OM Special Issue

news along the pike

Center for Drug Evaluation

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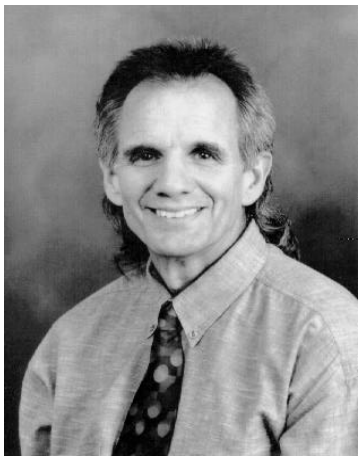
Volume 2

A Window on CDER's Office of Management

Welcome to a special supplement of News Along the Pike devoted entirely to management issues. Inside, you will find stories and updates on the new Division of Database Management, which consolidates the collection and maintenance of 10 separate data files into one organization; the hows and whys of PDUFA time reporting; news on the proposed FDA consolidation at White Oak, Md; the move in CDER to Windows 95, and the most recent news on proposed changes in Performance Management in FDA. As FY 1997 approaches, find out what the budget has in store for us. Also, since joining CDER one year ago, I have had the opportunity to appoint six veteran CDER employees into management positions and hire two new managers from outside. You will learn about them and the skills that they bring to the Office of Management (OM) in this special issue. The OM staff hopes that you find this package informative and interesting. To help keep you updated on these and other important management changes, look for an OM home page on the CDER WWW in the near future.

— Russ Abbott
Director, Office of Management



Stretching Dollar$

The OM has already begun discussions about the FY97 operating budget with organizations throughout CDER.

The starting point for these discussions began with "belt-tightening." With the Prescription Drug User Fee Act of 1992 (PDUFA) due to expire at the end of FY97 and the November elections just around the corner, the outcome of PDUFA extension negotiations is not clear. Funding for the next fiscal year remains to be determined. Therefore, the Commissioner's Office has opted to withhold additional PDUFA funds from the Centers at this time to maintain a strategic reserve.

This represents a significant change from FY96 when PDUFA funds represented nearly 40 percent of CDER's operating capital. In addition, the amount of non-PDUFA funding expected to be available to CDER in FY97 has decreased. Taken together, CDER will begin FY97 with an operating budget representing a 48.6 percent reduction in available funding from the previous year.

FDA Consolidation

So you say you've heard this before? You're right! Once again, planning is underway for the Montgomery County piece of FDA consolidation. The site currently under consideration is the home of the Naval Surface Warfare Center in White Oak, Md. If approved, this location will house the Offices of the Commissioner and Regulatory Affairs, as well as CDER, CBER, and CDRH. FDA will use about 130 of the 732 acre White Oak site.

Two agency-level task forces with representation from the Centers and the Office of the Commissioner have been formed to work with the consulting firms on the planning of both office and laboratory space needs. Some CDER employees (along with others from the other Centers involved in consolidation) have already been involved in this planning activity. Some have completed surveys for food service preferences, others talked with a group of representatives from the agency and the consulting firms who recently toured a sampling of CDER office and lab space, and a few others are serving on the two task forces mentioned above.

There are many unanswered questions surrounding consolidation. What we know now is that there is funding available for the macro-level planning currently underway and the agency's approach is to request a smaller but continuing level of funding from Congress rather than trying to fund the entire project all at one time. There are discussions taking place about the currently existing administration building located on the site and whether to tear it down and start over or renovate it as part of the project. There will most certainly be some amount of new construction of both lab and office space. Other concerns being addressed include the lack of public transportation to the site and parking. As the process continues, additional information will be provided to CDER employees through future articles like this as well as e-mail and other means of communication.

This location will house the Offices of the Commissioner and Regulatory Affairs, as well as CDER, CBER, and CDRH.

inside...

OM Creates Database Management Division

The Office of Management recently realigned its database management functions into the Division of Database Management (DDM). The main functions of DDM include maintaining and creating drug and chemical data files and technical information systems to meet the research and operating needs of CDER, preparing chemical and drug-related reports, and document handling. The reorganization will maintain and consolidate these functions by reassigning branches from the Division of Drug Information Resources (DDIR) and the Division of Management and Budget (DMB) into the new division.

