FDA/CDER AWARDS
Commissioner's Special Citation

Duane S. Sylvia.

Awards of Merit/
PHS Outstanding Unit Citations

Rabindra N. Patnaik, Ph.D.

Foreign Inspection Team: **Patricia L. Alcock,**

(Continued on page 7)

Innovations in Government

Drug Approval Reforms Compete for Award

The Ford Foundation and the John F. Kennedy School of Government at Harvard University announced on April 30 that "Reform of the U.S. Drug Approval Process" was one of 22 Federal government programs from across the nation picked as semifinalists in the 1997 Innovations in American Government Awards. FDA's success in speeding drug and biologic reviews while maintaining high standards for safety and efficacy earned it a spot in the pool of 99 government semifinalists selected from among 1,540 applicants. Semifinalists represent all levels of government, including 22 state, 47 county, city and town programs and 8 special governmental authorities.

The innovations awards recognize programs and policies that represent original and effective government efforts. These programs include Federal, state and local government initiatives addressing a wide range of public services. "As the Innovations Awards

(Continued on page 10)

June 16 Deadline for Leadership Fellows Program

Citing a "tremendously successful" inaugural year, CDER Director **Janet Woodcock, M.D.,** announced the beginning of the second round of the CDER Leadership Fellows Program, open to CDER employees at the GS-13 through 15 level and the Commissioned Corps equivalent. Those wishing to be considered for the program should submit a completed application by the June 16 deadline to **Janice Sheehy** in OTCOM at 827-1651. Applications are available in all of CDER's libraries and from Sheehy.

Twenty CDER employees will be selected to participate in the Fellows program which gets underway in September. Successful completion of the program will require at least two to three days per month. Applicants and their supervisors should understand this commitment and agree to fully participate in all aspects of the program. For additional information on the Fellows program, call **CDR Mary Lambert** in OTCOM at 827-1651.

Joe's Notebook

Moving Mountains Takes Many Hands

When I was a young editor I wrote a headline about the Navy doing something spectacular. I don't recall exactly what the Navy did, but I do remember the telephone call I received from a Navy captain calling from the bridge of his ship.

"The Navy didn't do anything," he chastised me, his voice sounding as though it came through an echo chamber.

"Sure they did," I replied smartly. I wasn't about to be caught on this one, I thought. "I have the Navy's news release right here."

"The Navy still didn't do anything," he said, "and the Navy didn't write that news release. Some hard-working sailor wrote it. This ship that's about ready to leave port doesn't do anything. Thousands of sailors working long and hard do something. The Navy is nothing more than empty ships and buildings until people get together and work long and hard to make things happen."

Nonetheless, the captain didn't continue to tell me the names of all the sailors on his ship. We still resort to abstractions and collective nouns to talk about what really is a lot of hard work by a lot of dedicated folks. Alan Altshuler, director of the Innovations in American Government program and professor of urban policy and planning at the Kennedy School of Government at Harvard University, finds he has to use abstract language when summarizing findings on not just thousands of individuals, but thousands of programs, each with thousands of people involved.

"The most difficult problems facing American society cannot be solved by government working alone," Atltshuler writes. "Much of the discontent with government stems from tales of capricious, adversarial actions by regulatory agencies in dealing with businesses and property owners. Recently, many agencies have adopted a more cooperative problem-solving approach. This new model requires a mutual focus on results and a sense of partnership to achieve those results."

Turning a model into reality takes more than just words, it takes a lot of heavy lifting. If you attended the CDER Spring Honor Awards Ceremony on May 9 you had a wonderful opportunity to put names and faces to actions that so frequently go noticed only as a collective activity. **Jackie Barber's** report provides the names of some of those who have been working the hardest to make CDER the very model of an accountable and predictable agency.

Jackie reminds you to check your e-mails for May 6. That's when she announced that the Center is now accepting nominations for the Fall Honor Awards ceremony being held on Nov. 21. Jackie also announced two new peer honor awards for the fall cycle: the CDER Leadership Excellence Award and the CDER Excellence in Communication Award. In her remarks, **Janet Woodcock** mentioned that people in CDER are working so hard that they rarely take time to celebrate their achievements. After the celebration, be sure to make time to nominate deserving individuals for the next round of awards. Jackie says she needs the nominations by close of business **June 16!** That's also the date applications for the Leadership Fellows Program are due. So crank up those word processors!

David Katague, last month's guest columnist in the Reviewer Mentor's Corner, writes to point out that his team's decision to use a multimentor approach wasn't hatched out of thin air; they've already experimented with the concept but forgot to credit it in the column. **Vithal Shetty** was also a co-mentor for **Milton Sloan** along with **Jim Timper.**

news along the pike

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

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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 photographs to contribute? Please contact a member of the Editorial Board or:

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Ombudsman's Corner

CDER Transformation—Thoughts on Virtuosity

By Jim Morrison

The CDER transformation is gaining momentum. Changes, both large and small, are now occurring with such rapidity that it is often difficult to keep up with them. One of the larger changes to be unveiled recently is the *CDER Virtual Journal (vJ).* The internal forum in which CDER scientific and regulatory staff can communicate freely about the issues that confront us daily has been needed for a long time. In case you haven't yet seen it, you can do so by accessing the CDERnet (type CDERnet at the address prompt in Internet Explorer).

