news along the pike

Center for Drug Evaluation and Research

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Volume 2 Issue 4

CDER Mission, Vision Weighed At Va. Retreat

The Center is taking the "first steps in the process of improvement and change," Center Director Janet Woodcock, M.D., said in a recent e-mail message to staff.

During a retreat March 17-20 in Leesburg, Va., senior staff worked to develope a common understanding of CDER's purpose, or mission, and what the organization would accomplish and how it would operate and be perceived if that mission were achieved in the best possible way, also known as the Center's vision and operating principles. The staff did not meet to discuss "government downsizing." In fact, Woodcock said, "my understanding of the Administration's budget for Fiscal Year 1997 is that it will require further austerities on CDER's part but, unlike a number of other government agencies, we will not be facing furloughs or reductions in force (RIFs). Therefore, while a reduction in appropriated and Prescription Drug User Fee Act (PDUFA) dollars is one of the realities we must currently deal with, people losing their jobs is not."

Nor did the group meet to discuss "the issue of change in the Center" she said. "We are doing a great job -- our progress has been lauded by consumer groups, members of Congress, the pharmaceutical industry and the administration. The challenge for us is to keep getting better in ways that allow us to accomplish as much of our mission as possible. We must continue to change, because the world is changing around us."

Woodcock noted that some critics claim that the Center does not understand its mission. However, she said, "the retreat revealed that the Center's mission is quite clear to the Center leadership. Our purpose -- the reason

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Managers Set Six Month Goals

Reaching Out By Videoconferencing

By Kevin L. Ropp

A rolling stone gathers no moss. And now, it seems, CDER is on a roll.

Top managers recapped goals achieved since the Center's reorganization last October and outlined new goals for Center operations for the next six months during CDER's first fully-interactive in-house video teleconference broadcast from Woodmont II to Parklawn and Corporate Boulevard April 1, 3 and 4.

Center Director **Janet Woodcock, M.D.,** opened the Spring Planning Meeting briefly discussing CDER's future. Her goals include:

- ensuring that mission and vision discussions permeate the Center
- continuing Track II of the Good Review Practice initiative, and
- continuing to improve information management throughout the Center.

"I'm really pleased with the outcome of the Spring Planning Meeting," Woodcock said. "Each program was able to show the progress they had made and to lay out what they expect to accomplish in the short term -- it was very impressive."

"One important function [of the meeting] is to acquaint everyone in the Center with what is going on in all of the different programs. I'm disappointed that more people didn't take the opportunity to find out what is going on. But, we are always improving and I hope there will be more attendees at our next planning meeting," she said after the conference.

Review Management

Following Woodcock, **Murray Lumpkin, M.D.**, Deputy Director for Review Management, highlighted the Center's drug review performance goals and accomplishments in the past six months. For example, he said, the Center's reviewers surpassed the Fiscal Year 1997 Prescription Drug User Fee Act (PDUFA) original new drug application goals in FY94. In addition, for FY95, reviewers have already exceeded the goals for application resubmissions and manufacturing supplements. He reviewed performance goals for the remainder of FY96. According to Lumpkin, the Center is on track to surpass FY95 goals for original new drug applications, efficacy supplements, manufacturing supplements, and resubmissions.

Lumpkin also discussed the office's personnel management and policy development and implementation goals for the remainder of 1996. Lumpkin said he hopes to recruit several new division directors. He also set several policy goals including:

- issuing a clear prescription to over-the-counter switch procedures, and
- renegotiating PDUFA.

Pharmaceutical Sciences

Roger Williams, **M.D.,** Deputy Director for Pharmaceutical Sciences, highlighted the goals of the Office of Pharmaceutical Sciences. These include recruiting four permanent office directors, establishing administrative and management processes for the office, organizing and

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White Oak Hearing Set

The General Services Administration and FDA will hold a public hearing Tuesday, April 16 to discuss a draft Environmental Impact Statement that has been prepared on FDA's proposed consolidation at the Naval Surface Weapons Center (NSWC) in the White Oak section of Silver Spring, Md.

The hearing is scheduled for 7 p.m. in NSWC's administration building auditorium. Area residents, citizens, and FDA employees are welcome to speak on their concerns about the consolidation at the site. For more information, call Beverly Corey in FDA's Office of External Affairs at (301) 827-0855.

— By Kevin L. Ropp

inside...

Managers Set Goals
Video Connects Center

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consolidating the office's chemistry function, and organizing and consolidating the office's product quality research function.

Williams also highlighted the Center's work with the International Conference on Harmonization (ICH). He gave an overview of topics and issues that have already been "harmonized" between countries and identified several new topics the Center will be addressing in the ensuing months. These topics include: Statistical Aspects of Clinical Trial Design, Choice of Control Groups in Clinical Trials, Tests and Specifications for Drug Substance and Drug Product.

Managing CDER

Director of the Office of Management **Russell Abbott** reviewed numerous goals from the past six months that have been accomplished or are nearing completion. In addition, Abbott set some new goals for the office: consolidate two Database Management Branches and the Division Director's office into one division to better manage resources; begin a more interactive budget process with CDER to increase budget communication and provide for more effective resource management; and establish a management office working group to facilitate a more interactive and cohesive administrative management process.