The realignment includes abolishing DDIR and reassigning the two existing branches, Drug Information Analysis Branch (DIAB) and Drug Information Services Branch (DISB), to the newly created division. Also, the Document Requirements and Services Branch (DRSB) and the Product Information Management Branch (PIMB) have been reassigned from DMB to DDM.

Performance Management

Guidelines for the new Performance Management Program are currently in the final stages of the approval process and have been forwarded to FDA senior management. The proposed guidelines recommend the following:

- A new simplified standard agency plan which provides six basic employee elements and three basic supervisory elements, as well as blank or empty elements and measures for individualizing a rating to include a specific assignment as necessary.
- Three levels for rating performance on an element. However, the final rating for the plan will have only two rating levels -- Meets Performance Measures and Fails to Meet Performance Measures.
- All elements will be designated "Critical."
- There will be no annual performance award bonuses (monetary or non-monetary) linked to final ratings. However, the FDA is currently revamping its cash awards process to allow for easier and faster recognition of sustained superior performance. In addition, the agency has determined that monies available for performance bonuses in prior fiscal years will also be available in FY97.

The performance cycle will be Jan. 1 through Dec. 31.

Implementation of the new program will be Sept. 1, thus extending the current rating period to Dec. 31. Employee performance for the 15-month period will be based on performance in the current Employee Performance Management System (EPMS) as well as the new Performance Evaluation Plan (PEP). Supervisors will modify employees' current plan by changing elements and performance measures into the new PEP format. A final rating of "Meets Performance Measures" or "Fail to Meet Performance Measures" will be given after Dec. 31 and will reflect performance during the 15-month transition period. The green EPMS plans will be attached to the new PEP in order to accurately document performance during the whole rating period.

All employees and supervisors are to be trained prior to implementation of the new Performance Management Program.

Future updates will be provided as soon as the guidelines for the new program are finalized.

New Faces

Ruth Clements - *Division of Management Services* - Clements started her federal career as a clerk typist in 1978 with the National Cancer Institute of the National Institutes of Health in Bethesda. She joined FDA in 1979 in the Office of Compliance, Bureau of Drugs. From the Bureau of Drugs, Clements moved to the agency's Division of Personnel Management in 1981, where she worked in a variety of positions from personnel assistant to staffing specialist, and finally to a personnel management specialist. She rejoined CDER in December 1993 in the Office of Drug Evaluation II as a program analyst and moved to the Office of Management in spring 1995. In February she was named director of the newly created Division of Management Services.

Bob Linkous - *Division of Planning, Evaluation & Resources Management* - Linkous graduated from Duke University in 1976 with a bachelors degree in chemistry and a specialization in biochemistry. In addition, Linkous completed the premedicine curriculum. He started with FDA's then-Bureau of Drugs in 1976 as a chemist in the Division of Drug Information Resources. Beginning in 1978, Linkous worked as a consumer safety officer in the Division of Cardio-Renal Drug Products and the Division of Anti-Infective Drug Products. In 1988, he was promoted to supervisory consumer safety officer in the newly formed Division of Antiviral Drug Products. Two years later he took over the responsibility for the Center's Extramural and Service Contracts. In 1994, he was made deputy director in the Division of Management and Budget. Earlier this year, Linkous was named director for the Division of Planning, Evaluation & Resources Management.

Jennifer Lee - *Division of Planning, Evaluation & Resources Management* - In 1987, Lee graduated with two bachelor degrees with honors from the University of Maryland in finance and marketing. In 1994, she graduated with a master's degree with honors in management from Johns Hopkins University. Lee started her government service in 1987 as a budget analyst in the Office of Personnel Management's Planning and Budget Division. She joined CDER's Management Systems and Analysis Branch as a management analyst two years later. The following year she worked as a program analyst in a drug reviewing division working on project management initiatives. In 1992, Lee became the special assistant to FDA's Deputy Associate Commissioner for Public Affairs. In 1994, she was named chief of Program Administration, Compliance and Analysis for the Health Education Assistance Loan Program in the Health Resources Services Administration. In March, Lee joined OM's Division of Planning, Evaluation & Resources Management as the acting deputy director.