I might quibble about the name. The word "virtual" connotes something almost as good as the real thing. For example, the movie *Virtuosity,* with Denzel Washington, features a virtual reality that flirts with but ultimately is separate from reality itself. However, the first issue shows the *vJ* to be a real journal in the best sense of the word. It is filled with relevant, important and timely articles on issues that affect us all. The *vJ's* premiere issue not only demonstrates the medium, but it sets a high standard for content.

Janet Woodcock's lead article on science, law and public policy reminds us how infrequently we have taken the time to discuss the philosophy of drug regulation and how important it is to understand the basis for what we do. It is a "must read." **Bob Temple's** scholarly review of the history of drug regulation can make you an instant expert on the subject. Other articles include such wide ranging subjects as carcinogenicity testing, meta analysis, drug advertising, bioequivalence, clinical trial design, the review of an NDA, and much more. They demonstrate that, if we all participate, a forum like the *vJ* allows us to learn about and to discuss openly and frankly the unique scientific issues that we face. Such a forum can not only inform but can also build more consistency and rationality into our work as well.

To be able to conduct such a discussion within the security of CDER's firewalls is a welcome change from the goldfish bowl in which we usually work. But the *vJ* is too valuable to hide it from public view. The many people who produced the *vJ* are also working on a companion version for the CDER Word Wide Web site. A forum that provides for an ongoing dialogue with patients, health care providers, the regulated industry, other regulatory bodies around the world and our many other stakeholders would be of inestimable value.

Not only is the *vJ* itself impressive, but the way it came into being epitomizes the CDER transformation. It originated in the Good Review Practices' (GRP) Track 2 Committee organized by **Julie Carlston** and **Debbie Henderson.** With the proactive nurturing of **Nancy Smith** and **Zan Fleming** plus the support and talents of **Steve Wilson, Grant Williams, Jack Pevenstein** and a host of people from all over CDER, it has become a reality—not a virtual reality. It was not budgeted or allocated FTEs, but it grew from the grass roots of CDER. The *vJ* is truly a model of how the transformation is changing the environment and culture of CDER. It brings to mind the original meaning of virtuosity.

Jim Morrison is the Center's Ombudsman.

Reviewer Mentors' Corner: Focusing on Smooth Transitions

By June Cory

The Reviewer Mentor Program began last year as a result of the Good Review Practices Initiative. It has three primary goals:

- To smooth the transition of new review staff into the CDER workplace.
- To augment the mentoring that is provided by the supervisor.
- To provide each new reviewer with an additional person to whom they can go for advice and assistance.

A training session was given to office directors, division directors and others who responded to **Dr. Woodcock's** request for volunteers. Many new reviewers have benefited from mentoring over the past year. To implement the program completely, every new reviewer should be assigned a mentor upon arrival at CDER. In some divisions, team leaders serve as mentors; in other divisions, experienced reviewers can serve in this role. Each division must decide how mentoring will be handled.

The mentor and supervisor should meet regularly to make sure that all aspects of the new reviewer's training will be covered, either by the supervisor, the mentor or by CDER orientations, workshops and courses. The Division of Training and Development coordinates training and evaluation for the Reviewer Mentor Program.

The Office of Training and Communications (OTCOM) offers many resources, including mentoring books in the CDER Medical Library. The OTCOM Division of Training and Development has audio tapes and videotapes on mentoring skills such as coaching and feedback in the new Learning Resource Center in Parklawn 12B-30. Training sessions in mentoring will be announced. The division can send you a mentoring training manual and give you more detailed information, or you can call me at 827-3489 or send me an e-mail at CORYJ.

Currently, CDER mentoring is intended for new review staff. In the future, we hope to expand mentoring opportunities to include other staff as well.

CDER has a Mentor Advisory Group consisting of: **Charles Ganley,** chair (HFD-110); **Tom Abrams** (HFD-040), **Susan Kummerer** (HFD-160), **Nahid Mokhtari-Rejali** (HFD-560), J**oy Mele** (HFD-715), **Vijay Nerurkar** (HFD-655), **Jack Pevenstein** (HFD-720), **Marsha Pincus** (CBER), **Anthony Proakis** (HFD-110), **Nancy Smith** (HFD-720), and **Jim Timper** (HFD-520). Please contact any of these individuals for additional guidance in mentoring.

June Cory is the Center's mentor coordinator.

Administrative Management Corner:

Team-Building Retreat Planned For Administrative Personnel

By Charlene Cherry

Attention management officers, management specialists, administrative officers and program specialists! Mark your calendars for June 11 and 12. Administrative personnel throughout the Center are the focus of some exciting new initiatives being planned by the Administrative Management Coordinating Committee (AMCC).

