news along the pike

July 1997

Center for Drug Evaluation and Research

Volume 3, Issue 7

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Pike's Corners . . .

For Remainder of FY 1997

CDER Establishes Hiring Controls

By Janet Woodcock, M.D.

A number of issues remain unresolved regarding the status of the FDA budget for fiscal year (FY) 1998.

The prospects for, and composition of, a re-authorized Prescription Drug User Fee Act (PDUFA) program continue to be under discussion; FDA reform remains a major issue with Congress; and the degree to which FDA will have to absorb Governmentwide streamlining reductions is currently unknown. For all these reasons, it is important that CDER remain within our full-time equivalent (FTE) ceilings and budget for the remainder of FY 1997, and be in a position as FY 1998 begins to have some flexibility in the recruitment and staffing of key Center positions.

We have had a very successful recruitment effort this year, filling more than 149 positions from outside of CDER to date. In addition, we currently have 92 more positions scheduled to be filled before the end of the fiscal year. However, with our exact FY 1998 final ceiling unknown at this time, we are perilously close to exceeding the probable CDER FTE ceiling for next year.

According to a June 19 electonic mail message, the CDER Senior Management Team decided that CDER should implement a hiring control process to allow us to continue to

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Drug Information Association Annual Meeting

CDER Speakers, Exhibit Highlight Event

By Mary Lambert

The 33rd Annual Meeting of the Drug Information Association was held in Montreal June 22-26 with the theme "Optimizing Pharmaceutical Development: The Global Experience."

This year's conference offered numerous tracks and scientific sessions, over 400 exhibits, tutorials, poster displays, and networking opportunities for participants.

"As a first-time attendee and presenter at the Drug Information Association conference, I was impressed with the insights I gained in one particular session regarding the regulatory process for INDs (investigational new drug applications)," said Dr. Cynthia McCormick, new director for the Division of Anesthetics, Critical Care and Addiction Drug Products and a 1997 CDER Leadership Fellow.

"I also gained more insights into the complexity of the process for reporting adverse events," she said. "The conference was great and so was Montreal."

Approximately 4,000 individuals registered this year. CDER participation was highlighted by numerous presentations and a joint FDA/ CDER exhibit booth.

Participants could attend sessions in many subject areas such as: safety; government inspections for good clinical practice compliance; public policy; regulatory affairs; clinical trials and other issues in drug development; medical communications; project management; systems/data management; information transfer; document management; biotechnology; epidemiology; legal and statistical issues; marketing/advertising; toxicology; good clinical practices; patient information; contract research organization; environmental assessment; emerging and re-

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Pike Editorial

Responsibility, Leadership Add Up To Astounding Results

The proverbial "light bulb" went on for me the other day. I had the opportunity to hear Kenneth J. Buck, acting director for the Department of Commerce's Division of Acquisition Management and Procurement, speak energetically and enthusiastically on a topic that, for some, might be considered boring. Buck brought life to his half-an-hour talk on leadership; what it takes to be a leader in today's Federal government; and how the most effective leaders are dedicated professionals who *believe* in themselves and their organizations.

While I doubt that he ever mentioned the word, I came away with the strong understanding that he felt personally "responsible" for the success of his organization.

Responsibility. That's a big word, and often one that's hard for many of us to accept. Sure, we all accept responsibility for our friends and families and for our own well-being.

But how many of us take full responsibility for the success or failure of the organization to which we belong? To me, responsibility means I am accountable not only for my family and my actions but for the success of the organization for which I work as well. Looking back on my career, I'm ashamed to admit that there have been times when I was one of the complainers; complaining about my superiors and what they've *done* to me—they didn't give me the promotion I deserve; they expect too much from me, after all I'm only one person. And how about this: "That's not my responsibility."

The light bulb flashed on. After hearing Buck, I realized that one important aspect of leadership is accepting responsibility for ourselves and for our organization. Just look at CDER. Over the years, *many people* have taken responsibility for this Center, and the result is that CDER has been recognized the world over for its professionalism and expertise in performing drug reviews. That's why we have teams of individuals traveling to Jordan to present seminars on generic drugs (see story, page 9). Jordan's government and private sector organizations want to know how we do what we do. And that's why we have CDER seminar speakers who compare drug approvals across nine major countries and claim that the United States is a leader around the world.

CDER has been acknowledged for making great strides in further improving this nation's drug regulatory system because many people are taking responsibility. If you need more examples, simply look to the many articles in this month's issue of the *Pike*. Read about: the Center's new electronic Establishment Evaluation System becoming operational; CDER, in collaboration with the prestigious Mayo Clinic, identifying heart problems associated with the off-label use of the two diet drugs phentermine and fenfluramin; team building efforts underway by the Center's Administrative Management Coordinating Committee; and the Division of Training and Development's core competencies initiative that, when completed, will help you do your job better.

