news along the pike

Center for Drug Evaluation and Research

March 1998

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Pike's Corners . . .

Innovations Recognition Ceremony

Speakers Highlight FDA's Public Service

"You have a monumental job, and you do it monumentally well," said HHS Secretary Donna Shalala at a recognition ceremony held the evening of March 3 to mark the FDA's Innovations in American Government Award. Last year, the FDA was named one of 10 winners of the prestigious public-service award presented by the Ford Foundation and Harvard's Kennedy School of Government in partnership with the Council for Excellence in Government (October Pike). The award recognized CDER, the Center for Biologics Evaluation and Research and the Office of Regulatory Affairs for management and user fee innovations that cut drug approval times in half while doubling the number of new drugs approved in a year.

More than 800 FDA employees and guests gathered for the three-hour ceremony and reception at Indian Spring Country Club. The recognition ceremony was sponsored by the Ford Foundation and the Council for Excellence in Government.

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Tysons Corner Meeting

ICH Launches Phase 2 of Harmonization

By Roger Williams, M.D.

The International Conference on Harmonization (August Pike) broadened its focus and launched a second phase of activities during a week-long meeting held last month in Tysons Corner, Va. In four days of meetings, the steering committee reconfirmed its commitment to making new pharmaceuticals available to patients with minimum delay. Harmonization aims at improving the efficiency of new drug and biologic development and registration in Europe, Japan and the United States. Among its actions, the committee:

- Received encouraging reports from the expert working groups considering the *Common Technical Document* and decided that consensus is likely by the year 2000.
- Agreed to broaden representation in ICH to appropriate parties because the second phase has implications for marketed drugs, over-the-counter medicines and their

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OHA Roundtable

Woodcock Briefs Health Professional Groups

By Norman Oliver

The second roundtable meeting between Center Director **Janet Woodcock, M.D.,** and 11 health professional associations took place Feb. 20. The roundtables are sponsored by the Office of Health Affairs and moderated by Associate Commissioner for Health Affairs **Stuart L. Nightingale, M.D.** "Last year was a successful and eventful year for the Center," Woodcock reported. "We achieved an extremely good result in approving drugs and expediting new drugs to the American consumers."

Woodcock predicted that the emerging issue for the next decade will be safe use of drugs. For the last 15 years, she said, the issue of getting drugs approved faster masked other issues that consumers have with drug products.

The roundtable also heard presentations from the Center's Division of Drug Marketing, Advertising and Communications. **Nancy Ostrove, Ph.D.,** provided an update on both the cooperative public-private plan to provide consumers with better and easy-to-read information about prescription drugs

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Joe's Notebook

Transformation Inspiration

CDER's transformation has a way of inspiring folks in the most unusual ways. For a summary of how far we've come, check out **Cindy Marks'** story on page 4. **Cathie Schumaker,** a supervisory project manager in the Division of Pulmonary Drug Products, says the transformation has inspired her to begin training for the 350-mile four-day bicycle AIDS Ride. The ride, with 1,400 participants signed up so far, starts June 18 in Raleigh, N.C., and ends June 21 in Washington. Cathie, rider No. 1,034, promises to provide monthly updates on her progress. Right now, she is doing a 40-mile ride once a week as part of her training. She would like to get in touch with other Center employees who might be doing the ride.

She says the inspirational paragraph from the AIDS Ride material reminded her so much of CDER's transformation that she wants to share it with us. Perhaps you, too, will see the similarities.

"The AIDS Ride is about us moving beyond our limits, both as individuals, and as a group. It goes beyond the challenges of training for the Ride. . . . It includes the way we treat one another and interact with one another throughout the year and during the Ride. The Ride is also about moving beyond our past experiences of the way we care about each other and into a context of possibility. It's about the possibility that we can work as a team, in total support of one another—in a way that recognizes that the well-being of the group is as important as the well-being of the individual. . . . The Ride is about responsibility, integrity, and a demonstration that the world can work, if people work together."

Anne Lubischer, a pharmacist at the Portland, Ore., VA Medical Center, called the other day about the story in *February's Pike* on medication errors. She handles the hospital's adverse drug event reporting and investigates medication errors. She wanted to know where she could contribute her "2 cents' worth" to the Agency. The point of contact is **Mary Gross** in the Office of External Affairs at (301) 827-3364. Anne, by the way, would like to see all hospital medications dispensed in individual packs with bar codes.

The *CDER Handbook,* discussed in November's Leadership Fellows Corner, has graduated to the Internet. You can access it from CDER's home page under the About CDER button. You may want to direct outside inquiries about our processes and activities to this user-friendly resource that includes links to appropriate guidances. **John Emelio,** who developed and coordinated the handbook as part of his fellowship, is back with us on the next page.

Mark Your Calendars. On the morning of April 27 at the Gaithersburg Hilton Hotel, CDER will sponsor a half-day conference, "Make the CDER Connection," for its secretaries and support staff who are encouraged to attend. **Devota Herbert** says to watch your e-mail for more information.