Another major new goal Abbott announced was an initiative to improve the Center's Chemical Information Management System and Phase IV On-line Database System. To improve the Chemical Information System, the office will install a new VAX computer system for better storage, search and retrieval capabilities of more than 10,000 chemical compounds. In addition, the office will create an on-line system for tracking Phase IV drug approvals.

An *Electric* Future

David Isom also updated viewers on three of the Center's major information technology initiatives: Administrative Management of Files (AMF); Computer Assisted Review of Safety (CARS); and CDER Electronic Submission Archiving.

Several components of AMF should be available by late 1996; and an integrated document management system should be up and running by late 1997. In addition, Isom said, during the next six months a pilot CARS system should be installed and ready for testing; a Federal Register notice should be issued announcing CDER's archiving policy, and initial document specifications and an implementation plan should be ready.

Where To See A Replay

The Office of Training and Communications (OTCOM) will screen the videoconference on April 23, 24 and 25 at Parklawn, 13B-39, and Corporate Blvd., S100, 10 a.m. to 2 p.m. Video copies are available from OTCOM, 827-1243.

The writer is a staff editor on News Along the Pike.

Editor's Note: Highlights of other planning presentations will appear in the next issue of The Pike.

CDER's Mission, Vision Discussed At Va. Retreat

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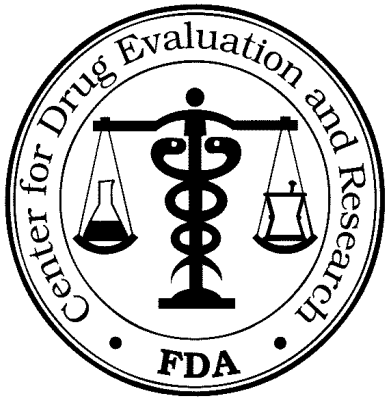
the taxpayers and Congress give us money -- is to make sure that safe, effective, truthfully labeled high-quality drugs get on the market promptly; and that unsafe, ineffective drugs don't get on at all." Acknowledging the tension between consumer protection and facilitation of patient access to therapies, she said, "protection and facilitation are both essential to a good result. It is clear that CDER has a single mission, one that is vitally important to the health of Americans, and one that we can be proud to be part of."

There was substantial difficulty, however, writing a concise mission statement that encompassed all that the Center does. "It is clear that 'access to good drugs' includes issues as disparate as economic access (generic drugs), facilitation of efficient drug development, appropriate scientific standards for quality, safety and efficacy, and good manufacturing practices. Consumer protection includes, for example, keeping ineffective, fraudulent, or poor quality drugs off the market, ensuring truthful labeling and promotion, and ensuring human subject protection during clinical trials.



"Our mission statement must encompass all these activities without becoming a laundry list of various processes," Woodcock said.

In addition to the Center's mission, the group worked on an organizational vision and operating principles. Said Woodcock: "We envision CDER carrying out its mission with such energy, commitment to continuous improvement, quality of science and actions, and transparency that it is known worldwide as the Center for excellence in drug regulation."

Operating principles can inform decision-making and facilitate change in the Center, she said. "For example, one principle that was important to the team was operating with openness and transparency in our internal and external dealings. Adherence to this value would probably influence the way we do many things, from our budget process to sharing scientific assessments with the outside world."

"Another key principle is 'outcome orientation.' Truly following this value would require us to be willing and ready to change anything we do, including parts of our drug regulatory system, if we are not adding value or getting the results demanded by our mission," Woodcock said.

After meeting with division directors over the next few weeks, retreat participants will be making presentations to all Center employees and requesting ideas and written comments. By June, complete mission, vision, and operating principles should be announced.

In presenting these, Woodcock said, "we will be making a commitment to act in accordance with our stated mission, vision, and operating principles and to hold others accountable for this as well."

Ombudsman's Corner

To See Ourselves as Others See Us

By Jim Morrison

Well, I've been on the Ombudsman job for over five months. I have talked with folks from the industry and from CDER about the way we interface, and, working with the Office of Training and Communications (OTCOM), I plan to do much more of that. It seems like a good time to share with you some of what I have learned, and I'll continue to do that periodically in this column.

Naturally, from my position as Ombudsman, I hear about and investigate only the cases where there have been serious miscommunications, delays and problems in our operations. If the cases and examples I get were reflective of CDER's normal functioning, we would not have been able to meet our user fee goals. Having said that, I believe we can learn much from our outlying cases, and if we can prevent future problems from happening, we can rob our critics of those prime examples they love to cite. We can also do our jobs better if we understand the problems faced by those with whom we interface.

I am always surprised to hear from knowledgeable people outside the agency that they are frequently mystified about how we operate, why we do many of the things we do or ask the questions we ask. The term "black box" is used by some of them to describe the drug review process.