Many individuals have taken personal responsibility for the success of these programs and initiatives. But how much more would be possible if each and every one of us took even more individual responsibility for the success of our offices, divisions, or teams? The result could be astounding.

—Kevin Ropp

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

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Ombudsman's Corner

There's No Substitute For A Caring Manager

By Jim Morrison

In my annual feedback column last October, I commented that over half of all internal complaints related to poor personnel management practices. Now, we all know about the decades of oppressive and sometimes dumb personnel rules and regulations that left government managers chafing and new hires perplexed. But that is not what I was referring to when I wrote about poor personnel management practices. I meant practices that individual managers in CDER chose to use to manage their people and their work.

Has anything changed in the eight months since that column? Well, with a new office structure for information systems management, a new review division created, departure of some managers and reshuffling of others, there has certainly been a change in the landscape. In addition, managers at all levels have been given a new tool for self-evaluation: the 360-degree assessments that we all completed recently. In that process, CDER managers and supervisors received feedback from their subordinates, peers and supervisor on a wide range of management performance factors. Information was also provided about where each of us stood with respect to norms established by thousands of other managers. In general, we fared well in most areas compared with a government norm. However, just being better than average is not where we should want to be.

I wish I could report that internal complaints have dropped off and that a new era in management brilliance has swept CDER to new heights of productivity and élan. Alas, I cannot. If anything, I am hearing reports that there are areas in CDER with significant morale problems. And while we continue to improve our Prescription Drug User Fee Act (PDUFA) performance, there are signs of increased stress.

As we gear up to implement whatever changes will come with the PDUFA reauthorization and its companion FDA reform legislation, it is essential that we make sure that we are most effectively using the resources we have. Our most valuable resource is people. We have been fortunate that the PDUFA increase in CDER staffing coincided with a weak job market that allowed us to recruit some really talented individuals. As demands on us increase, we cannot afford to squander the time and talents of our people. But that is exactly what we do when we fail to ensure that we have matched the right jobs to the right people. It is also what we do when we distract staff from their work by employing ill-conceived management practices.

We in CDER care almost universally about our public health mission, about consumer protection, and about our work. This caring attitude is one factor that binds us together and makes CDER a great place to work. However, we sometimes get so busy with the technical aspects of our work that we forget to care enough about our customers closest to home—the people with whom we work daily. In supervisors, this neglect often takes the form of the "thank you" not said or the constructive feedback not given, but we can improve this situation.

The 360-degree assessments provide valuable feedback to supervisors and managers. It's been a few months since we formally reviewed those assessments. We need to take them out again and look at how we were perceived in areas such as giving information, feedback, and appreciation to our staffs. In addition, we need to ask ourselves how effectively we communicate both positive and negative aspects of our staffs' performance. However much feedback our staffs think we give, if it is not honestly or effectively given, it misses the mark. We need to set specific managerial goals for ourselves, such as giving each person we supervise feedback every week or taking time to improve our own management skills. Above all, if we as managers do not create an environment of respect for all staff members, problems will surely occur.

If you sense that the climate in your work environment is strained, you may want to discuss it with someone you trust. There are many solutions to personnel problems, but the earlier they are identified and addressed, the more likely a successful outcome. If you want to discuss personnel issues, my door is always open, not only to employees with complaints, but also to managers seeking solutions.

Jim Morrison is CDER's Ombudsman.

CDER Establishes Hiring Controls

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recruit for key vacancies this year and to provide for a certain level of comfort going into FY 1998. For this reason, I am immediately instituting a Center Director's level of approval for any CDER personnel action that adds to the on-board number of any CDER office. This process will remain in effect for the remainder of this fiscal year and possibly into FY 1998, depending on the resolution of the CDER budget and ceiling. For the status of personnel actions already in process and for the details on the new approval process, please contact the management official appropriate for your organization:

ORM	-	**Bill Oswald**
OPS	-	**Helen Winkle**
OC	-	**Anita Harell**
OTCOM	-	**Linda Brophy**
OCD	-	**Tanya Abbott**
OIT	-	**Anne Rubino**
OM	-	**Ellen Johnsey**

As soon as we have information about our budget situation for next year, I will adjust FTE ceilings accordingly. Even under the best-case scenario, we will likely need to take FTE reductions; however, I do not expect this to severely impact upon our programs. I will keep you posted on the status of our budget and the PDUFA discussions.

Janet Woodcock, M.D., is Director of the Center for Drug Evaluation and Research.

Establishment Evaluation System Is Operational

By Janet Woodcock, M.D.

EES is no longer a pilot; EES is real!