Check those Rolodexes. If you need to contact **Roger Williams, M.D.,** our ICH author, **David E. Wardrop, Jr., Justina Molzon, Bill Myers** or **Carol Hall,** the immediate office of the Office of Pharmaceutical Science has moved to Room 6007 in Woodmont II. The phone number is (301) 594-2847.

April 23: Bring Your Children to Work Day

OTCOM's **Jack Pevenstein** is heading a CDER committee to make Bring Your Children to Work Day a fun and educational event for your kids. A special program is being planned from 10 a.m. to noon and will be videoconferenced to Parklawn, Woodmont II, Metro Park North and Corporate Boulevard. Keep an eye out for e-mails and flyers on this event.

news along the pike

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

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

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

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

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Ombudsman's Corner

Expert's Update on Workplace Violence: Know Warning Signs

By Jim Morrison

As a follow-up to last month's column, I thought I would pass along some lessons learned from Dennis Davis, Ph.D. He is the expert on workplace violence who gave an excellent and provocative presentation at the March CDER staff meeting.

Dr. Davis described the three levels or stages of violence. Each level tracks a progression of behavioral changes. Since the nice guy who suddenly snaps and kills people is a myth, it is important to recognize changes in behavior and deal with the warning signs early. These warning signs point to a person who no longer cares about himself (90 percent of workplace violence is committed by men). "If an employee does not care about himself and the consequences of his actions," Dr. Davis said, "you should be concerned for yourself and for others around him."

The first stage may consist of a variety of hostile expressions, including dehumanizing others by name-calling or derogatory comments; challenging authority; being frequently argumentative; alienating others; swearing excessively; using sexually explicit language; and otherwise verbally abusing others. We don't ordinarily think of these as violence, but they can signal future trouble and should be taken seriously

Most such warning signs never escalate into more serious behavior, but supervisors should deal with them promptly and appropriately. Failing to discuss the inappropriate behavior with an employee, however, implicitly condones that behavior and encourages an escalation to more violent behavior. Documenting such behavior is important, Dr. Davis said, not for the individual's personnel file, but for the supervisor's reference should further action be necessary. If the acts are sufficiently serious, the supervisor should bring in experts and inform the second-line manager.

Second-stage behavior typically includes: arguing frequently and intensely; blatantly disregarding organizational policies and procedures; inventing gossip about co-workers or sabotaging their work; committing petty vandalism or theft of the organization's property; making verbal threats or unwanted advances and, more importantly, putting them in writing or e-mail; and blaming others for any problems the individual has at work.

If such behavior is observed by or reliably reported to supervisors, immediate action is essential. Experts should be brought in, and the person should be counseled. The Employee Assistance Program has experts who can advise supervisors on dealing with such situations. They are only a phone call away (3-HELP) and have a trained staff of psychologists who are glad to help and to offer suggestions about how to get troubled employees into counseling. The supervisor and the Employee Assistance Program should not be the only ones informed, however. Confidentiality restrictions prohibit the program's staff from disclosing the problem. Therefore, it's wise to notify others in the supervisory chain and Employee Relations.

The third level of workplace violence is one that no one wants to witness. It consists of displaying weapons, actual acts of physical violence and may include arson, rape, homicide or suicide. In the event of a third-stage incident, Dr. Davis advises that witnesses have three responsibilities: first, get out of harm's way; second, warn others to stay away; and, third, call the authorities.

It is good to have emergency response procedures, but the most effective approach is to practice prevention. That means not hiring people with a history of violent behavior (effectively done reference checks can prevent many different problems), keeping alert to possible warning signs of potential violence, addressing problems early and seeking professional help before a crisis occurs.

Dr. Davis acknowledged that it is often difficult for a supervisor to approach an employee who is behaving oddly on the job or who is becoming aggressive to others. However, the alternative is to ignore the situation and wait for an escalation in violence. A supervisor should avoid confronting the employee in a hostile way. A caring but firm tone in a private conversation will usually be effective in first-stage cases. Resistance to taking advice or orders can be overcome by a supervisor using examples from his or her experience rather than dictating behavior to the employee. If the employee reacts negatively to the supervisor's attempt to address the problem, further action is indicated.

Jim Morrison is the Center's Ombudsman.

Dr. Canchola's Death Mourned

The Division of Gastro-Intestinal and Coagulation Drug products was saddened by the unexpected death of Jose Canchola, M.D., M.P.H., on March 15. At the time of his death, Dr. Canchola was serving as a medical officer in the division. Dr. Canchola joined the government in March 1972. He worked for the Division of Anti-Infective Drug Products from 1974 until 1987 before transferring to the division.

Dr. Canchola was a respected and much loved member of the GI Division, always eager to help his peers, supervisors and the people working with him. He will be genuinely missed by all.

Administrative Management Corner

Admin Guide on CDERnet

By John Emelio

Looking for information on employee benefits? Pay and leave information? Then visit the new Admin Guide on CDER's intranet at: cdernet/admin/admin.htm. The guide was developed by the administrative management team and includes information on human resources, travel, facilities, training, communication, budget and payroll. Comments or ideas for improvement can be sent to the AMT e-mail account.