Clarity in communications, timely meetings and scientifically justified requests for additional data, when necessary, are high on the priority list of the people I have talked with. The new MaPP (Manual on Policy and Procedures), "Formal Meetings Between CDER and CDER's External Constituents (#4512)," issued on March 7, covers meetings with external customers and should be of great help in improving communications. (The MaPP will be placed on Internet.)

Clearly, the regulated industry and applicants have an insatiable need for solid information about our policies and procedures. The Good Review Practice (GRP) guidelines are eagerly awaited outside the Center as a means of improved consistency in reviews and of a better understanding by the applicants about what we are looking for in submissions.

As science and policies evolve, as procedures change with new technologies and as personnel in reviewing divisions, in CDER management, and in the Commissioner's and the General Counsel's offices leave and are replaced, those who deal with the agency need up to the minute information about these changes. (I have found that need to be shared by our own staff.)

In the new drug review area, firms find that, because the life-cycle of an NDA is long, experience gained with one application may no longer be valid when the next one is ready to be submitted. There is no way to avoid the inevitable shifts in the regulatory landscape. However, we can be sensitive to the serious problems an applicant faces when the ground rules are changed, and we should not unnecessarily inflict those problems. For example, requiring a new study when an applicant followed the advice of a reviewer who has since departed is sure to elicit cries of "foul."

In spite of many efforts to improve consistency between review divisions, the industry folks still cite instances of differing procedures and interpretations of rules. When a company submits identical or similar supplements to different divisions, they report that sometimes they experience significantly different review times and outcomes. When we become aware of differing policies or procedures in the Center, we need to surface the inconsistency so it can be resolved. It is never appropriate for a reviewer to use an action on an application to challenge an established policy he or she dislikes. We are obligated to adhere to existing rules and guidelines until they are changed and the affected parties are notified.

To put complaints from the regulated industry in perspective, I have yet to talk with an industry scientist or consultant who does not express admiration and appreciation for the tremendous changes that have already occurred in the Center's review timeliness and in the professional attitude of its reviewers. We have achieved much, and we need to build on that success.

In the next issue, I'll discuss more of what I have learned in my discussions.

FDA Working Group Looking at "Mad Cow" Disease

By Kevin L. Ropp

The Center has formed a Bovine Spongiform Encephalopathy (BSE) working group to evaluate the threat posed to American consumers by the outbreak of "Mad Cow" disease in the United Kingdon last month.

CDER's working group, which includes representatives from the Center for Biologics Evaluation and Research and Center for Devices and Radiological Health, met April 8. Headed by CDER's Yuan Yuan Chiu, the group will: look at all aspects of BSE as it relates to drugs, and develop a written report within a month; determine what needs to be done to ensure drugs are not contaminated with BSE agents; search spontaneous adverse drug reports for neurological adverse events associated with Creutzfeldt-Jakob Disease; and develop a future tracking of new drug applications and investigational new drugs for drugs derived from animal sources.

BSE, or mad cow disease, is a transmittable disease of cow that is fatal once diagnosed. It is not transmitted from cow to cow, rather, the cause is believed to be associated with feeding cow with sheep parts infected with Scrapie or with cow parts infected with BSE. BSE is similar to Creutzfeldt-Jakob Disease, a rare spontaneous disease in humans, and to Kuru, a disease found in the New Guinea Fora Tribes. Like BSE, CJD is marked by degeneration of the brain cells. The cause of CJD could be either genetic or due to some other unknown factor. Although it has been alleged, there is no proof that the recent 10 new cases of CJD in UK were caused by eating beef from infected animals.

Since 1989, there have been controls in the United Kingdom forbidding the inclusion of animal parts in animal feeds. There are also controls in the U.K. that forbid selling certain parts of cow to humans for consumption. And, in the United States, there has been a ban on importing U.K. beef. However, there are no controls on drug products imported from foreign countries. which may contain ingredients derived from U.K. cows.

Computing

Tackling the Paper Piles With TeamLinks

By Margaret Stavish

There is going to be less paper pushing in the near future. Over the next few months, News Along the Pike will be distributed through TeamLinks, a software package from Digital Equipment Corp. Although it will continue to be made available in hardcopy for those that don't yet have TeamLinks or who wouldn't get it otherwise.

TeamLinks is a Windows interface to ALL-IN-1 that allows the user to attach documents such as those created in Word and WordPerfect, spreadsheets, datasets, and more. The software package has already been installed on many CDER computers and all users in the Center will have access to TeamLinks in the coming months. (Don't worry: ALL-IN-1 isn't going away and it will continue to be supported by the Division of Information Systems Design.)

Center-wide training for TeamLinks is underway. (Hands-on training is held

monthly: the next session runs April 22 through May 3.)

The Pike will be distributed through TeamLinks as an attached document. Below the subject line of the TeamLinks message will be the newsletter as an attachment. For Windows users, just double-click the attachment and there it is! For Macintosh users, click on the attachment, click on "File-Save As" and give it a name. To view the newsletter, locate the file on your hard drive and double click the document. The Pike will be in a Portable Document Format (PDF), which is read by Adobe Acrobat Reader and allows users to view documents in their original format (no font changes or tables shifting). Acrobat preserves all original pictures and graphs --most of which are produced in color but appear in the newsletter in black and white. (Even back copies of the newsletter will be added as time and resources permit.) For a hard copy, simply click on "File-Print-OK." That means no more, or at least greatly reduced, photocopying. (Can you hear distribution manager Donald Carrington's sigh of relief?)