The Establishment Evaluation System (EES), an Oracle client/server application designed to support the Agency's pre-approval inspection program, is up and running in CDER. The development team has completed virtually all of the installations of the system and training of system users within CDER.

EES is the computer tool that CDER uses to request, track and act on pre-approval inspections. At this time, we would like to declare CDER a paperless environment in the inspection request area. As of June 30, paper establishment evaluation requests are no longer accepted by the Office of Compliance, Division of Manufacturing and Product Quality. Facility information will be communicated from the review divisions via EES. Communications with field offices about the status and need for inspections of these sites will be primarily transmitted electronically via EES. Collateral source documentation, such as establishment inspection reports and Form 483s, will continue to flow as before.

The driving force for the EES system was the need to find a better way to communicate information necessary to the drug approval process, specifically inspections, requests, and results. EES replaces CDER's computerized tracking system, which was installed in the early 1990's and provides enhanced capabilities to work with inspection requests. EES provides for connections with field offices for data transfer and includes improvements in communications, tracking, data transmittal, and trend analysis for inspections. Users of the system include: chemists, project managers and consumer safety officers within the Office of Review Management in CDER's Office of Pharmaceutical Sciences; and compliance officers in CDER's Office of Compliance.

The completion of the CDER component represents a major milestone for the EES system; the system will be fully operational when the remainder of the Agency's district offices are brought online. Currently, 14 of 23 district offices and resident posts are connected, with the remainder scheduled to be completed by the end of the summer.

Potential future uses of this system are numerous and include the possibility of providing industry access to progress on their applications via an electronic bulletin board summarizing their firm's inspections in EES. Other possibilities include use by other centers (such as the Center for Veterinary Medicine) that use the same manufacturing facilities, and use by import officers in evaluating drug products flowing into the United States.

The implementation of EES represents a significant step toward an integrated electronic review environment in CDER, which is one of my highest priorities. Congratulations to all who have contributed to this important effort.

Janet Woodcock, M.D., is Director of the Center for Drug Evaluation and Research.

Administrative Management Corner:

Retreat Works To Build Administrative Management Team

By Charlene Cherry

The Administrative Retreat held June 11 and 12, was a resounding success! Over 70 management officers and program specialists attended the retreat at the Rockville Civic Center, which provided a serene backdrop that allowed everyone to roam, mingle, relax, get acquainted, and have fun. The true concept of the "Administrative Management Team" (AMT) has begun to take shape.

Participants representing the Division of Management Services, and the Division of Planning, Evaluation and Resource Management also attended, providing a well-rounded forum representing all areas and perspectives of CDER administrative management.

Many changes have been enthusiastically reported and more are anticipated as a result of the insights gained at the retreat. A more friendly and collegial atmosphere and an improved communications network has emerged among AMT members. A draft vision for AMT includes the words: professional, proactive, quality, cooperation, trust, pride, respect, flexible, positive, and creative. AMT's vision demonstrates members' drive and determination to provide the Center with top-notch administrative support.

Over 70 CDER management officers and program specialists attended the Administrative Retreat, June 11-12 at the Rockville Civic Center.

The first day of the retreat focused on getting to know each other. Results of the Myers-Briggs Type Indicator (MBTI) were discussed. Martha Spice and Alan Gilberg

(Continued on page 5)

CDER's Newest Office Focuses on Information Technology Services and Planning

By David Isom

CDER has formed the Office of Information Technology (OIT) to provide a more focused approach to CDERwide information technology (IT) support, services, investment planning, and strategic planning.

In addition to maintaining basic IT support and services, the office has two primary responsibilities. The first is to provide CDER with centralized IT investment and strategic planning to maximize CDER's efforts to move toward an electronic regulatory submission and review (ERSR) environment. The second is to bring CDER into compliance with the Information Technology Management Reform Act of 1996 (ITMRA). Elements of the ERSR are part of CDER's National Performance Review, Government Performance and Results Act, and Prescription Drug User Fee Act 2002 goals. ITMRA requires prioritizing IT funding to balance potential benefits against costs and risks, and aligning strategic goals with proposed IT investments. Since ITMRA and CDER's IT goals have enhanced the visibility of information technology, these efforts must complement each other to give CDER the maximum opportunity for success. OIT will be putting processes in place by the end of this fiscal year to meet these planning and resource management requirements.

The OIT organization reports directly to the Center Director and includes several new components along with elements of the former divisions of Information Systems Design and Database Management.

OIT's immediate office includes an IT Strategic Planning Coordinator, a Technology Support Services Staff, and a Quality Assurance Staff. OIT also has three divisions that are focused on management of the IT infrastructure, applications development, and CDER-wide data management.

