news along the pike

Center for Drug Evaluation and Research

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R1

From the Director

'96 Priorities: Beat PDUFA

By Janet Woodcock, M.D.

The Center turned in an outstanding performance in 1995, a year of successes of which we can all be proud. The new drug review group far exceeded its '95 user fee performance goals and put to rest the notion that FDA review is synonymous with "slow." The generics staff produced a remarkable number of reviews and approvals as their workload escalated and their program was downsized. New OTC products appeared in the stores. CDER's reorganization moved into its final stage, we opened a new building and contributed major initiatives to reinvent government or REGO. The Intenational Conference on Harmonization (ICH) meeting in Yokohama, Japan capped a two-year effort by many Center staff in negotiating international standards. Many other programs and initiatives too numerous to mention made significant progress. People from all parts of the Center contributed to making this success happen. Congratulations and thanks to you all!

"People from all parts of the Center contributed to making this success happen."

This column lays out CDER's priorities for 1996. Almost everyone in the Center has too much to do: competing priorities are the order of the day. In the face of this kind of workload, it is important to focus on what is really important. It is also essential to *finish* the top priority items rather than working a little on everything and completing nothing. As you weigh your personal and team priorities,

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Advertising and Promotion

Surf's Up at Cyber Beach

DDMAC Surveillance Begins on Web

By Melissa M. Moncavage

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has recently added a new dimension to its surveillance of drug advertising and promotions on the Internet. Because it has tremendous potential impact, some consider the information highway, specifically the World Wide Web, the hottest topic in drug promotion this year.

The astronomical growth in personal computers over the past decade has ignited interest in the Internet and a subsequent explosion of new web sites. Some 24 million people in the United States and Canada are using the Internet, according to a demographic survey released last October by Nielsen Interactive Services.

So it's understandable why many of the Web sites already include ads and, what appears to be, promotional labeling for prescription drugs and other FDA-regulated products.

Two characteristics make promotion on the Web unique. First, the Web eliminates the distinction between consumer and professional promotion and information. Consumers can access professional information more easily than with traditional media. Second, the Web is fluid. With hypertext, boundaries are often blurred and distinctions between Web sites can be hard to define. It may be difficult to determine whether an ad is false and misleading or has fair balance if the boundries are not clear.

DDMAC has received questions ranging from technical details to broad-scoped concerns from the pharmaceutical industry, law firms, consultants, and other groups involved with advertising and promotion of drugs. Among the questions most frequently asked are:

1. What is advertising and what is labeling on the Web? If DDMAC considers something advertising, will it be regulated as print or broadcast?
2. Will all Internet information about prescription drugs be considered direct-to-consumer advertising, even if it's

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Management Eyes Mission

Center Leaders Retreat, March 17-19

CDER Senior Management retreated March 17-19 to define the process of "transforming" CDER, specifically to discuss issues of leadership and change. The attendees included the senior management team, the Office Directors, senior management officers (Dave Durant, Helen Winkle, Tanya Abbott) and a few staffers from The Office of Training and Communications. The meetings were held at Lansdowne, near Leesburg, Va. This was the first step in defining where we're going as a Center and how we should get there. The long term objective is to actively engage every Center employee in this process of defining a vision for CDER and bringing about the changes needed to realize that vision. The Center is being assisted in this effort by the Council for Excellence in Government. Look for a summary of the three-day event in the April issue of The Pike.

— Debbie Henderson

inside...

From the Director

Beating User Fee Goals Tops CDER's 1996 Prioities List

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please consider how they fit into the Center's overall priorities. This is not to say that Center staff should drop everything and work exclusively on these four areas: naturally, programs are responsible for managing their workload. Additionally, I hope we all understand that matters involving human health and safety, or emergency needs, always take precedence over other business.

CDER 1996 Priorities

1. Exceed user fee goals
2. Improve management
3. Complete CDER reorganization
4. Implement information technology (IT) initiatives

"Exceed user fee goals," is self explanatory. Most of us understand that the REAL challenge under user fees is how to institutionalize the goals, to fit them into our program without compromising our other areas of responsibility. As part of our mission, we are committed to getting priority drugs to patients quickly, and also to providing prompt and efficient review of applications under the user fee program: however, the protection of human subjects, the monitoring of marketed drug safety, and the provision of advice during drug development, for example, are also very important. Nevertheless, we know that the outside world is fixated on review times, and that our review performance has been our best defense against attempts to dismantle the drug regulatory program. Therefore, it remains the utmost priority to exceed the goals. This program "sunsets" at the end of FY 1997 and renegotiations for future user fees will take place against the backdrop of the FY 1996 performance.