Acrobat Reader will soon be downloaded to all computers in CDER. To download the software yourself prior to the automatic download, follow these directions:

Installing Acrobat Reader: Windows

1. Connect to the x: drive. To connect to the x: drive:
   a. Exit Windows.
   b. Type: LANMENU
   c. Type: CONN
   d. Type: COMMON CDFDA
2. Start Windows. Type: WIN.
3. Close all applications except Windows.
4. In Program Manager click on File - Run.
5. At the Command Line type: x:\acrobat\acrrd21.exe
6. Click on the OK button.
7. Read the License Agreement. Click on Accept.
8. An Acrobat Installer dialogue box will appear. Click on Install.
9. A Registration Dialogue Box will appear. Click on OK.
10. A dialogue box will appear asking for your Name and Organization. For Organization type CDER.
11. Click on OK.
12. A dialogue box will appear that says "Installation is complete." Click on OK.

Installing Acrobat Reader: Macintosh

1. Close all applications.
2. Open Chooser. To do this:
   a. Click on the apple in the upper left hand corner.
   b. Select Chooser from the pull down menu.
3. Select the following:
   a. AppleShare
   b. AppleTalk Zones: CDER
   c. DECshare on MINNIE
4. Click on the OK button.
5. You will be prompted for your name and password. Type your email username and password.
6. Click on the OK button.
7. Select CDER COMMON.
8. Click on the OK button. The CDER common icon will appear on your desktop.
9. Double click on the CDER ommon icon.
10. Scroll to Acrobat for Mac. (Note: This will be very slow.)
11. Drag the folder to your Mac Hard Drive. This will take a few minutes.
12. Locate the Acrobat for Mac folder on your Hard Drive.
13. Double click on the Acrobat for Mac icon. Three files will appear:
   a. Acroread.mac
   b. coupon.pdf
   c. readme - Reader 2.0.1
14. Double click Acroread.mac. This will install the Acrobat Reader onto your computer. Note: You will be prompted many times. Click on Continue or Install if prompted. Your will also get messages saying "SAM Intercept - Suspicious Activity Alert." Choose Allow or Yes.
15. You will receive a message that the software was installed successfully. The system will prompt you to restart your computer. Choose restart.

Margaret Stavish is a Computer Specialist in the Division of Information Systems and Design and is responsible for the Layout and Design of News Along the Pike

Point of View

Developing New Ways of Thinking, Interacting

The Center Looks at Retooling in a New Era of Government

This is the first in a series of articles that will introduce the concept of building learning organizations to CDER employees.

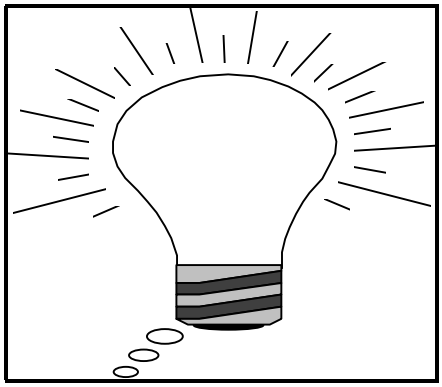
By Nahid Mokhtari-Rejali, Ph.D.

In March 1995, I was selected by the Office of Personnel Management to participate in the 1995-96 Executive Potential Program (EPP). This 12-month program provides training and development experiences for higher potential individuals and prepares them for managerial positions in the Federal Government. In addition to five, one-week residential seminars, participants must complete at least two 60-day developmental work assignments away from the position of record, to interview at least three senior executives, and to complete a three-day shadowing assignment of a high-level agency official.

Among other requirements, each person was assigned to a cluster group (a team of eight) to explore and address current issues facing managers in the Federal work force. We chose to work on "Building Learning Organizations in the Federal Government" for our team presentation. The theory is based on Peter Senge's book, "The Fifth Discipline: The Art & Practice of Learning Organization," which describes the learning organization as a place "where people continually expand their capacity to create the results they truly desire, where new expansive patterns of thinking are nurtured, where collective aspiration is set free, and where people learn how to learn together." The purpose of our presentation was to introduce this concept to the future executives and encourage them to initiate the principles of learning organizations in their agencies. The presentation was given on Dec. 6 in Williamsburg, Va., before EPP participants and their senior executives. (I am very proud that our team's presentation was recognized as one of the best and was on Internet (WWW Home Page) for several months.)

The concept of learning organizations started about 40 years ago at Sloan School of Management at MIT. The Fifth Discipline, System Thinking Discipline and other four complementary disciplines (Personal Mastery, Mental Model, Shared Vision & Team Building) contribute important principles and tools that make individuals, teams, and organizations more able to make the shifts from seeing the world primarily from a linear perspective to seeing and acting systematically. There are a lot of places, mainly in the private sectors such as AT&T, Ford, Saturn, IBM, Harley-Davidson, Shell Oil, and Federal Express, where, over the last 10 years, people have made significant headway by implementing these disciplines. However, during the past five years, a few government agencies like the Army, IRS, FDIC, FAA, and PTO have also begun heading toward being learning organizations.