Immediate Office

The IT Strategic Planning Coordinator is **Pat Sporn**. Pat is responsible for coordinating CDER's IT strategic planning and performance monitoring. Pat will also help OIT coordinate a CDERwide technical working group to work on the description, use, configuration management, and support policies of CDER's Enterprise Computing Environment. For significant IT projects managed outside of OIT, Pat will provide guidance on ways to develop adequate documentation and reporting to help CDER balance potential benefits against costs and risks, and to ensure alignment with strategic goals.

The Technology Support Services Staff is led by **Dave Moss**. This staff coordinates several cross-cutting services for CDER such as IT training, Help Desk support, equipment loans, procurement,

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AMCC Retreat Works to Build Administrative Management Team

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of Growth Dynamics facilitated the retreat. Alan provided a lively interpretation of the MBTI and how it related to our results. AMT members can now better appreciate and respect the differences in each other and those they service.

The second day of the retreat focused on identifying ways to better support each other. Ideas centered around resources, sharing what we know, interpersonal communications, respect, process streamlining, opportunities for interaction, role clarification, and leadership. The results of a customer service survey, conducted just prior to the retreat, were shared with the group. Many participants were pleasantly surprised at the level of satisfaction and support expressed by their customers, but agreed that the data would be very useful to further improve service.

Retreat participants received a certificate and commemorative mug inscribed as follows: "CDER Administrative Management Team . . . Supporting CDER's Mission." The team now faces the challenge of fulfilling their vision. The success of this shared vision is dependent upon the commitment of each team member. If the enthusiasm generated at the retreat continues, there is no doubt that AMT will succeed! Your support and encouragement of the Administrative Management Team will ensure our success.

Charlene Cherry is Executive Secretary to the Administrative Management Coordinating Committee (AMCC), and Chief of the Management Analysis Branch in the Division of Planning, Evaluation and Resource Management.

AMCC—Let Us Hear From You

The AMCC would like to hear from you. Communicate with us via e-mail. Provide us with your comments, suggestions or ideas on how the AMCC can facilitate providing quality support to the CDER community. Simply address your e-mails to—AMT. *(Please refer individual administrative problems to your management officer or program specialist).*

And coming soon—AMCC on CDERnet! Look for information and updates on AMCC activities on the Office of Management Home page.

CDER's New Office of Information Technology

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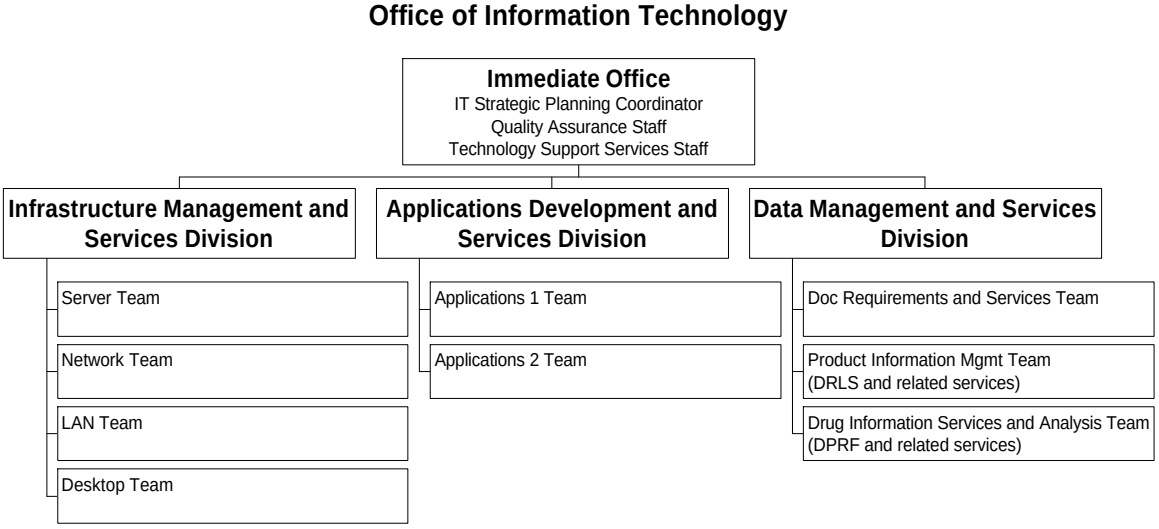
surplus, and OIT's pending Intranet Home Page. This staff is working with the Office of Training and Communications (OTCOM) to integrate IT training into CDER's overall training program. This staff also includes an Electronic Submissions Coordinator to write electronic submission technical guidances (per Electronic Signature Rule) and serve as the technical liaison for CDER's computer-assisted new drug application program. OIT will soon form a CDER Electronic Submissions Guidance Technical Working Group to address the technical details related to the Center's electronic submission efforts.