John Emelio is a management analyst in the Office of Management.

Strategic Planning Corner

Transformation History Predicts Future Success

By Cindy Marx

Have you wondered what happened to the change initiative? No, it hasn't fallen into a black hole. The change initiative, or transformation, is in full operation and picking up speed. The goal of transformation and strategic planning is to improve our relationships with stakeholders and customers and to better serve the American public. So hold on as we review CDER's transformation from its beginning to where we are now.

CDER's transformation began with the welcoming of **Janet Woodcock** as center director in May 1994. Dr. Woodcock recognized CDER as an organization with continuing growth in responsibilities but limited resources. CDER needed to become an adaptable organization capable of responding to future challenges.

In September 1995, Dr. Woodcock formed the "change team," made up of the senior management team and office directors. During 1996, the change team attended go-aways facilitated by the Council for Excellence in Government. Through team-building, open communication and trust, the team developed the Center's mission, vision and operating principles statements.

The mission of CDER is to assure that safe and effective drugs are available to the American people. Our vision is to build a vital community serving the public by making significant improvements in human health through excellence and innovation in drug regulation. Our operating principles are to seek excellence; respect people; practice sound, objective decision-making and scientific evaluation; reinforce integrity and accountability; and communicate, cooperate and collaborate.

The change team came together again in May 1996 to develop four major transformation goals:

- Convert "staff" to "community" united behind our mission, committed to a shared vision and living our operating principles (values).
- Work collaboratively and cooperatively with industry, academia and others to improve the drug development and review process.
- Improve management processes.
- Develop and implement a plan to identify and integrate new information management and technology into all activities.

The CDER leadership fellows and the change team formed four results teams to break down each goal into concrete, achievable projects.

Last summer, the "stretch planning group" was formed by Dr. Woodcock to provide insight and recommendations for the next steps in CDER's transformation. The group of 10 reviewers, project managers and management support people is charged with developing an innovative and inspirational approach to envisioning the CDER of the future and a proposed path to get there. Their work goes beyond the conventions of the organization and should provide conceptualizations of how CDER can transform through developing its people and leaders. The group is in the final stages of writing its report.

In late 1997, the Special Projects Staff, headed by Associate Director for Strategic Planning **Charlene Cherry**, was established to help manage and facilitate CDER's transformation and act as consultants throughout the process of defining our strategic direction. **Susan Carey** and **Cindy Marx** currently make up the rest of the Special Projects Staff (January *Pike*).

Significant transformation contributions are coming from CDER's Office of Training and Communications; the CDER Leadership Fellows Program, which fosters and develops leadership skills of selected fellows; and the CDER Reviewer Career Path, which should provide a professionally satisfying and scientifically meaningful career path for outstanding CDER reviewers.

The true transformation of CDER is a gradual and perpetual process but has already shown evidence of positive changes.

Cindy Marx is a Program Analyst in the Office of Management, Special Projects Staff.

EEO Corner

CDER Women to Share Secrets of Success; Diversity Day Festivities

By Gloria Marquez Sundaresan

In observance of March as Women's History Month, CDER EEO Information Training and Sharing Satellites will conduct a videoconference titled "CDER Women Share their Strategies for Success." This program will take place March 29 in the videoconference rooms (Parklawn Room 13B-37, Corporate S-200 and Woodmont II Conference Room G).

Toy-Ping Taira, Office of Pharmaceutical Science, has arranged for several women in the Center to share their experiences and the pathways that led them to a successful career. There will be a 5- to 15-minute presentation from each panelist followed by a question-and-answer session. The panel session will take place from 10:30 a.m. to 12:30 p.m.

From 12:30 p.m. to 1:30 p.m., a brown bag lunch will feature authors Robin Karr-Morse and Meredith Wiley speaking about their book, *Ghosts from the Nursery*. "Karr-Morse and Wiley emphasize the importance of experiences absorbed during the fetal stage and in the first two years of infancy for brain development," said a review in Publishers Weekly.

Light refreshments will be served after the program.

From March 30 to April 3, the Office of Equal Employment and Civil Rights, the Office of Regulatory Affairs and the Office of Women's Health are co-sponsoring a program for Women's History Month. FDA's display, "Take Time to Care—Use Medicine Wisely," will be set up in the Parklawn cafeteria from

(Continued on page 5)

Reviewer Affairs Corner

Reviewer's Handbook Provides Wide Range of Information

By C. Russ Rutledge

The Reviewer Affairs Committee has written a document that should make life easier for reviewers and others throughout CDER. The *Reviewer's Handbook* is designed to make searching for information a much easier task, especially with questions such as: "Who do I contact?" "What is this group's function?" and "How do I do this?"

The handbook includes information about where to find help for various subjects, giving sources both within and outside CDER and FDA.

The handbook presents descriptions of the type of help various organizations can offer, contacts and phone numbers. There are sections on reviewer's rights and responsibilities, tips for conducting reviews, e-mail etiquette, communication with organizational units, format for memoranda, time management and other topics. Another section explains promotions, the performance evaluation plan and the performance management program.