As a reviewer in CDER, and a scientist



with an academic teaching background and a belief in continuous learning, I became very interested in learning organizations. During the work of this project with other agencies (EPP participants), I developed a greater interest in people and what their amazing abilities can create. One of the basic forces fueling worldwide interest in learning organizations is that historically authoritarian, hierarchical government organizations have failed to tap the capacities of all people. The traditional notion that the top level thinks, and middle and lower ranks act, has to change. The interesting thing about learning organizations from the standpoint of what life is like within an organization is that it is*the people*who learn, not organizations, not top management, and not systems. This whole revolution toward learning organizations puts the human being right into the center of the organizational equation in a way that has never been done in the past. Therefore, people really do become the most important organizational assets, and not just a handful of extraordinary scientists and a few physicians as senior executives, but people in all levels.

Now, when you think in these terms about a new world in which people somehow are in the center, you begin to appreciate some of the deeper territory that's always limited the way organizations operate. For the last six years that I have been with the Center, I've often heard from my colleagues that "that's the way the system works!" We often think of organizations operating the way they do because of their system, because of their management practices, rules, procedures, and individuals. But the fact is that all of that was created, it did not drop from the sky! At a deeper level, we have the system, procedures; and practices we have, because we created them. They are the product of the way we thought. We thought that people needed to be controlled, so we created the rule books. We thought they people doing their jobs individually, so we created individual job descriptions. None of these will change until we start to develop fundamental new ways of thinking and interacting with one another.

Center Director Janet Woodcock, M.D. has said that a learning organization is part of CDER's strategic plan. Last month, CDER management retreated to Lansdowne to talk about leadership and change. The real reorganization in CDER is about to come! This is not the time for cynicism and despair! It is the time to participate in what we want to create for our future. No organizational transformation is going to occur if we wait for a few higher executives to go to many other retreats to figure it out for us and expect us to buy into it. The essential territory for bringing about the change in creating learning organizations is actually in us, not outside of us. It has to do with how we think and how we interact! To make a difference in the quality of our work life has to be in everyone's agenda. We need to foster a new way of thinking and working together. We can do it!

Or, as Mahatma Gandhi said, "To believe what has not occurred in history will not occur at all is to argue disbelief in the dignity of man."

The writer is a chemist in the Division of Dermatologic and Dental Drug Products.

AMF Update

AMF Plan to Short-Circuit CDER Paper Flow

By David Isom

So much has been happening with the Administrative Management of Files (AMF) project that we thought we should initiate a monthly AMF update. In each newsletter, we will give you an update on the AMF activity in the Center. We will let you know the status of the various AMF components and any immediate future plans. Since AMF is composed of multiple components, we will also highlight one AMF component each month.

As reported in the April 1995 issue of The Pike, the AMF project will develop a set of computer tools or components that improve the way we develop, manage, and retrieve information related to a drug review. These tools include document and workflow management capabilities, user-friendly access to information in COMIS, and on-line access to approved drug labeling and division file repositories.

The cornerstone of the AMF project is the Division Files Document Management. This component provides document management technologies that improve the way CDER retrieves, tracks, and archives all the documents generated during the IND and NDA review processes. These new capabilities will let CDER staff easily and quickly access workflow information, communications, and documents from an electronic desktop.

Currently, the Division of Oncological Drug Products is serving as the test group and has been actively involved in the initial development of this component. We have learned many valuable lessons and have received many suggestions for improvements and enhancements. Later this month, we will start customizing the Division Files Document Management component for the Division of Pulmonary Drug Products. Another division will follow later this year.

Another active AMF component is the Decision Support System (DSS) which provides a Windows-based interface into the existing COMIS database. DSS includes enhanced searching capabilities plus a variety of ways to access additional COMIS data. Staff in the Division of Pulmonary Drug Products, Oncological Drug Products, Neuropharmacological Drug Products, and Antiviral Drug Products are currently testing the DSS. As with the Division Files Document Management component, we received many invaluable ideas for enhancements as a result of these tests. In addition to making the DSS available to all CDER staff this year, immediate future plans for the DSS include the addition of workload graphing capabilities and enhanced data retrieval features. Long term plans include integration with an online charge and history card.

In March, an extensive training program was initiated for the Division of Biopharmaceutics Division Files component of AMF. This component differs from the Division Files Document Management component described above in that it uses Excalibur imaging software to provide a repository of the image and text [retrieval services from a central repository] of Biopharmaceutics Division file documents. This repository includes reviews, memos of telephone conversations, meeting notes, correspondence, and other types of documents. Excalibur provides extensive search and retrieval features but does not have the workflow capabilities provided by the Division Files Document Management component. Now, all CDER staff can access information related to a Biopharmaceutics review. To date, approximately 150 CDER staff members have been trained in using Excalibur. If you missed the training sessions in March, additional training classes will be offered in the upcoming months.