The Quality Assurance (QA) staff is led by **Judy McIntyre**. This staff is responsible for quality assurance of CDER's core information systems during their development life cycle and production. The QA staff will ensure optimal performance and availability of core databases and develop, review, and maintain CDER's database nomenclature standards. This staff will also put processes in place to provide those who develop and maintain local databases with the information needed to coordinate data with core databases.

Divisions

The Division of Infrastructure Management and Services is led by **Mike Buster** (Acting Director). This division is responsible for the availability, reliability, and performance of CDER's computing infrastructure. This includes network services, local area network services, server management, and desktop support. In FY '98, this division will start moving CDER into the New Technology (NT) networking environment as defined in the Agency's Information Systems Architecture. With the rise in departmental NT servers, this division will soon coordinate regular CDER NT administrator meetings to ensure these administrators are an integrated part of CDER's Enterprise Computing Environment.

The Division of Applications Development and Services is led by **Greg Brolund** (Acting Director). This division is responsible for the analysis, design, development, implementation, and maintenance of CDER's core database applications. This division will soon have standard reporting procedures for new and ongoing projects including project timelines and progress summaries. They will also provide a mechanism to assist users in defining a project plan and expectations document for proposed projects.

The Division of Data Management and Services is led by **Greg Warzala**. This division provides CDER's data management services (including our document room services), and core database operations and services such as the Drug Product Reference File, Drug Registration and Listing System, the Center Ingredient Dictionary, and tracking of AIDS protocols, Phase IV, and Patent and Exclusivity information. This division is working to make this information available through the Internet, and they will have a key role in our move to an electronic regulatory submission and review environment with the operation of our new electronic document room.

"The future regulatory review environment includes the seamless transfer of information among study sites, sponsors, and worldwide regulators. Many factors will influence this process, but the application of information technology will play a key role."

—David Isom

The future regulatory review environment includes the seamless transfer of information among study sites, sponsors, and worldwide regulators. Many factors will influence this process, but the application of information technology will play a key role. I welcome the opportunity to support CDER's efforts to move to this environment while still providing the solid day-to-day IT services that CDER depends on.

David Isom is Acting Director of the new Office of Information Technology.

CDER Seminar Ends Season with Lively Discussion

By Zan Fleming

The 1996-1997 schedule of the CDER Seminar concluded June 17 with a stimulating comparison of review performance by major regulatory authorities.

Kate Thomas of the Center for Medicines Research (CMR) in the United Kingdom based her presentation on an examination of selected new drug approvals across nine major countries, including the United States, during 1990-1995. With few exceptions, approval times have dramatically fallen among the regulatory authorities in these countries.

In 1995, the average approval time was two years or less in most countries, and some reviews have been completed in six months or less in the United States and United Kingdom. Marked differences in review time are still seen among the studied authorities, even when the NDA and its counterparts for the same drug are submitted within the same timeframe. Thomas maintained that these outcomes are not necessarily explained by differences in the efficiencies of individual regulatory authorities. Other factors are important, including the regulatory processes employed by the authority and the amount of time taken when companies respond to regulatory questions raised during the review.

To assess the factors underlying these differences and make valid comparisons of these authorities' review performance and processes, Thomas and her colleagues at CMR have identified nearly a dozen review process milestones that are reported by one or more of these authorities. These milestones allow for some comparisons, but only a few are reported across all nine regulators. The CMR data reveal that the United States and the United Kingdom lead in overall performance and at major milestones.

Thomas' presentation included one of the longest audience discussion periods following a CDER seminar. The discussion, expertly led by **Dr. Mac Lumpkin**, went on for nearly half an hour with most of the audience staying to the very end. Polite but probing questions reflected skepticism about making comparisons of authorities with vastly different approaches and depths of review. Thomas acknowledged these differences but maintained that comparing major milestones will help to establish international benchmarks for review performance.

This presentation capped the CDER Seminar's most successful season to date. Forty-five weekly and special seminars played to record audiences following the opening seminar by **Dr. Janet Woodcock** last September. For the first time in the 21-year history of the CDER Seminar, one or more conferences were held on every Wednesday of the season except for holidays. Videoconferencing to Woodmont II and Corporate locations and live seminars at Corporate were also inaugurated this year.

The CDER Seminar resumes in September, but during the summer break, "vJ Live" will be held during the 1:30 p.m., Wednesday time period. This informal conference will feature the authors of articles in the first edition of CDER's Virtual Journal (vJ). One article will be briefly presented each week by the author(s) followed by an interactive discussion with the audience.

Zan Fleming is a medical officer in the Division of Endocrine and Metabolic Drug Products.

CDER Speakers, Exhibit Highlight Event

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emerging therapeutics; pharmaceutical outcomes; and developing transitional economies.