This document is designed to be a living source of information, with the intent that sections be updated and rewritten as appropriate. Comments for updates are both welcomed and encouraged; the handbook's introduction explains how to submit them. Some sections are currently blank and will be filled in as people with knowledge on the subjects draft these sections and send them to the committee for inclusion. The committee would appreciate any submission of such drafts to help complete this handbook.

Intrigued? See your division's committee representative for a copy of the *Reviewer's Handbook.*

In addition, the handbook may be copied from the X:drive at: X:\coorcomm\rac\subcmte\handbook\revhnd10.f98.

You can view it on CDER's intranet by clicking on the blue text at the beginning of this column.

Russ Rutledge is a consumer safety officer in the Division of Manufacturing and Product Quality.

Project Management Corner

Deadline for Comments on Whitepaper Extended One Month

By Jean Yager

Now circulating within CDER for comments is the draft *Proposal for the Enhancement of Multidisciplinary Team Approach to Review of Submissions,* also known as the project management "whitepaper." Deadline for comments has been extended to the end of April.

The draft document first provides a brief background of team-based project management in CDER and the reasons for further development of this approach. It then proposes how to define and enhance the team-oriented approach to reviews of applications.

This proposal was initially developed to assist our efforts in developing a training program for the Center on team-based project management. This initiative was subsequently broadened to include the entire team approach to the review of submissions to support the Center's goal of improving its management processes. To accomplish this, the team responsibilities for reviewers, supervisors and managers as well as project managers have been described.

An iterative dialogue within the Center should help further delineate team responsibilities for these positions. This document should provide a forum for input. Earlier versions of this document have been reviewed and commented upon by the project management staff and many of the review staff. The current version is still in draft form because additional changes and modifications are anticipated as the Center moves toward a common vision of the team review process.

Until the end of the month you can view a PDF version on CDER's intranet by clicking on the blue text at the beginning of this column in the electronic version of the *Pike.* Please send all comments to **Jody Payne** (PAYNEJ, Woodmont II, Room 6003). If you have any questions or would like to discuss the proposal please contact me by phone (4-5480) or e-mail (YAGERJ).

Jean Yager is the Center's director of project management.

EEO: New Surgeon General to Speak at Diversity Day Celebration

(Continued from page 4)

11:30 a.m. to 1:30 p.m. FDA pharmacists will be on hand to answer questions about using various medications. Written materials in both English and Spanish will be available.

The keynote speaker for the third annual Diversity Day celebration will be newly appointed Surgeon General and Assistant Secretary for Health David Satcher, M.D. CDER will hold this event April 8 in Parklawn conference rooms D and E.

Different groups will participate in cultural exhibits that start at 9 a.m. The opening ceremony begins at 10 a.m., and the event concludes at 3:30 p.m.. The activities are intended to give everyone a treat for their body, mind and spirit. As usual, there will be an international food sampling to nourish the body, speakers who can enlighten the mind, and music, dance, a fashion show and cultural entertainment to uplift and delight the spirit.

Gloria Marquez Sundaresan is an EEO specialist in the Center's EEO Staff.

Information Technology Corner

ICH Works to Ensure Secure Electronic Communications

By Greg Brolund

The International Conference on Harmonization is an enormous science-driven initiative that brings together the regulatory authorities of Europe, Japan and the United States, as well as experts from the pharmaceutical industry in the three regions. ICH (see page 1) aims to curtail regulatory duplication by working toward a common worldwide drug and biologic registration package.

One of the ICH technical working groups is the multidisciplinary group 2, or M-2 expert working group. The M-2 group was established to facilitate international electronic communication by evaluating and recommending electronic standards for the transfer of regulatory information that meets the requirements of pharmaceutical companies and regulatory authorities.

The M-2 expert working group has proposed solutions to diverse international information exchange needs identified by the members of the three ICH regions. Both CDER and the Center for Biologics Evaluation and Research participate on the M-2 expert working group.

M-2 is important to several mission-critical initiatives in CDER:

- First, the Adverse Event Reporting System (April Pike) depends on the M-2 electronic transmission standard for the receipt of secure adverse event reports transmitted over the Internet.
- Second, FDA and U.S. industry representatives to M-2 are working to have the file formats and structure that are defined in industry guidance for electronic regulatory submissions eventually accepted as ICH standards for international use. This is closely related to the effort just begun by ICH to create the *Common Technical Document.*
- Finally, the M-2 expert working group is developing a standard for the exchange of secure electronic mail between regulatory authorities and industry. CDER reviewers frequently need to send and receive electronic mail that contains privileged information and cannot use All-IN-1 or TeamLinks for this purpose without additional encryption software. CDER will soon be conducting a pilot program for secure electronic mail with selected U.S. firms.

A compatible international solution could increase the effectiveness of communication with regulated industry and other regulatory authorities by removing security and artificial barriers to electronic communications. For example, you will be able to send and receive electronic mail with the regulated company with confidence that it has been received.

More information about the M-2 recommendations and activities can be found on the World Wide Web at: http://www.ifpma.org/m2-site/m2-main.html. The address of the ICH site is: http://www.ifpma.org/ich1.html.