The AMCC formed a work group, the Leadership and Design Team, to design and implement a process that will help Center administrative personnel work more effectively together, appreciate their differences and continue to build skills that will effectively serve customers for the long term. The team's objective is to develop a process for ongoing excellence in the administrative support functions and personnel management. Martha Spice, a respected organizational development specialist and consultant, is facilitating the Leadership and Design Team in this effort.

The first activity being planned as a part of this process is a one-and-a-half day retreat, scheduled for June 11 and 12. Center Director **Janet Woodcock** is urging all management officers, management specialists, administrative officers and program specialists to attend and strongly encouraging supervisors to provide their administrative personnel with the opportunity to take part.

Although the retreat is still in the design stage, the Leadership and Design Team envisions many exciting opportunities for attendees to network, teambuild, learn, interact with their counterparts throughout the Center, and have fun. The Myers-Briggs Type Indicator Survey is also an activity being considered as part of the retreat. Administrative personnel will be administered the instrument and the results will be discussed at the retreat.

To find out more information, you may contact any member of the Leadership and Design Team including: **Tanya Abbott, Charlene Cherry, Tricia Desantis, Bill Oswald, Steve Hayleck, Tammy Russell, Julie Basore, Richard Vengazo, Cynthia Marie Tolson, Anita Harrell, Kathy Abel** or **Zulema Miguele.** We hope to see you there as a part of the administrative management team.

Charlene Cherry is Chief of the Management Analysis Branch in the Division of Planning Evaluation and Resource Management and Executive Secretary to the AMCC.

EEO Corner

Asian Pacific American Heritage Month

By Gloria Marquez Sundaresan

CDER employees observed May as National Asian Pacific American Heritage Month by participating in cultural awareness activities, taking part in training and career development events, and cosponsoring activities at the Parklawn Building.

Cultural awareness was featured on Sunday, May 4, when several CDER employees, family members and friends took a trip to the Airlie Concert Series in Warrenton, Va. The audience was captivated by piano and violin selections from several Airlie resident artists, a classical Indian dancer, and a traditional storyteller. A string band, composed of about 20 artists from the University of the Philippines alumni and their friends concluded the performances. Although the instruments resemble guitars, each has 14 strings and produces a richer sound. For some, it was a new type of music, but for the Filipinos it prompted a spontaneous sing-along. CDER attendees, along with guests, included: **Ken Kobayashi, Patrick Guinn, Ting Eng Ong, Marta Locklear** and myself**.**

For career training and development, several CDER employees took part in the Federal Asian Pacific American Council (FAPAC) Congressional Seminar and National Leadership Training Conference May 3-8 at the Dirkson Senate Office Building and the Rockville DoubleTree Hotel, including: **Ken Kobayashi, Anwar Goheer, Puri Subramaniam** and **Kumar Mainigi.** The invocation at the May 6 dinner was given by **Margaret I. Bell**. As ex-chair of FAPAC, I took part in one of the panel discussions.

In thanking **Janet Woodcock** for her support, **Ken Kobayashi** made this comment about the FAPAC conference: "I must confess that I wasn't entirely sure what to expect at the conference. However, I found it very informative, enlightening and an excellent opportunity to meet interesting people with whom I would not otherwise have had contact."

Other employees attended the Congressional Asian Pacific American Caucus Institute Legislative Conference, including: **Asoke Mukherjee, Brenda Uratani, Christina Chi, Ting Eng Ong** and **Patrick Guinn.**

CDER cosponsored the Parklawn Asian Pacific American Community program held May 15 at the Parklawn Conference Center. Besides the Hawaiian food, the day was filled with cultural presentations such as exhibits, music and a variety of Hawaiian, Indian and Tahitian dances.

Gloria Marquez Sundaresan is a member of the EEO Staff.

New Edition of 'Blue Book' on Internet

A new edition of the ever-popular FDA publication, *Requirements of Laws Enforced by FDA*, is now available on the FDA's Internet site. Also known as the "Blue Book" or "Pub 2," this valuable industry guidance document has been updated by **Nat Geary** of the Industry and Small Business Liaison Staff in the Office of External Affairs. A printed version of the book will be available by early summer. The Internet URL address is:

<http://www.fda.gov/opacom/morechoices/smallbusiness/blubook.htm>.

Project Management Corner

FDA/Industry Project Managers' Workshop Coming in Fall

By Susan Cusack

Have you ever wondered how the other half lives? I don't mean the "rich and famous." I am referring to our counterparts in industry—the project managers and regulatory affairs specialists who work in drug development. Over the last year, the FDA has been exploring ways to bring project managers, regulatory affairs specialists and certain persons in review positions in industry and the agency together to promote better understanding and ultimately improve drug development and approval times.

Toward that end, the FDA has announced a public workshop to be held jointly by CDER and the Center for Biologics Evaluation and Research (CBER) with the cooperation of the Drug Information Association Project Management Special Interest Advisory Committee. The workshop will explain the roles of the regulatory and project management staff in both centers and the roles of their counterparts in industry. The two-and-a-half day meeting will held be held Oct. 29-31 at the Bethesda Marriott. The CDER Web site has information at: <http://www.fda.gov/cder/meeting/projmanagementfr.htm>.