The FDA and CDER staff who attended this year's conference each gave multiple presentations. Those who attended from CDER included: **Janet Woodcock**; **Robert C. Nelson**; **Robert J. Temple**; **Roger L. Williams**; **Nancy D. Smith**; **Minnie Baylor-Henry**; **Julie G. Beitz**; **Cynthia McCormick**; **Lou Morris**; **Paula Botstein**; **Murray M. Lumpkin**; **Mark J. Goldberger**; **Kaye Fendt**; **David A. Lepay**; **Stan Woollen**; **Renata Albrecht**; **Stephanie Gray**; **Patricia DeSantis**; **Paula Botstein**; **Deborah Kallgren**; **Lana Pauls**; and **Jean Yager**.

FDA staff from the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, and the Office of the Commissioner also gave presentations during the conference.

The joint FDA/CDER Project Management exhibit highlighted performance accomplishments in the regulatory review of applications. The exhibit featured presentations of current project management procedures and supporting tools used to facilitate the review process, recent data on CDER's user fee performance, and a demonstration of CDER's World Wide Web Home Page along with various informational brochures.

Nearly 600 people visited the exhibit to see our Home Page demonstration, to ask questions, and to pick up informational brochures and other materials. Conference participants made many very positive comments, usually expressing surprise and pleasure that FDA and CDER were exhibitors.

I had the privilege of serving as project officer for planning and implementing the CDER exhibit for this conference and staffed this exhibit booth each day of the conference. A number of CDER employees, in addition to their presentations, helped staff the exhibit. They included: **Jean Yager**; **Deborah Kallgren**; **Patricia DeSantis**; **Lana Pauls**; **Cynthia McCormick**; **Nancy Smith**; and **Kaye Fendt**.

Mary Lambert is a special assistant in the Office of Training and Communications.

CDER, Mayo Clinic Identify Heart Problems with Phen-Fen Use

By Pam Winbourne

On July 8, FDA alerted physicians to 33 cases of unusual abnormalities in mitral, aortic, and tricuspid heart valves in women between the ages of 30 and 72 who had been taking phentermine and fenfluramine in combination for 1 to 28 months. The drugs were approved separately over 20 years ago for single-drug, short-term (a few weeks) treatment of obesity. However, beginning in 1992, the scientific literature touted the use of these drugs in combination for longer periods of time. The "off-label" use of phentermine and fenfluramine together has since become widely prescribed. The use of these drugs in combination has become so popular that the term phen-fen was coined.

FDA's Lead Deputy Commissioner **Michael Friedman** recently stated, "These are drugs that should be taken only by obese patients in conjunction with a weight loss regimen that includes a reduced-calorie diet and exercise program, in accordance with approved labeling." At the same time, researchers at the Mayo Clinic and Mayo Foundation, Rochester, Minn., announced the results of a case series of valvular disease in women who took the combination of fenfluramine and phentermine for the management of obesity. This study will be published in an August issue of the *New England Journal of Medicine*.

There is no conclusive evidence of a causal relationship between the development of valvular disease and the use of fenfluramine with phentermine. However, because of the serious nature of the cardiac problems and their rare occurrence in otherwise healthy obese women in this age range, FDA notified patients and health care professionals. FDA is also meeting with manufacturers to discuss possible labeling changes.

FDA will continue to monitor adverse events reports and encourages all health care professionals to report any cases of cardiac valvular disease or other serious events associated with the use of fenfluramine, dexfenfluramine, or phentermine to the FDA's MedWatch program at 1-800-FDA-0178. FDA is especially interested in information regarding dosage and duration of therapy, whether there were any other medications being taken by the patients on a chronic basis, whether there was any history of pre-existing cardiac disease, the results of the patient's cardiac evaluation, and the degree of obesity at the time the drug therapy was started.

Pam Winbourne is a writer/editor in OTCOM's Division of Communications Management.

Core Competencies' Initiative Will Help You Do Your Job Better

By Stephen Hayleck

Training: what's in it for you? Whether you're a manager or an employee, there's either too much training, not enough training, or training for the sake of training.

Many of us in CDER have heard of the ongoing Division of Training and Development's (DTD) assessment of the Core Competencies of jobs in the Center. The purpose of the Core Competencies project is to determine the skills or tasks needed by a high-performing employee to do their job. In plain English, what do you need to know to do your job effectively? The intent of the project is to develop and deliver training that is focused on improving your ability to do your job.

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

This modified task list is then used on a larger sampling of people in the job being surveyed. For example, 30 percent of the chemists are asked to rate the relative importance of each task. The focus group reviews the findings of the survey and makes recommendations and changes.