Another AMF component, the Approved NDA Labels Repository, also uses Excalibur imaging software. A test repository has been developed and provides access to the approved package inserts and approval letters for all NDA labels approved in 1994 and 1995. Recently, an approved NDA label testing group was initiated to help CDER refine, enhance, and test the Approved NDA Labels Repository. As with the other parts of AMF, the Center hopes to gain valuable insight as a result of this testing process.

We are very excited about the AMF activities and progress over the past few months. If you have any questions or wish to participate in any of the AMF components, please contact David Isom (e-mail, ISOM).

The writer is the AMF project manager.

Pharm/Tox Retreat Set for May 21

Pharmacologists in CDER's Office of Review Management have planned a day-long retreat on May 21 at the Hyatt Regency in Bethesda. The meeting, sponsored by the Pharmacology-Toxicology Coordinating Committee, will focus on the recently published ICH preclinical guidelines, REGO and the Good Review Practices initiative. The retreat will provide reviewers and team leaders with an opportunity to discuss the impact of these changes and address how the pharmacology discipline can continue to effectively meet PDUFA goals.

– ***Sharon Olmstead***

FDA Statisticians Make Association Count

FDA's statistical scientists have formed the FDA Statistical Association (FDASA). The mission of the FDASA is to serve as a collective voice in promoting the advancement of statistical sciences within the regulatory environment of the FDA, to address issues specific to the concerns of all FDA statisticians, and to foster FDA-wide consistency and harmonization on crucial regulatory statistical issues. The FDASA has a current membership of approximately 100 professionals.

The '95-'96 officers are Satya Dubey, President, and Peter (Tony) Lachenbruch, President-elect. Each center in the FDA has an elected representative. The '95-'96 representatives are:

Cornelius Lynch, CBER
Nancy Smith, CDER
Harry Bushar, CDRH
Stuart Chirtel, CFSAN
Margaret Lamb, CVM
James Chen, NCTR

– Nancy Smith

Office of Research Resources

Research Funds Available Now!

Applications Due by April 30

By Ralph Lillie

On March 1, CDER announced the availability of FY96 funds for support of intermural review science research in the efficacy and safety of new drugs. This support is directed at review science research, which is broadly defined as activities involving the exploration of approaches, methods, or data that could potentially enhance the quality or efficiency of the IND/NDA review process, or the design and evaluation of clinical protocols. Priority will be given to review science research that would ultimately enhance the process of pharmaceutical development, design and conduct of clinical trials, IND & NDA preparation, submission and review, and the regulatory use of such data in carrying out the Center's mission.

Proposals will be evaluated according to:

1. relevance to the goal of improving the quality and efficiency of the IND/NDA review process
2. scientific merit
3. cost
4. likelihood of success
5. knowledge, skills and experience of the investigator.To be eligible, investigators must be either full- or part-time CDER review scientists.

For more information please refer to the original announcement, which was transmitted via e-mail on April 1 or reference the X drive:

X:\RVSCNCOM\RVSCNRFP.6

To be considered for funding, proposals should be submitted by April 30. If you intend to submit a proposal, please notify Ralph Lillie, Executive Operations Staff [HFD-006, Rm. 6049, Woodmont II], via e-mail (Lillie) or call 301/594-5466.

NATIONAL LIBRARY WEEK
April 15 - 19

Feeling tired and stressed? Perhaps the Medical Library can help. Remember, stressed spelled backwards is desserts! In celebration of National Library Week, please join us for delicious desserts at the Library's Open House in the Parklawn Building on Wednesday, April 17, noon til 2 p.m.

The library will also be having a week-long World Wide Web contest. Stop by and enter the contest by trying out the library's WWW workstation. Make a selection from the fish bowl, "surf" to the identified URL and try to answer the question posed. All who attempt to answer their questions will be entered automatically in a raffle. We will draw names and award prizes at the end of the week.

If you haven't yet tried the Web, National Library Week will be your opportunity. Pick up handouts on Web browsers, Internet terminology and "cool" Web sites. Even experienced surfers will discover interesting and useful new sites!

The Medical Library is in 11B-40, and festivities run throughout the week.

*— **Kathy Kruse***

Parklawn Classic

Yo! It's Time to Stretch and Sign Up to Walk, Run

Last call for the 21st Parklawn Classic! On April 26 at 11 a.m. hundreds of FDAers -- CDER Director Janet Woodcock, M.D. among them -- will take the five-mile course for runners that begins on the Rock Creek path near the soccer field on Veirs Mill Road. Associate Director for Medical Policy Bob Temple, M.D. will don a bright orange vest for his self-described role as "roving doc in the woods" to render first aid on a very strenuous portion of the run. Hmmm. There's also the 2.5-mile health walk that begins at the north parking lot just off Fishers Lane.

Registration is free for walkers (T-shirts are $9); and runners, $10 by April 25; $20 on race day. Register in the R & W store, Parklawn, 5-01, or call the Classic Hotline at 443-5350; TDD 594-6990.