Further information about the cost of the public meeting and registration forms will be made available through the Drug Information Association, a nonprofit professional association, 321 Norristown Road, Suite 225, Ambler, PA, 19002-2755 (Contact: **J. Robert Assenzo,** 215-628-2288; FAX 215-641-1229).

Agency contacts include: **Mary Jane Walling,** CDER (HFD-105), 301-827-2268; FAX 301-827-2317 and **Susan Sensabaugh,** CBER (HFM-90), 301-827-4216; FAX 301-480-3352.

Susan Cusack is a consumer safety officer in the Division of Medical Imaging & Radiopharmaceutical Drug Products.

Reviewer Affairs Corner: Reviewers' Day June 2, Survey '97

By Karen Oliver

The Reviewer Affairs Committee (RAC) cordially invites all primary reviewers to Reviewers' Day, a networking event.

- DATE: June 2.
- TIME: 11:30 a.m. to 1 p.m.
- PLACE: Parklawn Building, Conference Rooms D and E.

RAC is holding this celebration in honor of you, the reviewers. We do hope you will join us for this special event and take the opportunity to meet the committee members, including chairperson **Janet Higgins** and vice-chair **Vijaya Tammara.**

Subcommittee members will also be available to discuss topics of interest including comparability pay, CDER Honor Awards, MAPPs, handbooks, the RAC Survey '97 and other topics of interest.

Refreshments will be served, so please mark your calendar for this fun event, meet and network with your colleagues, and join us in celebrating RAC's Reviewers' Day.

RAC Survey '97 Kicks Off

We are also inviting you to participate in the RAC Survey '97. Once again this year, the RAC is conducting a survey to help identify your needs and issues of concern. Your RAC representative will distribute the survey to primary reviewer and will be available to answer any questions.

Please take 15 minutes or so to complete the form. The kickoff for the survey is the first week in June. We are here for you and look forward to seeing you. For questions or comments, e-mail OLIVERK or HIGGINSJ.

Karen Oliver is a regulatory health project manager in the Division of Gastro-Intestinal and Coagulation Drug Products.

CDER Volunteers, Runners Make Strong Showing at Parklawn Classic

By Bronwyn Collier

"Is it going to happen?" That was the big question on the lips of many eager regulars as the Parklawn Classic Committee struggled to continue the popular event this year. In these days of tight budgets the picture looked dim, but HHS agency heads and the Secretary rallied and endorsed the Classic to promote healthy lifestyles among HHS employees. **Laura West,** management specialist from the Office of Drug Evaluation III, used her persuasion skills to rally the troops and pull off the Classic.

With the endorsement of the Classic, the volunteers came flooding in (all 275). They handled logistics, walker and runner safety, water, T-shirt distribution, registration, security and many more jobs. Special thanks to **Tony Chite, Enid Galliers, Cathie Schumaker, Indira Kumar, Corinne Moody, Susan Kummerer, Curtis Wright, Karen Oliver, Michael Folkendt, Julie Dubeau, Melodi McNeal, Joy Bennett, Debbie Kallgren, Sheree Lancaster, MaryJane Walling, Melissa Ashmore,** and **Sandy Cook.**

CDER staff figured strongly in overall participation and medal contention in the 2.5-mile walk and 5-mile run. Every walker received a commemorative ribbon. In the run, a bronze was awarded to CDER's **Paul Loebach** who came in third overall for men (30:18 minutes). CDER medalists in their age categories included **Erica Sugar, Lisa Rarick, Laura West, Brenda Uratani, Russ Abbott, Rich Potter, Dotti Pease,** and **Richard Adams.** Lead Deputy Director **Mike Friedman** was at the finish line for the run handing out enthusiastic congratulations to everyone. Check out all the run results on the Parklawn Classic Web site <http://classic.dhhs.gov>.

Bronwyn Collier is the special assistant in ODE III.

AMF Corner

Division Files Pilot System Launched in Oncology

By Kathleen Alt, Greg Brolund and David Isom

In the March issue of the *Pike*, we discussed some of the capabilities included in phase one of the Division Files System (DFS) pilot. We also mentioned our plans to deploy the pilot system in the Oncology Division in May. Well, May is here and the DFS pilot is underway. To recap, DFS is a key part of CDER's Administrative Management of Files (AMF) initiative. DFS provides document management, tracking, archiving, signature, and search and retrieval capabilities for internally generated documents. It provides an electronic repository for final versions of review documents, letters, meeting minutes and telecons.

This first phase of DFS provides the ability for CDER staff to import documents ready for signoff into DFS, dynamically route the documents for signoff, automatically archive the document in the electronic repository and search for the documents stored in the repository.

The DFS team, along with the DFS working group, has been developing the pilot system for about the past six months. After a thorough integration and testing period, the DFS software was installed on machines in the Division of Oncology in early May. The first training class was held May 14.

The DFS rollout is following the same deployment process as other AMF systems. First, the DFS team previews the system for users who will be part of the pilot group. The preview includes a demonstration of the software, and a discussion of the installation schedule, training schedule and what is involved in a pilot deployment. Then, after installing the software and conducting the training, the 30-day pilot period begins.