Ellen Johnsey - *Division of Management Services* - Johnsey has served as the branch chief, Program Management Services Branch since October 1995. She directs personnel-related programs assigned to the Recruitment Team and the Program Resources Team which impact on the effectiveness, efficiency, and productivity of the Center's mission. Prior to her present position, she served as special assistant and ombudsman to the OM director. Johnsey began her federal career in 1975 and joined FDA in 1977 as a personnel management specialist. Johnsey received a bachelor's degree in 1974 from Central Michigan University and a master's degree from George Washington University in 1977.

Gary Anderson - *Division of Database Management* - Anderson received a bach-

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...Windows 3.1 is a dead product!

Windows 95: Coming Soon To A Screen Near You!

By Lana Kostecka

Installation of Microsoft's Windows 95 on about 1,500 personal computers (PC) in CDER is in high-gear and is expected to be completed by the end of September. Why all the fuss?

Windows 95 provides users with better memory management, plug and play, 32-bit compatibility, and it's faster than Windows 3.1. Better memory management allows for more available resources for programs. Plug and play enables effortless hardware installation. The 32-bit capability permits true multitasking, allowing users to use multiple applications simultaneously. It also allows users to work more efficiently because virtual memory is used by 32-bit applications.

Another good reason for installing the new program is that software and application developers are not upgrading or enhancing Windows 3.1 or DOS applications anymore. CDER, therefore, will have to phase out its support of DOS and Windows 3.1 products.

The Windows95 installations on Pentiums and 486/100s have been going better than expected although DISD is still running into problems. Some delays are expected as staff install new equipment.

Windows95 has already been installed on most PCs in Corporate and WOCII. DISD is in the process of installing the software in Parklawn and will then load it on the PCs in the remaining buildings.

The experience with 486/66s has not generally been good. What the division plans to do is load Windows95 as quickly as possible all Pentiums and 486/100s in the Center. We'll then go back and attempt to do a modified installation on the 486/66s.

DISD is now installing Pentiums for Automated Management of Files and EES, or Establishment Evaluation Systems, which means that virtually all Office of Review Management reviewers and most Office of New Drug Chemistry chemists as well as some in Compliance will be getting new equipment. Nearly all other PCs in CDER should be upgraded to 486/66s over the next several months.

But installation of Windows 95 is a tedious process that, depending on the amount of software that the individual user needs, can take an experienced technician up to four hours to install. So, please, be patient while DISD tackles this enormous undertaking. There will obviously be disruption as the software is loaded on each PC, although DISD will attempt to keep that to a minimum.

IP, or Internet Protocol, addresses are provided for PCs with WINDOWS95 within two weeks of installing the software. The World Wide Web is easy to access with WINDOWS95 and the IP address.

If you use Windows 3.1 now, moving to Windows 95 is relatively simple and easy to learn. DISD will be providing a two-hour demonstration of Windows 95 on the day of installation. Topics will include entering and exiting Windows 95, working with the desktop, taskbar, and start menu, switching between applications, customizing Windows 95, utilizing screen savers with passwords and security issues, file management, mapping to network drives, utilizing the recycle bin, and troubleshooting system lockup problems. A handout of transitional topics (from Windows 3.1 to Windows 95) and a Windows 95 trifold will also be provided with the demonstration.

Please take advantage of this training since it was designed *exclusively* for CDER!

The writer is Computer Specialist in the Division of Information Systems Design.

A New Look for OM Leadership

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elor's degree in accounting from the University of Illinois (1977) and a commission in the Air Force in 1978. He held various budget and accounting positions before being selected for graduate school at the Air Force Institute of Technology where he received a master's degree in Operations Research in December 1983. After briefly working with a Department of Defense contractor, he was hired by OM in February 1993 where he took over the responsibility of the Drug Registration and Listing System. Anderson currently supervises the Product Information Management Branch in the Division of Database Management which, works in conjunction with a contractor to review, enter, correspond, and analyze industry supplied data about the commercial drug market.