CDER PEOPLE

Minnie Baylor-Henry will become the permanent Director of the Division of Drug Marketing, Advertising, and Communications (DDMAC). The announcement was made April 12 by Robert Temple, M.D., Associate Director for Medical Policy. Baylor-Henry is a pharmacist and an attorney. She has served as DDMAC's Acting Director for the last year.

She joined FDA in 1991 as a reviewer in DDMAC and was primarily responsible for the review of promotional material for gastrointestinal products. In 1993, she joined the staff of the Division of Federal-State Relations in the Office of Regulatory Affairs as the National Health Fraud Coordinator. She returned to DDMAC as a Branch Chief for one of the Enforcement Branches. Prior to joining FDA, Baylor-Henry was a Vice-President with a hospital system in the District.

On April 12, **Larry Lesko,** Ph.D., was named Director of the Office of Clinical Pharmacology and Biopharmaceutics (OCPB). He had been Acting Director of that Office for the past six months and had "shown impressive leadership and management while implementing the new office structure and participating with me to foster initiatives in the Office of Pharmaceutical Sciences," said Roger Williams, M.D., Deputy Director for Pharmaceutical sciences.

"Larry is a nationally recognized expert in clinical pharmacology and pharmaceutics, who possess knowledge of chemistry, pharmacokinetics, biopharmaceutics, pharmacodynamics, statistics, and clinical trial design."

He also brings to the office extensive academic and industry experience in drug development research, Williams said.

While in the Office of Generic Drugs (OGD), Lesko managed the research contract which led to the SUPAC initiatives and helped

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Memory Lane: 501 First Street

Earlier this year, Guy Gugliotta wrote a Washington Post feature article on a "nondescript" Federal building for sale in the District. Veteran FDA Research Chemist Tom Doyle worked in the building for years and offered this memory:

Dear Mr. Gugliotta:

We never called it anything but "501 First Street" either (we usually left off the "SE"). I'm among those who once worked in that "Federal laboratory" mentioned in your fine piece about the "nondescript, unnamed building" up for sale (The Post, Jan. 6th).

It was a good home for many of us between 1961-1983. We were (usually) the FDA's Division of Pharmaceutical Chemistry, about 25 strong. Isolated from the rest of FDA, we were a close-knit group, still are, although the division no longer exists.

We parked free on the street, and on my first day in '63, a D.C. policeman stopped me on the way in to deliver a lecture on jaywalking, a major concern to the force in those days. Sometimes the guard never showed to open the building in the morning, so, as one of the youngest and lightest, I'd climb through an unlocked window.

There was no elevator in the two-story building; we had to haul the tanks of nitrogen and other gases up and down the stairs on dollies. One of our members suggested in '73 that a dumbwaiter be installed, but GSA replied that although the idea had conceptual merit, the "building is scheduled for demolition in a year or two."

Never happened, yet, but when we moved we took with us the sign over the front door that said "Food and Drug Administration - 501 First St. SE." We still have it, and that's the place's only proper name; won't argue about nondescript.

Many of us are still with FDA, but scattered. Still good chemists, unexcepted but not unexceptional. With the threats of downsizing and other worries in the air, we might make a bid.

Sincerely,

Thomas D. Doyle, Ph.D.,
Member of the 501 First Street Gang

Elizabeth Kelly Dies

Directed CDER Library

Elizabeth Kelly, former director of CDER's Medical Library, died March 30 after suffering a stroke. She was 83. She had been living with her family in New Jersey since retiring from FDA on Sept. 29.

Ms. Kelly worked for the Federal Government for 60 years, most of it with this agency. She spent her first decade of service as a secretary, and in administrative and editorial positions. She formed the Medical Library in 1948. At that time, all information research and organization was done entirely on paper. She overcame a number of formidable challenges in building the library to its current status as a worldwide resource of drug and pharmaceutical information.

Ms. Kelly made many important professional contributions including developing and editing the "FDA Clinical Experience Abstracts" from 1961 through 1976, which systematically monitored and indexed adverse drug reactions.

She was admired by her colleagues for her hard work and selfless devotion to FDA, her Irish sense of humor and gentle laugh, and her fondness for telling stories about former FDA commissioners and other folk.

Ms. Kelly is survived by two sisters, a brother, and numerous nieces and nephews.

— Carol Assouad

Note: Ms. Kelly was profiled by Kathy Kruse in the Oct. 25 issue of The Pike.

news along the pike

Have ideas, news, or photographs to contribute? Please contact:

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CDER

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guide the development of the SUPAC-IR Guidance. His leadership skills, extraordinary scientific knowledge, and familiarity with FDA program activities will benefit both OCPB and the Center, Williams said.

While in OGD, Lesko managed the research contract which led to the SUPAC initiatives and helped guide the the development of the SUPAC-IR Guidance. His leadership skills, extraordinary scientific knowledge, and familiarity with FDA program activities will benefit both OCPB and the Center, Williams said.

Elaine Frost has been appointed branch chief in the Office of Training and Communications' Division of Communications Management (DCM). Frost has been a television producer at the Center for Devices and Radiological Health, has supervised technical writers at the National Institutes of Health, and has operated her own public relations firm. She began on April 1.