The DFS team provides onsite user support during the pilot period. As a result of the pilot, the team hopes to identify any major software fixes that need to be corrected before phase one is deployed Centerwide. The team also hopes to identify any enhancements that users would like to see included in future phases of the DFS. At the end of the pilot period, the DFS team conducts a debriefing with the user group to ensure that we collected all comments and feedback.

Depending on the success of the pilot, we hope to begin deploying DFS Centerwide this summer starting with the Pulmonary Drug Products and the Metabolism and Endocrine Drug Products divisions. During this time, the DFS development team will also be working on phase two of the software. Capabilities identified for phase two include automatic COMIS update for completed documents that are added to the repository, a Web-browser capability into the repository, and full-text searching.

Kathleen Alt and Greg Brolund are on the AMF project team, and David Isom is the AMF project manager.

FDA Seeks MedWatch Reports to Evaluate Therapeutic Switches

By Laurie B. Burke, R.Ph., M.P.H

CDER and the FDA are requesting that health care professionals provide MedWatch reports of adverse events associated with the practice of "therapeutic switching." This involves the substitution of one prescribed drug with a totally different drug. This does not include brand-name to generic drug switches, which involve the substitution of bioequivalent drug products.

Both health care professionals and patients have expressed concern about health care programs that increasingly use limited drug formularies to manage costs. Many of these programs use therapeutic switching interventions to encourage the use of formulary drug products. We have received several reports of adverse events associated with therapeutic switches.

Since the effects of therapeutic switches are not routinely studied during new drug development, we must depend on post-marketing experience to determine the risks of these switches. While most therapeutic switches are uneventful, some have the potential for adverse consequences. For example, even though drugs within a class may have similar effectiveness profiles, they may not have the same adverse event profiles. Furthermore, once a patient's dose is adjusted to one particular drug, switching to another could cause an adverse event if there is no readjustment of the dose for optimal effect.

Through the MedWatch home page and the next issue of FDA's *Medical Bulletin,* we are asking health professionals who are aware of safety problems associated with therapeutic switching to send in a MedWatch report as expeditiously as possible. More information about MedWatch and adverse event reporting is available on the Internet at:

<http://www.fda.gov/medwatch>.

In these reports, we are asking for the names of both the originally prescribed drug as well as the drug to which the patient was switched. As with other MedWatch reports, the identity of patients involved is confidential and legally protected. The identity of the reporter may be shared with the manufacturer unless the reporter requests otherwise. You can refer health care professionals to MedWatch at 1-800-FDA-1088 so they can report by telephone or obtain a reporting form. Reports can also be faxed to 1-800-FDA-0178.

Laurie B. Burke is a senior regulatory research officer in the Division of Drug Marketing, Advertising and Communications.

(Continued from page 1)

Tawni M. Brice, John M. Dietrick, Melissa J. Egas, Richard L. Friedman, Edwin Melendez, Edwin Rivera Martinez and **Michael J. Verdi.**

ORM Office and Division Directors: **James M. Bilstad, M.D., Debra L. Bowen, M.D, Wiley A. Chambers, M.D., Robert J. DeLap, M.D., David Feigal, Jr., M.D., Stephen B. Fredd, M.D., Donna J. Freeman, M.D., John K. Jenkins, M.D., Paul D. Leber, M.D., Raymond J. Lipicky, M.D., Patricia Y. Love, M.D., Lisa D. Rarick, M.D., Solomon Sobel, M.D., Robert Temple, M.D. , Michael Weintraub M.D., Jonathan K. Wilkin, M.D., Curtis Wright, M.D.** and *PHS Outstanding Unit Citation:* **CAPT Paula Botstein, M.D.**

ONDC and OGD Chemistry Division Directors: **Yuan-yuan Chiu, Ph.D., Charles P. Hoiberg, Ph.D., Frank O. Holcombe, Ph.D., Rashmikant M. Patel, Ph.D.** and **Eric B. Sheinin, Ph.D.**

Commendable Service Awards/ PHS Unit Commendations

Kathryn W. Kruse.

Iftekhar Mahmood, Ph.D.

Jeffrey S. Murray, M.D.

Moo Kwang Park, Ph.D.

Alexander T. Rakowsky, M.D.

Maria C. Shih.

Ellen R. Tabak, Ph.D.