Greg Brolund is the associate director for technology and policy in OIT and the ICH M-2 rapporteur.

OIT Offers Free Training for Popular Computer Programs

By Heather Chafin and Tim Mahoney

Have you ever needed to give a presentation with pizzazz but didn't know how to use MS PowerPoint? Does looking into reference manuals send you into a tizzy and make your palms sweat. Do you think to yourself: "There has got to be an easier way to learn software packages?" Well, there is!

The Center has its own customized computer training classes through the Office of Information Technology in coordination with the Office of Training and Communication. Monthly classes are given at no cost.

Each of the software applications offered reflects tools needed to reach the goals outlined in CDER's mission, whether it's in the actual review or administrative support.

These applications allow CDER end-users to use technology to work within the network, create text and table documents, create budgets, track numeric data in the drug review process, create slides and presentations, communicate with others, review electronic forms and navigate within databases used in the review process.

Classes are now being offered for:

- Introduction to MS Windows 95.
- MS Access V7.0.
- MS Excel V7.0.
- MS Powerpoint V7.0.
- MS Powerpoint charts (advanced).
- MS Word V7.0.
- MS Word formatting (advanced).
- TeamLinks.
- Russell Calendar Manager.
- Accessing local area network resources using Windows 95.
- Adobe Acrobat Exchange.
- The Enterprise Administrative Support Environment.

More classes are planned. Class descriptions and schedules can be found on the OIT intranet site: oitweb/oit.

You can also e-mail OIT's training coordinator, **Lana Kostecka,** at KOSTECKAL. Be sure to watch your e-mail to sign up for classes.

Heather Chafin is a computer specialist and Tim Mahoney is a help desk technician in OIT's Technology Services Support Staff.

Implementation Chart for Modernization Act

CDER has the lead on more than three dozen tasks identified by the FDA to implement the Modernization Act of 1997. FDA has posted on its Website a chart detailing the tasks at: http://www.fda.gov/po/modact97.html. The chart lists tasks, a description of the initiative, any deadline listed in the statute for the initiative and the name of the contact person at the FDA.

PQRI Corner

Collaborative Research Concept Has Favorable Debut

By Karl Flora, Ph.D., and Ajaz Hussain, Ph.D.

More than 150 representatives form the drug industry, academia and CDER expressed strong support for the Product Quality Research Initiative (December Pike) at its initial meeting held February 10 and 11. The exchange of information indicates this collaboration concept has potential for success. In finalizing the concept, the Center is nearing completion of arrangements with the American Association of Pharmaceutical Scientists to establish an independent and neutral body for administration of PQRI programs and projects.

In the opening session of the day and half meeting, **Roger Williams, M.D.,** Deputy Center Director (Pharmaceutical Science) and other speakers representing both industry and academia outlined the purpose of PQRI. They spoke about the mutual advantages of collaborating on product quality research projects. All agree that research is defined broadly to include data mining, public workshops and literature reviews as well as traditional laboratory research.

The organizational structure of the International Conference on Harmonization serves as the model for PQRI's structure —a steering committee, technical committees and working groups.

Alice Till of the Generic Pharmaceutical Industry Association and Thomas White of the Pharmaceutical Research and Manufacturers of America presented the industry perspective. Industry has had little role in setting research priorities in the past, Till said. "The time has come to tangle with the details," she said. "The overall process must be driven by demonstrated need and less by technological advances." Her criteria for evaluating potential projects included the amount of the projected regulatory relief, cost vs. benefit, breadth of applicability and balance of short- and long-term studies.

White endorsed many of Till's comments. He said any research projects would need well-defined scope, mission, objectives and outcomes. He also said that there would need to be agreement on issues of management, supervision and priority setting.

Gordon Amidon, a professor of pharmaceutics at the University of Michigan College of Pharmacy and current president of the American Association of Pharmaceutical Scientists, stressed the need to promote product quality research and the importance of that research to the academic sector.

Ajaz Hussain, Hank Malinowski and **Thomas Layloff** presented talks on previous CDER scientific research projects that have had a significant impact on enhancing regulatory policy. Conference participants agreed that the formulation and drafting of policy, usually in the form of guidances to industry, are FDA functions.

Eric Sheinin and **Vinod Shah,** representing, the Chemistry, Manufacturing, and Controls Coordinating Committee and the Biopharmaceutics Coordinating Committee, respectively, discussed the interaction of these committees with PQRI in formulating Center policy.

Technical committee breakout sessions allowed participants to formulate a workable hypothesis for overall research, address and expand on proposed projects, and suggest additional projects. The four technical committees for drug product, drug substance, biopharmaceutics, and science management will be providing separate updates in future *Pike* articles.

The public meeting affirmed that the Center has helped create a viable concept and structure for collaborative product quality research.

Karl Flora and Ajaz Hussain are the director and deputy director, respectively, of the Division of Product Quality Research.