Tom Payne - *Division of Planning, Evaluation & Resources Management* - Payne started with the government in 1971. He has 21 years of experience that includes seven years in the Army and three years with FDA. He has been a telecommunications management staffer, auditor, budget analyst, supervisory accountant, management analyst, and operations research analyst. He has worked for the White House Communications Agency; U.S. Army Audit Agency, Letterkenny Army Depot, Pa.; Depot System Command, Ft. Richie, Md.; and Office and Planning and Evaluation (FDA). Payne has a bachelor's and a master's degree in management from Shippensburg University. In April 1996, he was selected branch chief, Planning & Resource Management Branch in the Division of Planning, Evaluation & Resources Management.

George (Ross) Bolger - *Division of Database Management* - In 1974, Bolger came to the Bureau of Drugs, Division of Drug Information Resources, as a pharmacist. Two years later he joined the Office of Compliance's Drug Defect Reporting Program. In 1987, he and the program were transferred to the Office of Epidemiology and Biostatistics where he redesigned and managed a new marketplace surveillance program known as Drug Quality Reporting System (DQRS). He joined OM in October 1995 as chief of the Document Resources Services Branch in the Division of Database Management. Bolger has a bachelor's degree in pharmacy from the University of Connecticut.

Jim Cockran - *Division of Management Services* - Cockran joined the Navy in 1967 and received an honorable discharge in 1969. He worked for the Department of Agriculture before joining FDA's Facilities Branch in February 1971. He worked as a maintenance mechanic leader at Beltsville Research Facility (BRF) and attended schools for building operations and maintenance. In May 1988, Cockran moved to FB-8 as an assistant building manager. In June 1990, he was appointed as a facilities specialist in the Parklawn building and worked as a team leader. In April, Cockran was named branch chief, Facilities Branch with the Division of Management Services.

Spread the Word

OM has held a series of meetings with CDER management staff that discussed CDER's budget picture for FY97. Topic discussions identified centrally funded items such as information technology, training, library funding, renovations, and other items.

With direction from the CDER's Senior Management Team (SMT) and management staff in each CDER organization, the Office of Management developed a scenario that outlines the minimum amount of money needed by some of the centrally funded areas. Remaining money will be distributed to the offices on a per capita basis. A critical part of this approach was to identify what activities were left without funds, such as those previously paid for with 100 percent PDUFA funding.

Armed with this information, SMT can now begin to make an informed decision regarding the available resources in FY97 and the funding/non-funding of program priorities. Pending review and decision, CDER's budget will be made final and distributed to the offices before the beginning of the fiscal year on Oct. 1.

User Fee Act Time- Reporting: *Why do we have to do it?*

FDA entered a new era on Oct. 29, 1992, when Congress passed and the president signed the Prescription Drug User Fee Act of 1992 or PDUFA. That bill, public law 102-571, changed the landscape in CDER and CBER. Fees are charged to all persons who submit human drug applications for review. In addition, annual fees are assessed for each prescription drug product and prescription drug manufacturing establishment. The Act also gives FDA specific deadlines for reviewing drug and biologic applications and for taking other application-related actions.

The two Centers are allowed to charge for specific activities related to review of human drug applications. The law covers all major activities in the CDER new drug review process, pre-approval inspections of prescription drug establishments and other facilities, research conducted in connection with the review process, and necessary support activities. In order to receive the resources from the fees, FDA contracted with Arthur Andersen and Company in 1993 to develop a methodology that could justify our resource needs. That effort resulted in the requirement by the Office of Financial Management for our collection of user fee time reporting data.

The two Centers are allowed to charge for specific activities related to review of human drug applications.

A second time study was conducted through a joint effort of CDER staff and staff from the Andersen consultants in spring 1995. One recommendation was for a more automated method to meet FDA requirements for a quarterly reporting system. In the fall of 1995, a team from OM worked together to develop and implement an on-line system designed to capture the time spent by employees who are actively working on new drug application reviews and related activities. This on-line system

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User Fee Act Time- Reporting: *Why do we have to do it?*

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is used by all the drug product review divisions in the Office of Review Management, the biometrics divisions in the Office of Epidemiology and Biostatistics, the new drug chemistry divisions in the Office of New Drug Chemistry, and the pharmaceutical evaluation divisions in the Office of Clinical Pharmacology and Biopharmaceutics.