CDER Botanical Working Group: **Joel A. Aronson, Javier Avalos, Ph.D., Estela A. Barry, Cynthia A. Bigger, James M. Bilstad, M.D., Chi-wan Chen, Ph.D., Conrad H. Chen, Ph.D., Shaw T. Chen, M.D., Ph.D., Yuan-yuan Chiu, Ph.D., Joseph J. DeGeorge, Ph.D., Albinus D'Sa, Ph.D., Tao Du, Ph.D., James G. Farrelly, Ph.D., Lois M. Freed, Ph.D., Harry M. Geyer III, Ph.D., Dou H. Jean, Ph.D., David B. Katague, Ph.D., Michael D. Kennedy, Robert Osterberg, Ph.D., Nahid Mokhtari-Rejali, Ph.D., Herman M. Rhee, Ph.D., Moo-Jhong Rhee, Ph.D., Wendelyn J. Schmidt, Ph.D., Arthur B. Shaw, Ph.D., He Sun, Ph.D., Robert Temple, M.D., Michael C. Theodorakis, Ph.D., Kuie Meng Wu, Ph.D.** and **Mona R. Zarifa, Ph.D.**

CellCept Review Team: **Lauren Black, Ph.D., Daniel L. Boring, Ph.D., Paul A. Flyer, Ph.D., Mark J. Goldberger, M.D., Joyce A. Korvick, M.D., Kofi A. Kumi, Ph.D., John A. Lazor, David A. Lepay, M.D., Chandrahas G. Sahajwalla, Ph.D.** and *PHS Unit Commendation:* **LCDR Matthew J. Tarosky.**

CFC Work Group of the Medical Policy Coordinating Committee: **Joseph J. DeGeorge, Ph.D., Christina L. Good, Parinda Jani, John K. Jenkins, M.D., Susan S. Johnson, Ph.D., Robert J. Meyer, M.D., Wayne H. Mitchell, Babatunde A. Otulana, M.D., Rashmikant M. Patel, Ph.D., Guiragos K. Poochikian, Ph.D.** and *PHS Unit Commendation:* **CAPT Ching-Long J. Sun.**

EES Pilot Implementation Group: **Joseph D. Doleski, Janine M. Davis-D'Ambrogio, Melissa J. Egas, Shirnette D. Ferguson, Mark A. Lynch, Vera S. Parks** and **John M. Singer.**

Equal Opportunity Achievement Award

Paul M. Seckler.

Outstanding Achievement Awards

Craig M. Bertha, Ph.D.

Patricia L. Downs.

Susan S. Johnson, Ph.D.

Nashed E. Nashed, Ph.D.

Barbara E. Shekitka.

Paul K. Stauffer.

Vijaya K. Tammara, Ph.D.

Laura M. West.

Group Recognition Awards/ PHS Unit Commendations

Bioassay Research Team: **Yuan-yuan Chiu, Ph.D., Joseph G. Contrera, Almetia L. Hoskins, Joseph P. Hanig, Ph.D., Susan Jenney** and **Barry A. Rosenzweig.**

Bleomycin Task Group: **I. Jerome Abramson, Ph.D., Sylvia H. Colson, Kristy R. Cutting, Jeffrey H. Cutting, Valerie A. Flournoy, Joseph P. Hanig, Ph.D., Connie R. Kiessling, William M. Kiessling, Karen S. Kreuzer, Mercedes H. Loftis, Emma R. Singleton,** and **Calvin Walker, Ph.D.**

CDER/Field Method Advisory Panel: **George H. Boone, Frederick L. Fricke, Jr., Elise A. Murphy, Eric B. Sheinin, Ph.D., Donald Shostak** and **Michael Smela, Jr.**

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MERETEK UBT Breath Test Collection Kit Review Team: **Mercedes S. Albuerne, M.D., Yuan-yuan Chiu, Ph.D., Maureen P. Dillon-Parker, Doria R. DuBois, Ph.D., Claudia Gaffey, M.D., Sydney A. Gilman, Ph.D., Sharon Hansen, Ph.D., Eldon E. Leutzinger, Ph.D., Nasim R. Moledina, M.D.** and **Kenneth A. Seethaler, Ph.D.**

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CDR Paul F. Zimmerman.

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CDER Administrative/Program Management Excellence Awards

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CDER Support Staff Excellence Award

Sandra J. Benton.

Sonya M. Hughes.

CDER Team Excellence Award

ALBENZA Review Team: **Oluwadare M. Adeyemo, Ph.D., Philip M. Colangelo, Ph.D., CDR Philip Coyne, Jr., M.D., Pauline Fogarty, Joel Jiang, Ph.D., David B. Katague, Ph.D., Brad G. Leissa, M.D.** and **Daphne Lin, Ph.D.**

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Division of New Drug Chemistry III Chemists co-located with the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products: **Vispi P. Bhavnagri, Ph.D., Allan H. Fenselau, Ph.D., Bartholomew C. Ho, Ph.D., Sonya M. Hughes, Sue-Ching Lin, Hasmukh B. Patel, Ph.D., Su C. Tso, Ph.D.** and **Charlotte A. Yaciw.**

Donepezil Review Team: **Stanley W. Blum, Ph.D., Mohammad Hossain, Ph.D., Waclaw J. Rzeszotarski, Ph.D.** and **Vijaya K. Tammara, Ph.D.**

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OTHER CDER AWARDS

CDER Special Recognition Award

CAPT Timothy W. Ames.

Bonnie B. Dunn, Ph.D.

1997 CDER Fellowship Program—Certificates

Andrew M. Bonwit, M.D.

LT Lydia V. Kieffer, Pharm D.

Chang Qing Li, M.D.

Amarylis Vega, M.D., M.P.H.