'New Horizons'

8 Secretaries Complete Professional Development Program

By Sarah Thomas

One year ago, CDER's Division of Training and Development announced "New Horizons," a three-year professional development program for secretaries and support staff. In the program's first year, 47 support staff employees signed up to participate in the program. Eight members of this group have already completed their courses and received a certificate of graduation at a special ceremony last month.

The graduates were **Katrina Garry, Susan Hammonds, Karen Konkolewski, Marilyn Leach, Patti Morningstar, Christine Shipe, Loretta Slaybaugh** and **Patrice Wilson**.

As part of the graduation, an orientation for prospective new members was held. For those who missed this opportunity to hear more about the program, it is open to CDER's career and career-conditional full-time permanent secretaries and support staff in grades GS-1 through 9. The career development program requires an individual development plan and completion of eight courses over a three-year period with minimal cost, if any, to your office or division.

The courses cover four core areas: communications, skill building, career transition and computer skills. A certificate will be issued to those who successfully complete the required training. Either you or your supervisor may nominate you for participation.

The Division of Training and Development is happy to report that this program has been received with enthusiasm. If you have questions about the program or would like to sign up, call: **Sarah Thomas** (7-3491), **Dee Rhodes** (7-1261), **Iris Khalaf** (7-3493) or **Charlotte Henning** (7-3494).

Sarah Thomas is an education specialist in the Division of Training and Development.

Health Professional Groups Receive Briefing on CDER Issues

(Continued from page 1)

(February 1997 *Pike*) and the Center's guidance on direct-to-consumer advertising (August *Pike*). **Laurie Burke** outlined the Center's new draft guidance on promotional activities by pharmacy benefits management companies (January *Pike*). Finally, Dr. Woodcock reported on the FDA Modernization Act (December *Pike*), the task forces identified to implement it (http://www.fda.gov/po/modact97.html) and the performance goals under the PDUFA reauthorization (January *Pike*).

In her introductory remarks, Dr. Woodcock highlighted the FDA's winning of the Ford Foundation's Innovations in American Government Award for its management and user fee innovations in the drug approval process (October *Pike*). She pointed out that the Center continues to decrease review times under the user fee program and met all its six-month deadlines for priority drugs (February *Pike*). Streamlining initiatives resulted in improved generic approval times despite a lack of user fees and cuts in the generic program's staff (February *Pike*).

Dr. Woodcock reported on the Center's progress toward building a world-class drug safety surveillance system called the Adverse Event Reporting System (April *Pike*). In addition to a revitalized program and new regulations, the system employs harmonized terminology and a common coding system in the three regions covered by the International Conference on Harmonization (August *Pike*).

The private sector's progress in efforts to distribute written patient information with 75 percent of prescriptions by the year 2000 will be evaluated by the FDA, Ostrove reported. "The FDA has surveyed quantity," she said. "It's up, but we haven't looked at quality. Some are wrong. Our plan is to survey pharmacies to collect information about prescriptions, then evaluate the usefulness of that information."

Participants responded that it will be a challenge to make the information useful. Many drugs have multiple indications, but in most cases the physician doesn't write the intended use on the prescription. The result is a bland and generic patient information sheet.

They also expressed a concern that the professional labeling, also know as the package insert, is frequently difficult to obtain and once found almost impossible to read. "We are working on getting all the inserts on the Internet," Dr. Woodcock replied in describing the Center's effort to improve dissemination of drug information.

Other issues discussed included:

- *Direct-to-consumer advertising.* Participants recognized the potential value of informing patients about treatment options. They were concerned, however, that marketing forces could lead to unnecessary product switches, potential adverse events and a breakdown in candid communications between pharmacists and physicians. Burke reported that CDER and the FDA are still requesting health care professionals provide MedWatch reports of adverse events associated with therapeutic switching (May *Pike*).
- *Advertising directed to physicians.* Woodcock and Ostrove said the Center is seeking input from the professional associations on the usefulness of the so-called "brief summary." Although the brief summary is described vaguely in the law, FDA regulations specify that it must include each specific side effect and contraindication. As a consequence, drug companies most commonly print all the warnings and precautions directly from the approved labeling. "Over the last several years we have heard that all the risk information is not useful," Ostrove said. Dr. Woodcock, echoing the comments of some participants representing subspecialties, pointed to the possibility of allowing risk information to be targeted depending on the audience of the journal in which the ad appears.
- *Professional labeling.* "We've received a lot of negative comment on package inserts from physicians," Dr. Woodcock said. CDER could use more feedback as it is working on a way to format professional labeling so it is more useful, Ostrove said.
- *The FDA Modernization Act.* "There is a huge portfolio of things to do," Dr. Woodcock reported. "Everyone wants input into how we do things." She and Dr. Nightingale urged the associations to provide comments to the FDA points of contact identified in the task force chart (see page 6).
- *PDUFA reauthorization.* The goals cut review times for standard drugs to 10 months. The more important savings in drug development time will come from the requirements for meetings with industry that will have the Center delineate endpoints and sample size, Dr. Woodcock said.
- *Formulary workshop.* Burke reported that the FDA is working with the Health Care Financing Administration and the Agency for Health Care Policy Research to sponsor a public workshop that would issue a consensus statement on what constitutes a high-quality formulary. It would identify a minimum formulary for disease groups and initially focus on those covered by Medicare. This topic developed out of last year's roundtable where it was identified as a very high priority concern and suitable for a workshop.
- *Emergency communications.* Participants enthusiastically endorsed OHA's program to set up conference calls between CDER's experts and professional groups on important FDA public health announcements just as they are becoming public, such as the withdrawal of fenfluramine and dexfenfluramine (September *Pike*).