A separate system was established to regularly collect information on the estimated percentage of user fee activities by those groups that are not required to report time spent on user fee activities. The groups include support staff and divisions from the Office of the Center Director, Office of Management, the Office of Training and Communications, and the Office of Review Management. Other support divisions that are non time-reporting units include the Division of Drug Marketing, Advertising, and Communications; the divisions of the Office of Compliance; the Division of Over-the-Counter Drug Products; the divisions of the Office of Testing and Research; the Division of Pharmacovigilance and Epidemiology; and the Quantitative Methods and Research Staff of OEB. Together, these two systems are referred to as the CDER PDUFA Time-Reporting System which is used by CDER to justify the allocation of user fees.

Staff from the Division of Planning, Evaluation, and Resource Management (formerly the Division of Management and Budget) edit, analyze, and consolidate the data collected from this total system into a report that is provided to the FDA Office of Financial Management (OFM). This report shows the percentages for each of the cost groups of the Center. Each time-reporting division receives a user fee percentage and contributes toward the calculation of the weighted-average percentage for its office and the Office of the Center Director. Each non-time-reporting division receives its calculated user fee percentage and contributes toward the calculation of the weighted-average percentage for its office and the Office of the Center Director. All data from the reviewing divisions that is collected by the on-line system is available by the Office of Management for any required audit by FDA, DHHS, or the General Accounting Office.

CDER's Spread to New Sites Spawns Parklawn Backfill

Many of you have been hearing for months about CDER plans to reuse some of the space in the Parklawn building that was vacated when the Center moved Offices of Drug Evaluation IV and V to new office space at Corporate Blvd. Well, after many months and many variations, an agreement has been reached by CDER and FDA on a backfill plan. Much of the credit goes to Deputy Center Director Murray Lumpkin, M.D., for pressing the agency for additional space in the Parklawn building so that the Divisions of Gastro-Intestinal and Coagulation and Pulmonary Drug Products would not have to move from their present floors. Instead, the division will grow into additional space adjacent to their current locations. As has been done in Woodmont II and Corporate Blvd. locations, there are also plans to physically house the collocated staffs of biopharmaceutics, biostatisticians and chemists with their appropriate review divisions. Also as part of the backfill will be the consolidation of the Office of Training and Communications from its current locations in three buildings to one floor in Parklawn. The Office of Pharmaceutical Science will also do some rearranging in keeping with its post-reorganization structure.

New Name, Improved Game

The Division of Management and Budget (DMB) has been renamed the Division of Planning, Evaluation, and Resource Management (DPERM). The two remaining branches in DPERM have also been renamed. The Management Systems and Analysis Branch (MSAB) is now the Management Analysis Branch (MAB), and the Program and Resource Management Branch (PRMB) is now the Planning and Resource Management Branch (PRMB). DPERM will continue to maintain and/or perform financial and budget activities, extramural programs, management analysis, and other related management functions such as Federal Managers Financial Integrity Act (FMFIA) and time reporting in CDER.

John Gamble Harter Dies, *Guided Pilot Drug Program*

John Gamble Harter, M.D., 69, former CDER Pilot Drug Evaluation Staff director, died July 11 at Shady Grove Adventist Hospital. He had liver cancer.

Dr. Harter joined FDA in 1973 after working as a medical researcher at Harvard University and for private pharmaceutical companies. At FDA, he was the supervisory review officer for cardiovascular and anti-inflammatory drug products, narcotic, and nonnarcotic analgesics, anesthetics, and drugs to treat addictive disorders.

Harter served as pilot drug evaluation staff director from its inception in 1989 until his retirement in 1994. After retiring, Dr. Harter worked as a consultant to pharmaceutical companies. The pilot program was established to improve drug development and to cut review time for new applications.

"He was innovative in the drug review process. Not always to the liking of everyone inside or outside FDA," said Dottie Pease, a CSO who worked with Dr. Harter for 15 years.

He also initiated a peer-review process that eliminated supervisors in pilot drugs.

Instead, qualified staff members performed leadership functions and helped solve scientific problems on a rotating basis. He developed the multiple signature blocks so that all review team members signed an action letter. He was an innovator of project management techniques as part of an effort to get a better handle on NDA reviews.