CDER AWARDEES AT FDA CEREMONY

FDA Commendable Service Award

Intra-Agency Working Group on Advertising and Promotion: **Minnie V. Baylor-Henry, R.Ph., Roma J. Egli, Lesley R. Frank, Brad G. Leissa, M.D., Melissa Moncavage, Louis A. Morris, Ph.D.** and **Nancy M. Ostrove, Ph.D.**

FDA Group Recognition Awards

Fraudulent Findings at a Foreign Active Pharmaceutical Ingredients Manufacturer: **Richard C. Adams, Nicholas Buhay, Eric P. Duffy, Ph.D.** and **Mark A. Lynch.**

Interagency Regulatory Alternatives Group: **Wiley Chambers** and **Robert**

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FDA Statement on Generic Premarin Released May 5

FDA's Center for Drug Evaluation and Research announced May 5 that at this time it will not approve synthetic generic forms of the estrogen-replacement drug Premarin. This is because these generic products have not been shown to contain the same active ingredients, and therefore to work the same, as the innovator drug in treating women with menopausal symptoms and preventing osteoporosis.

In her announcement, CDER's director, **Janet Woodcock, M.D.,** said, "Based on currently available data, there is at this time no way to assure that synthetic generic forms of Premarin have the same active ingredients as the brand-name drug. This is essential for determining they are equivalent to the brand drug, and is also a legal requirement for their approval."

Because generic drug manufacturers do not have to repeat the clinical studies used to develop the innovator, brand-name drug, they must assure their products are as safe and effective by showing that the active ingredients are the same and that they are bioequivalent—that is, absorbed and used by the body in the same way as the innovator products.

Premarin, the brand name for conjugated estrogens, is derived from the urine of pregnant mares and contains a number of different estrogens. Precisely how each of these various estrogens contribute to the drug's overall effectiveness has not been definitively determined. Premarin's approval in 1942 predated the current requirements for such comprehensive analysis of products under review for marketing approval.

Previously it was thought that two estrogens—sodium estrone sulfate and sodium equilin sulfate, were the sole active ingredients in Premarin. Newer laboratory and clinical studies show this may not be the case. Rather, other components in Premarin may contribute to the drug's effectiveness for menopausal symptoms and osteoporosis prevention.

In addition, recent studies submitted by Wyeth-Ayerst, the manufacturer of Premarin, show that after repeated doses of Premarin in women, the blood concentration of the active metabolites of the estrogen delta (8,9) dehydroestrone sulfate (DHES) is about the same order of magnitude as the concentration of the active metabolites of estrone and equilin. "Although this finding does not prove that the DHES in Premarin has an important therapeutic effect," Woodcock says, "it underscores the lack of precise knowledge of the makeup of Premarin and the relative importance of its components, and therefore the lack of a standard on which to evaluate a generic copy."

Over the years, there has been controversy about the required composition and testing of generic conjugated estrogens. In 1991, FDA issued new bioequivalence testing guidelines for the drug, based on recommendations of its Generic Drugs Advisory Committee. In 1970, conjugated estrogens were officially defined in a U.S. Pharmacopeia monograph as a mixture of sodium estrone sulfate and sodium equilin sulfate. In 1992, in addition to those components, other constituents were described as "concomitant components" and as impurities. In November 1994, Wyeth-Ayerst filed a citizen petition requesting that DHES be reclassified as a concomitant component.

The firm maintained that the compound contributes to the drug's potency, and therefore, effectiveness, and further requested that FDA require the compound to be included in any generic copies of the drug. The following July, FDA's Fertility and Maternal Health Drugs Advisory Committee reviewed Wyeth-Ayerst's request. At the end of the deliberations, the committee unanimously concluded that not enough data were available to determine whether or not components besides estrone sulfate and equilin sulfate must be present in order for Premarin to achieve its established levels of efficacy and safety.

An ad hoc agency working group on conjugated estrogens was formed in the summer of 1995 to review the scientific data on the composition of conjugated estrogens. Recently, the working group presented a final report compiling scientific information related to the composition of Premarin.

The Center has now concluded that Premarin must be better characterized before its active ingredients can be definitively identified, and that the bioequivalence guidance for conjugated estrogens should be reexamined.

The agency encourages the initiation of studies that will permit the scientific determination of the active ingredients in Premarin and provide a potential for approval of generic versions of the drug. Several brand name and generic tablets and patches containing estrogens are available besides Premarin to treat menopausal symptoms, a number of which are also approved for long-term use to prevent osteoporosis.

More information is available on CDER's Web site at: <http://www.fda.gov/cder/cepage.htm>.

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Osterberg.

Microbiology Rapid Methods Working Group: **Constance Bulawka.**

Points to Consider for Monoclonal Antibodies Rewrite Group: **Victor F. Raczkowski, M.D.**

CDER/OCC Generic Litigation Group: **Wallace P. Adams, Jason A. Gross, Donald B. Hare, Rita R. Hassall, Gordon R. Johnston, Ramakant M. Mhatre, Saundra T. Middleton, Wayne H. Mitchell, Justina A. Molzon, Shriniwas G. Nerurkar, Rabindra N. Patnaik, Thomas G. Phillips, Edward M. Sherwood, Douglas L. Sporn, Robert J. Temple, M.D.** and **Roger L. Williams, M.D.**

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Supplemental Indications Task Group: **Jane A. Axelrad, Jonca C. Bull, Celia A. DeLawter, Chistina L. Good, Joseph P. Griffin, Steven M. Rodin, Robert J. Temple, M.D., Janet Woodcock, M.D.**

Jackie Barber is CDER's awards officer.