Health professional organizations with representatives at the roundtable were: American Academy of Nurse Practitioners, American Academy of Pediatrics, American College of Obstetrics & Gynecology, American College of Physicians, American Medical Association, American Nurses Association, American Pharmaceutical Association, American Society for Clinical Pharmacology and Therapeutics, American Society of Health-System Pharmacists, National Association of Boards of Pharmacy and National Committee for Quality Assurance.

ICH Launches Phase 2 of Harmonization at Tysons Corner

(Continued from page 1)

generic equivalents.

- Outlined a process to preserve the future of harmonization by updating and supplementing guidances when necessary and monitoring their use.
- Established working methods for the Phase 2 harmonization of new technical requirements that result from scientific progress and innovative developments in drug research.
- Finalized two clinical guidances.
- Decided to develop a new guidance and consult two more for future work.

The expert working groups for the *Common Technical Document* met for the first time at Tysons Corner. The working groups are considering efficacy (human clinical trials), safety (animal pharmacology and toxicology) and quality (manufacturing). Their objective is to reach agreement on an information package of technical data, in the same format and with the same content, that would be submitted for registering new drugs and biologics in all three ICH regions.

Participants realized that the second phase needs to widen its consensus building discussions among experts to include other "appropriate and interested parties." The steering committee also agreed to arrangements with the World Health Organization and its regional offices to facilitate information exchange about harmonization activities that have a wider global impact.

Once guidances are finalized by the steering committee, the regulatory bodies in each region complete the process by incorporating the guidances into their regulatory mechanisms. In the United States, the FDA publishes the full text of the draft in the *Federal Register* for comment. After public comments are considered and appropriate revisions made, FDA publishes a notice with the full text of the guidance in the *Federal Register*.

Guidances finalized at the Tysons Corner meeting were:

- *Ethnic Factors in the Acceptability of Foreign Clinical Data.* This guidance shows how to overcome the impact that ethnic factors may have on the efficacy and safety of a new medicine when used in different populations. When implemented in conjunction with other ICH clinical guidances, it will minimize the need to perform duplicate clinical studies and enhance the worldwide availability of medicines while ensuring adequate safeguards are met.
- *Statistical Principles for Clinical Trials.* This will harmonize the design, conduct, analysis and evaluation of clinical trials to achieve statistically valid results. With improved design, duplicate studies can be further minimized while the development and global registration process is made more efficient.

The steering committee took account of other important initiatives already underway and recommended that work start immediately on:

- *Good Manufacturing Practices for Pharmaceutical Active Ingredients.* ICH commitment to this project should expedite the development of a single international set of principles that can be implemented globally and provide greater assurance of the quality of the active ingredients used to manufacture medicinal products.

Other guidances under consideration for future work are: *The Conduct of Clinical Trials in Children* and a review of *Stability Testing for New Drug Substances and New Products.*

Once guidances are published in the *Federal Register*, they can be found on CDER's Web site, http://www.fda.gov/cder/guidance/index.htm. More information can be found on the ICH Web site, http://www.ifpma.org/ich1.html.

CDER representatives at the meetings in Tysons Corner were: **Greg Brolund, Melissa Chapman, Yuan Yuan Chiu, Joe DeGeorge, Stephanie Gray, Jaime Henriquez, Charles Hoiberg, Murray Lumpkin, Jim MacGregor, Justina Molzon, William Myers, Andrea Neal, Robert Nelson, Robert O'Neill, Robert Osterberg, Nancy Sager, Norman Schmuff, Eric Sheinin, Robert Temple, Ubrani V. Venkataram, Roger Williams, Steve Wilson,** and **Janet Woodcock.**

Roger Williams, M.D., is the Deputy Center Director (Pharmaceutical Science) and is the FDA's lead delegate to the ICH steering committee. As Deputy Center Director, he is responsible for CDER's international activities.

CDER Agreement to Make Toxicity Prediction Software Available

By Edwin Matthews, Ph.D., and Joseph F. Contrera, Ph.D.

The Office of Testing and Research has entered into a cooperative research and development agreement to enhance a commercial artificial intelligence software package to improve its ability to predict the potential toxicity of drugs.

This effort is currently focused on improving the prediction of the potential carcinogenicity and the reproductive and developmental toxicity of drugs. The Office of Women's Health, which provided partial funding for the project, is interested in evaluating predictive toxicology software to provide supplemental regulatory decision support on the inclusion of women of child-bearing age in Phase I clinical trials when the results of preclinical toxicity studies are not yet available.