What's next? The knowledge and skills needed to do a particular job are derived from the task analysis. The focus group uses the final task list to decide the knowledge and skills. An example of a task is the entry of data into a computer. The required skill is using a computer or a particular software program.

Finally, a determination is made as to what training is needed to develop an individual's knowledge and skills. The focus group, together with advisory committees, determines what training courses are needed to meet the knowledge and skills requirements. Using the computer example, a course in a particular statistical software program may be needed.

A possible drawback is that this method only captures a snapshot of what people are currently doing and not what they need to respond to future changes in CDER. Therefore, the final product is reviewed by steering committees to ensure that it reflects a vision of future needs.

The result is that DTD will provide training that will focus more clearly on the job needs of each individual toward accomplishing CDER's mission. We hope that you will no longer be sent to training for some unknown reason!

Steve Hayleck is a training specialist in the Division of Training and Development.

CDER, FDA Team Present Generic Drugs Seminar in Jordan

By Kevin Ropp

Generic drugs offer slim profit margins in the American pharmaceutical industry. However, in Jordan generic drugs are big business—in fact, it's the country's third largest industry.

Recently, a team of CDER and FDA officials conducted a seminar for a group of Jordan's government and pharmaceutical industry representatives on how generic drugs are regulated in the United States. "The purpose was to provide information to the Jordanian pharmaceutical industry" on our system of regulation, said **Gordon Johnston**, deputy director of CDER's Office of Generic Drugs. "They are working to build a regulatory framework in Jordan and are asking assistance from FDA as they consider the policies and procedures that will best suit them."

Sponsored by the Jordan University for Science and Technology's College of Pharmacy and the Jordan Export Development and Commercial Centers Corporation (JEDCO), approximately 125 people from the Ministry of Health (MoH), academia, and the pharmaceutical industry attended the May 26-28 seminar. JEDCO is an agency created by a joint partnership between the Ministry of Industry and Commerce and its private sector business community. "The people who attended were really looking for answers—they were looking to FDA for information," Johnston said. "They certainly understand what's going on in the world" and what is needed to be competitive in the international arena.

In addition to Johnston, others from CDER and FDA who attended included **Dr. Tony El Hage**, from CDER's Office of Compliance, **Dr. Patrick Marroum**, from the Office of Clinical Pharmacology and Biopharmaceutics, and **Mary Doug Tyson** from FDA's Office of International Affairs.

Johnston said that Jordan's MoH "was continuing to develop regulatory processes that were initiated in 1994 when the regulatory agency was created." FDA discussed hosting MoH staff to learn about our processes. In addition, the Jordan government also requested that FDA conduct additional workshops in Jordan.

A major challenge that faces Jordan's pharmaceutical industry is the current lack of strong laws protecting intellectual property rights (IPRs), Johnston explained. There have been recent problems where some Jordanian companies have not observed ownership of trademarks and brandnames. This means that Jordan's generic manufacturers have copied approved (and protected) brandname drug products from companies in other countries. However, Jordan has requested membership in the World Trade Organization (WTO) and they fully appreciate the importance of implementation and enforcement of IPR laws in order to gain membership to WTO. "Jordan's generic industry is not in full agreement regarding international trademarks," Johnston said. This issue was emphasized to the FDA team when they visited the U.S. Embassy.

"The U.S. Pharmaceutical Research and Manufacturers Association (PhRMA) is lobbying our government to urge Jordan to give high priority to passage of legislation that would require observance of internationally accepted patent laws and trademarks," he said. "Nevertheless, they (Jordan's pharmaceutical manufacturers) look at the United States as the leader in terms of quality."

While FDA's team was in Jordan, they had an opportunity to do a little sight-seeing, visiting Petra—"the premiere historical site in Jordan," said Johnston. Petra is a city carved into the solid rock cliffs about a mile into an extremely narrow gorge. The site was featured in the movie *Raiders of the Lost Ark*. Said Johnston: "It is magnificent, absolutely stunning."

Project Managment Corner

Rita Hoffman Earns Regulatory Affairs Certification

By Susan Cusack

This "corner" of the Pike was originally pitched as an information exchange site for CSOs and Project Managers. Among other things, the Project Management Coordinating Committee (PMCC) envisioned a forum for sharing the personal and professional achievements of CDER CSO/PM's. Therefore, it is a great pleasure to report that **Rita Hoffman,** a CSO in the Division of Prescription Drug Compliance and Surveillance (DPDCS), has earned Regulatory Affairs Certification (RAC). Although accreditation has been achieved by others in the FDA, Rita is the first individual within CDER to earn RAC accreditation.

The RAC accreditation program is sponsored by the Regulatory Affairs Professionals Society (RAPS) and recognizes professionals who demonstrate (through the RAC examination) a high level of knowledge of U.S. laws, regulations, policies and guidelines pertaining to FDA-regulated products with an emphasis on drugs, medical devices, biologics and general regulatory issues. Certification sets a standard of knowledge desirable for regulatory affairs professionals and promotes professionalism.