CDER's Learning Resource Center Opens Doors at Parklawn

By Janice Newcomb

The Division of Training and Development has opened the CDER Learning Resource Center (LRC). The LRC complements the Center's formal training and development programs by providing self-study instructional materials for CDER staff. Many of these are available as CD-ROMs for multimedia computers, video and audiotapes, as well as books and workbooks. The LRC provides alternative opportunities for learning and can help you zero in on particular skills without the time and expense of a full course.

Located in the Office of Training and Communications at the Parklawn Building, Room 12B-30, the LRC is open from 7:30 a.m. to 4:30 p.m. A small sampling of the extensive list of current topics included in the LRC are:

- Management and Leadership. *Practical Coaching Skills for Managers*, in video, audio and workbook. *Motivating People in Today's Workplace*, also in video, audio, and workbook.
- Teams. *Handbook of Best Practices for Teams* and the *Team Leader's Survival Guide*.
- Computer training. CD-ROM tutorials for various Microsoft products and *Learning the World Wide Web.*
- Communications skill building. *How to Deal with Difficult People*, a video, audio, and workbook set.
- Career Development. *How to Present a Professional Image*, a video and workbook set.
- Interpersonal skills. *Focused Listening Skills*, another video, audio and workbook set.
- Health. *The Mayo Clinic Family Pharmacist*, an interactive CD-ROM.
- Health regulation. HCFA's laws and regulations manuals on CD-ROM.
- Science. A pilot pharmacokinetic and pharmacodynamic multimedia learning program on CD-ROM.

A complete catalog of all materials has been sent to each division. Catalogs are also available in the LRC or by calling **Charlotte Henning** at 301-827-4580.

Most of the materials are available for checkout, including videotapes, audiotapes, books, workbooks and instructional kits. The CD-ROMs currently available cannot be checked out, but can be used on any one of three workstations in the LRC.

Janice Newcomb is the director of the Division of Training and Development.

Drug Approval Reforms Compete for Innovations Award

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competition enters its second decade, the challenge of providing value to citizens remains undiminished," said Professor Alan Altshuler, director of the Innovations program at the Kennedy School. "These semifinalists demonstrate that government can offer highly creative solutions to important public problems."

Four criteria are used to evaluate each application: originality of the approach, effectiveness in addressing important problems, value of services to clients and the potential for replication in other jurisdictions. This summer, 25 finalists will be selected — from among which 10 winners will be chosen. Winners will receive $100,000 awards from the Ford Foundation, and the other finalists will each receive $20,000 awards. The nonprofit Council for Excellence in Government will administered the awards.

FDA's drug review reforms have contributed to the increased number of drugs and biologics approved recently—many in record time. For example, last year the agency approved 63 percent more new drugs and biologics than it had the year before. The agency has also dramatically reduced the time taken to approve drugs and biologics—from a median review time of 20.8 months in 1993 to 14.8 months in 1996.

The major elements of FDA's reform program cited in its application included:

- The Prescription Drug User Fee Act (PDUFA) of 1992, which provided a mechanism allowing the pharmaceutical industry to provide the agency with additional resources for enhancing its drug and biologic review efforts. These resources were tied to performance goals for ensuring timely agency review of new drug applications.
- Accelerated approval of treatments for serious or life-threatening diseases. Under this program, these drugs and biologics may be reviewed and approved on the basis of surrogate endpoints (clinical indications of efficacy) as long as the drug or biologic sponsor commits to postmarketing clinical trials in order to acquire more definitive data.
- The refinement of a ranking system for new drugs based on their potential medical benefit—ensuring that the greatest, most immediate attention is provided to "breakthrough" drugs and biologics for serious conditions.

As the Kennedy School was making its announcement, the Center's Office of Review Management reported on successful accomplishment of a primary PDUFA goal: making the Center an essential "current account" operation.

"The fiscal year '93, '94 and '95 PDUFA submission cohorts are now totally closed," reported **Mac Lumpkin, M.D.,** Deputy Center Director for Review Management. "That means that every original NDA submission, every NDA resubmission, every efficacy supplement, every efficacy supplement resubmission, every manufacturing supplement and every manufacturing supplement resubmission in all three submission cohorts have been acted on. That represents actions on 287 original NDAs, 84 NDA resubmissions, 255 efficacy supplements, 67 efficacy supplement resubmissions, 3,165 manufacturing supplements and 490 manufacturing supplement resubmissions. And that doesn't include clearing out the pre-PDUFA backlog."

The Innovations in American Government program is on the World Wide Web at <http://www.ksg.harvard.edu/innovations>.