Another potential CDER application is to support regulatory decisions on further toxicity testing when new contaminants or degradants are discovered in drugs. In addition to toxicology prediction applications, the software can be used to rapidly identify drugs that are structurally similar. This can be useful to CDER reviewers for relating the toxicity profile of a new drug to structurally similar agents in FDA files. The OTR-enhanced software significantly outperforms standard software in validation studies. How OTR's enhancements achieved this result will be the subject of an article in next month's *Pike.*

Edwin Matthews is a toxicologist and Joseph Contrera is the assistant director for regulatory research in the Office of Testing and Research.

Innovations Award Speakers Highlight FDA's Public Service

(Continued from page 1)

"You show what government can do when we are allowed to do it right," Shalala emphasized. "You have one of those jobs that gets noticed only when things go wrong. In 1992, you were given the monumental task of streamlining the drug review process without sacrificing the public health. You did it with the simplest of ideas—companies pay user fees and you hired more scientists to conduct the reviews."

A joint service honor guard presented the colors. The band Street Life, led by **Glenn Scimonelli**, who also works in the Center for Devices and Radiological Health, played the national anthem and provided entertainment.

Robert H. Seevers, Ph.D., a CDER senior leadership fellow, gave the welcome and introduced the master of ceremonies, Patricia McGinnis, president and CEO of the Council for Excellence in Government. The council administers the $100,000 Ford Foundation grant, which is to be used primarily to promote the replication of FDA's innovations in other government agencies.

Other speakers were:

- David Gergen, editor-at-large of *U.S. News and World Report,* and chair of the award selection committee.
- Morley Winograd, senior policy advisor to Vice President Al Gore and director of the National Partnership for Reinventing Government.
- **Michael Friedman, M.D.,** FDA's Lead Deputy Commissioner.

"Your work helps raise public confidence in government," McGinnis said. "After decades of steady decline, confidence in government is going up." She said that the council's research shows that the public would have more optimism in government if other agencies could act as the FDA has on drug review reform.

Gergen reported that the national selection committee was "swept away" by the FDA's presentation. He said the Agency's effort to cooperate with "many reluctant partners" was one of the keys to its winning performance.

Winograd presented the FDA's 61st Hammer Award to CDER's Office of Compliance export certificate program (see below). The Innovations and the Hammer awards "prove that reinvention is more than rhetoric and contributes to people's lives," he said.

Dr. Friedman concluded with the observation that past successes are the prelude to heightened expectations for future performance. He expressed confidence in the commitment, scientific excellence and ability of FDA's employees to deal with the many new challenges facing the Agency, including the increasing number of products to be reviewed as well as new responsibilities in tobacco and food safety.

CDER's **Carol Assouad** and **Elaine Frost** were co-chairs of the Innovations Recognition Committee that made the arrangements for the ceremony. CDER members of the committee were: **Timothy Ames, Celeste Bové, Nancy Haggard, Lisa Kammerman, Chin Koerner, Pat Leonard, Corrine Moody, Lana Pauls** and **Steve Wilson.** Also on the committee were: **Mary Meyer, Marsha Pincus** and **Gail Sherman,** CBER; **Carrie Smith-Hanley,** Office of the Commissioner; and **Audrey Borja, Marie Urban** and **Paul Wiener,** ORA.

Photos can be viewed on CDER's intranet at: http://cdernet/innov_celebration/index.htm.

—Norman Oliver

Office of Compliance's Export Certificate Team Wins Hammer

By Edward Miracco

After much dedication and hard work the Certificates to Foreign Governments Team in the Office of Compliance's Division of Labeling and Nonprescription Drug Compliance has won the coveted Hammer Award.

Kudos to **Roxana Fay, Jim Hamilton, Lavonia Huff, Jackie Leung, Jocelyn Lewis, Mary Thompson, Bradford Williams** and **Marilyn Wolf,** the winners of the Hammer Award.

This award comes from Vice President Al Gore's National Partnership for Reinventing Government, formerly known as the National Performance Review. It was approved for the Cert Team's extensive reinvention of the issuance of drug export certificates. The award was presented March 3 during the Innovations in American Government Award recognition ceremony. The certs, as they are called by those who work with them, are required by many foreign governments as a mechanism for assuring that U.S. drug products exported to their countries are manufactured by a facility that complies with current drug good manufacturing practices.

The Cert Team processes more than 4,000 certificates each year. This process consists of a time-consuming array of steps which culminate in the issuance of an official U.S. Government and FDA document bearing the HHS gold seal. It used to cause a significant backlog of requests. The backlog reached as high as 2,600 in July 1996. However, by changing much of the processing and significantly improving efficiency, the Cert Team completely eliminated the backlog. Now processing of an export certificate takes a maximum of 20 calendar days with most taking far less time.

The streamlined processing allows U.S. drug manufacturers to obtain their certificates much more quickly. This expands trade, fosters the sale and export of greater quantities of U.S. manufactured drug products and permits foreign countries to obtain pharmaceutical products they may desperately need for the treatment of their populations.

Edward Miracco is a consumer safety officer in the Office of Compliance.