If the idea of voluntarily choosing to take any test sends cold chills down your spine or you feel that the acronym "RAC" is a little to close to "rack" for comfort, consider this. Achieving certification demonstrates an individual's knowledge, drive and commitment to the regulatory profession as well as giving formal recognition and accreditation to those professionals who meet the eligibility requirements and who have demonstrated a superior knowledge level.

For more information on the Regulatory Affairs Professional Society or Regulatory Affairs Certification, visit the RAPS homepage at http://www.medmarket.com/tenants/raps/raps.html.

New Library Service

CDER Library, NLM Offer Free Internet Services

Bethesda, MD—Vice President **Al Gore** and the National Library of Medicine (NLM), a part of the National Institutes of Health, launched a new service to provide all Americans free access to MEDLINE—the world's most extensive collection of published medical information—over the World Wide Web. Prior to the June 26 announcement, users had to register and pay to search MEDLINE and other NLM databases.

In announcing the new free service, Health and Human Services Secretary **Donna Shalala** said, "American citizens now have at their fingertips both the scientific information gathered by the National Library of Medicine, as represented in MEDLINE, and the extensive consumer health information in healthfinderTM, the service for the public that we announced in April. We are committed to using the new technology, including the World Wide Web and the Internet, to provide health information to the public."

"The National Library of Medicine's debut of free Web-based searching could not be more timely," said NLM Director **Donald A.B. Lindberg, M.D.** "The health care delivery landscape is changing. Citizens are increasingly turning to the Web as a source of information to improve their daily lives, including their health. So, it is vital that they, and the health professionals who serve them, have access to the most current and credible medical information."

"Medical breakthroughs are happening so rapidly that I believe health care professionals and consumers alike should be able to tap into the most recent medical information," added pioneering heart surgeon **Michael E. DeBakey, M.D.**, chair of NLM's Board of Regents. "Such information is often the critical link in reaching the correct diagnosis, resulting in lives saved, unnecessary treatment avoided, and hospitalization reduced. Even with all our modern advances in health care, I still consider good information to be the best medicine." Dr. DeBakey emphasized this same point this past spring in testimony before a Capitol Hill appropriations subcommittee.

"The medical library community is pleased that this vast treasure trove of medical knowledge will be opened up to the general public," said **Rachael K. Anderson**, president of the Medical Library Association. "Patients and their families are regularly turning to health sciences librarians to find reliable health information. Free MEDLINE means that we can now provide consumers with better access to the quality information they need, and librarians can help them to tap into the full power of this authoritative source."

According to **Carol Assouad**, acting director of CDER's Medical Library, the free Web-based MEDLINE searching includes access to Internet Grateful Med, to an experimental system called PubMed that includes links to publishers' web sites for full-text journal access, and to AIDSLINE and HealthSTAR.

Features of the new service include:

- Use of the full range of Medical Subject Headings (MeSH) and the UMLS Metathesaurus; and
- The ability to limit searches by language, publication type, and age groups by using pull-down menus.

Currently, searching Internet Grateful Med requires a valid User ID and password, however, users will not be billed. CDER employees may use their Medical Library-supplied ID. A new version of Internet Grateful Med will be released in July that will no longer require a User ID and expands free access to several additional NLM databases including AIDSDRUGS, AIDS-TRIALS, DIRLINE, HISTLINE, HSRPROJ, OLDMEDLINE, and SDILINE.

PubMed is an experimental search system that provides free access to MEDLINE and to selected online journals in a single search. Search features include:

- Sets of related articles (primarily those references cited in the article) pre-computed for each article in MEDLINE.
- Choice of search interfaces from simple keywords to advanced Boolean expressions.
- Searching by MeSH index terms (main topics and subheadings) and field restrictions.
- Links to publishers' Web sites for full text-journals. Initially 24 journals are available, some by subscription only (the Medical Library staff will investigate the possibility of obtaining subscriptions to these).
- Clinical query form with search filters for diagnosis, therapy and prognosis.
- Links to molecular biology databases of DNA/protein sequences and 3-D structure data.

"We are working with NLM staff to work out the process for new features such as document requests via the Web and we will keep you informed of the new features, databases and journals as they are added to the web site. In the meantime, the Medical Library will continue to provide Medline Express via LERN until we are sure about reliability and responsiveness issues," Assouad said.

The NLM Home Page address is http://www.nlm.nih.gov. CDER employees can obtain updated and additional information about NLM databases and information services at the site or direct questions to Carol Knoth (KNOTH), team leader of the Library's Reference and Outreach Services Team.