"He believed in the importance of the individual reviewer and worked to make each reviewer a respected team player, " Pease said.

Survivors include his wife, Mary Douglas Tyson, who works in the FDA Commissioner's Office of International Affairs, and five children from a previous marriage.

AMF Corner

Approved Labeling Repository

By Dave Isom

One of the objectives of the Automated Management of Files (AMF) project is to establish a centralized electronic repository of approved drug labeling. And one AMF component underway is moving toward that objective.

The Approved NDA Labels Repository is now available through your desktop PC and will eventually contain all current approved final printed labels (FPLs) along with their approval letters. Carton and container labels will in time also become part of the repository.

The repository now contains all 1994 and 1995 approved package insert labeling along with their approval letters. Scanning of 1996 labeling is now underway. The repository was started by scanning labels into an Excalibur fileroom. However, CDER is working with the Pharmaceutical Research and Manufacturers Association (PhRMA) to develop a way that industry can help FDA maintain the repository by submitting approved labels in Adobe's PDF format. This would greatly reduce the need to scan labels. PhRMA has provided samples of these PDF labels, both package inserts and carton labels, for evaluation by the labeling team and test group. The samples looked great and were identical in every way to the paper labels (including colors). A PDF labeling submission pilot is being planned for September.

The labeling repository will help CDER staff quickly locate current labeling, and will permit searching across multiple labels. In the near future, the repository should permit electronic label comparisons. Customized training classes are now available each month. Watch your e-mails for the announcements. If you would like access to the repository, please contact Helen Mitchell through your e-mail.

Thanks to the commitment and initiative of the labeling team members and the repository test group. Without them, this effort could not have happened.

The writer is the project manager for AMF.

Chemical Abstracts Substructure Searching Now

The Medical Library has created a new Chemical Abstracts (CA) substructure searching service for CDER reviewers. Reviewers can request substructure searches of the CA registry file which can be used to supplement substructure searches of chemical files which are done routinely for all new chemical entities received in the Center and for any compounds requested on an individual basis. The files contain information on all chemical entities ever received in CDER in an Investigational New Drug or New Drug Application. The CA Registry file expands on this by providing information on over 14.5 million unique substances identified for CA from 1957 to the present.

Chemists Rona Sun and Kay Kim will make substructure searches and the requester will receive records for chemicals structurally similar to the one requested. .

Call either Rona or Kay directly on 3-3910, or e-mail -- SUNR or KIMK, respectively in MEDLIB. **— Kathy Kruse**

New PhRMA President Selected

The Pharmaceutical Research and Manufacturers of America (PhRMA) announced its unanimous selection of Alan F. Holmer as president of the industry association effective July 15.

PhRMA said Holmer's experience in the legislative and executive branches of government and his global perspective make him an outstanding advocate for the research-based pharmaceutical companies.

Holmer is an honors graduate from Princeton University and earned a law degree from the Georgetown Law Center. He is a partner with the Washington, D.C. law firm of Sidley & Austin, where he heads the firm's international trade practice.

Gerald Mossinghoff, who has been PhRMA's president for 11 years, is retiring.

However, Mossinghoff will stay on after July 15, as senior counsel to aid in the transition.

PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies.

— Marcia Trenter

Web World

By Marcia Trenter

A remarkable five months, from conception to implementation, reflects CDER's cross-functional teamwork at its best, says OTCOM's Director Lucy Rose.

On line? Check us out! Your comments will help to develop what is certain to become a frequent reference for all our constituents. For questions or comments please contact CDER's Webmaster, Paul Stauffer, via e-mail (STAUFFERP) or dial 443-1538.

Web Warriors may find the following addresses useful as they scamper through the electronic frontier.

- FDA - http://www.fda.gov
- HHS - http://www.os.dhhs.gov
- NIH - http://www.nih.gov
- CDC - http://cdc.gov

Need more information regarding CDER's home page? Please reference the following. E-mail dated June 28 from Carol Assouad, Acting Director of the Medical Library and CDER's home page committee chair. News Along the Pike, May 15 edition. FDA Consumer, June edition. FDA Today, June edition. Welcome to the Internet FDA, April publication (FDA) 96-1250.

news along the pike

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