Two writer/editors also joined the Communications Division on April 1. They are **Kevin L. Ropp**,former editor of the agency's monthly newsletter, "FDA Today," and **Lori A. Frederick,** most recently from the Inspector General's Office of the Nuclear Regulatory Commission. Ropp has worked in a variety of writing and public affairs positions including the Defense Logistics Agency in Alexandria, Va. and at Fort Detrick in Frederick, Md. Frederick is a technical writer who has a special interest in computer graphics and data bases.

Lisa Laubgross, a Booz, Allen Associate, computer technician, left CDER April 12 to return to Booz, Allen headquarters in McLean. She is a Certified Meeting Professional and has been named Conference Services Manager for Booz, Allen's Conference Center that opened April 1 in McLean. For the past year, Laubgross has been a copy editor on The Pike and has made a significant contribution.

Videoconferencing

Live from Rockville: "Here's Looking at You"

By Lori A. Frederick

Simulcasting the March 29 "Spring Planning Meeting" to video-conferencing to viewing rooms in the Parklawn, Woodmont II, and Corporate Blvd. locations marked the advent of a new era in the way CDER and the Office of Training and Communications uses high technology to communicate in the Center and clears the way for increased interactive videoconferencing with the pharmaceutical industry.

According to Angie Youngblood, videoconferencing manager, the equipment functioned "without a glitch," and succeeded in fulfilling its purpose to provide enhanced communications among participants and attendees. In fact, the system and its operator were commended at the conference by both ODE II Director James Bilstad, M.D. and OTCOM Director Lucy Rose.

With additional help from Lana Kostecka (DISD), the system incorporated Proxima desktop projection, which allowed for projections directly through a personal computer. For example, the audience was able to view slides exactly as they appear in the software (MS-PowerPoint) in which they originated. Please note that a "Guide to Graphics" will appear in a future Pike issue to assist in maximizing presentation graphics for conference purposes.

The viewing audience had panoramic views, on a rotating basis, of concurrent slides and audiences at other viewing sites.This format was used during the questions and comments following each presentation.

In addition to increased communications and participation without the necessity of lost travel time, the system allows for the taping and re-broadcast of events. The CDER Spring Planning Meeting will be replayed on April 23, 24, and 25 from 10:00 a.m. to 2:00 p.m. at Parklawn (13B-37) and Corporate (S100).

The future plans for videoconferencing include additional functions such as interactions with industry and increased conference participation. Also, it is hoped that the Metro Park North and MOD I locations will be added conference sites by this fall. For additional information, or to request a copy of a video, you can contact OTCOM. Future copies will be made available through CDER's library.

The writer is a staff editor in the Office of Training and Communications.

Videoconferencing Focal Point Training

The Office of Training and Communications (OTCOM) has developed a videoconferencing training program for CDER employees. The program's goal is to provide an opportunity for individuals to become a "videoconferencing focal point" for their respective organizational unit. It is important to have an adequate number of people in each CDER building trained to use conferencing equipment. The debut of this medium took place earlier this month (see story on Page 1).The training covers the following areas:

1. Equipment operation
2. Trouble-shooting
3. Scheduling and support communications

An individual from each division may assume focal point responsibilities. However, individuals who may be interested in focusing on one specific area of videoconferencing are also welcome to participate.

Course Description: Training is divided into two parts. Part I (3 hours) provides an overview of CDER's videoconferencing initiative, reservation procedure, basic room operation, equipment overview, and common problem solving techniques. Part II will be 1 hour overview with an opportunity for the trainee to master a videoconference.

Getting Certified:Trainees will be certified upon completion of the course. Participants must attend both portions of the training. Missed sessions can be rescheduled by e-mail, Angela Youngblood (YOUNGBLOODA), Division of Communications Management Branch.

Eligibility: All CDER employees; no technical expertise is required. The supervisor's approval is required to be the division's focal point.

Training Dates:

	Phase I	Phase II
Corporate Blvd.	May 8-9	May 10
Parklawn Building	May 15-16	May 17

Registration: CDER employees can register by e-mail or by completing the form on Page 10. OTCOM has initiated a new automated registration system that will give you the opportunity to register for OTCOM courses using the CDER All-in-One system or you can fax the registration form attached.

INFORMATION: Angela Youngblood (YOUNGBLOODA), 827-1243; fax: 827-3056.

Videoconferencing
Focal Point Training

REGISTRATION FORM

NOTE: This form should only be used for "Videoconferencing Focal Point Training."

COURSE TITLE: "Videoconferencing Focal Point Training".

COURSE DATES:

NAME:

DISCIPLINE: (e.g. chemist, program specialist)

ORGANIZATION: HFD-

OFFICE ADDRESS:

TELEPHONE NUMBER:

FAX NUMBER:

TRAINING DATES:

_____
Approving Official (Supervisor)

	Phase I	**Phase II**
Corporate Blvd.	May 8-9	May 10
Parklawn Building	May 15-16	May 17