> ***"The new drug review group far exceeded its '95 user fee performance goals and put to rest the notion that FDA review is synonymous with 'slow'."***
>
> **— Janet Woodcock, M.D.**

The second priority, "improving management," has been set by CDER's senior managers as our top strategic, as opposed to tactical, priority. There can be no doubt that we are in a time of smaller government and shrinking programs. We must perform as efficiently and effectively as possible if we are to accomplish our broad mission of drug regulation. There will be a Center-wide effort, starting in March with the CDER Office Directors, to re-evaluate our mission and the way we match our resources to it. This effort will ultimately involve everyone in the Center. In the meantime, I am asking everyone to "think locally" and to assess the process and people management in your part of the Center, with an eye toward improvements. Look at the way we manage processes, (e.g., project management, SOP's, tracking systems), work content (e.g., guidances, "Good Review Practices," policies) and people (e.g., training, adequate supervision, accountability, rewards) and think about how any of these can be improved. I know that we can make enormous gains in efficiency through better management.

The third priority, "completing the reorganization," is about finishing something and moving on. We are reorganized: it is everyone's responsibility to tie up the loose ends and do the fine-tuning, to avoid the ongoing conflicts over jurisdiction or roles that can sap an organization's vigor.

Our final priority relates to information management initiatives. Better information management is of crucial importance to CDER. Much of what we do is based on obtaining, evaluating, storing, summarizing or providing information. The move from paper-based to electronic processes is a painful one, requiring the investment of scarce dollars and resources. Many of you will be asked this year to assist in designing, testing, or evaluating systems. Please help when you can. More information about our progress in the information management area will be disseminated soon.

Not all of CDER's priorities will apply to everyone. For example, those not involved in the user fee program will not need to focus on priority number one. This should not inhibit them from making contributions to other priority areas, nor from prioritizing their own initiatives based on Center-wide priorities. There are opportunities for everyone to make valuable contributions.

Surf's Up at Cyber Beach

DDMAC's Web Watch

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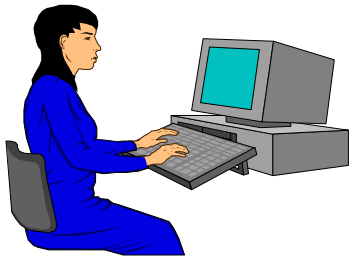
intended for health professionals?
3. How will DDMAC deal with interactive communications on the Internet, such as chat rooms that could be sponsored by drug firms that get into discussions of unapproved uses? Would these be considered unsolicited requests by drug firms?
4. How will DDMAC regulate information that originates from a file server in another country?
5. How will DDMAC view hypertext links between Web sites? Which links will pharmaceutical companies be responsible for when they advertise or provide information about their products?

DDMAC is working with FDA's Office of Policy and other centers to answer these



questions as well as questions about health fraud on the Internet. And FDA is not alone. The Federal Trade Commission recently held a hearing on the effect of new technologies on advertising via the Internet. Attorneys General from a number of states, CEOs, consumer groups, and academics all testified before the panel and offered a range of views and opinions that will play some role in shaping future Internet policy on drug advertising and promotion.

If, while surfing the web, you spot prescription drug promotion that concerns you, please contact DDMAC's Melissa Moncavage, e-mail MONCAVAGE, or call 301/827-2828, and alert her. If the promotion looks like health fraud, contact Roma Egli in Non-Traditional Medications by e-mail at EGLIR or 301/594-0070.

Happy surfing!

The writer is a Public Health Advisor and the Internet contact in DDMAC.

Pediatric Corner

CDER Review Finds No Misuse of Fentanyl

By Barbara Palmisano, M.D.

Post-marketing review by FDA has found no evidence of adverse events as a result of misuse of Fentanyl Oralet (oral transmucosal fentanyl). The review stemmed from the 1993 controversial approval of the preoperative sedation for painful procedures that is delivered to pediatric patients in lozenge form resembling a lollipop. The review was completed recently and presented to the Anesthesia and Life Support Advisory Committee in December 1995.

There were no spontaneously reported adverse events during the initial year of marketing, which underscores the belief that the drug is being administered properly. The data from Phase IV studies, mostly in operating room environments, showed that there was a small incidence of respiratory depression which is not unexpected for a drug of this class. However, all cases were appropriately managed without harm to the patients.

Fentanyl is a potent opioid well known in anesthesia and intensive care for intravenous use. Several features of this formulation and its approval are unique. First, it was developed specifically for pediatric patients although adults were also included in the study. Seventy percent of patients in the NDA studies were pediatric. Second, it is a means to deliver a potent sedative narcotic in a palatable dosage form. The drug is delivered in a raspberry flavored lozenge on a stick. It is intended as an alternative to 'shots' for pediatric patients before surgery and before certain emergency room procedures such as, suturing lacerations and reducing orthopedic fractures and dislocations. It can also be used for children with chronic diseases before painful procedures such as bone marrow aspiration.

When the drug was approved, it was agreed that the labeling, packaging, and introduction of the product should make it clear that it was not a frivolous medicine and not to be used where there is no clinical need for an opiate effect. The package insert specifies in detail the conditions for proper use of the product which limits its use to the hospital setting with monitoring by individuals trained in management of the pediatric airway and immediate availability of resuscitation

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Reviewers' Corner

Efficacy Review Problems and Possible

By Ana Szarfman, M.D., Ph.D.

As a medical reviewer of anti-infective drugs I evaluated large amounts of data and identified several patterns of data "mis-presentation." In this article I will briefly describe factors that can significantly alter estimates of treatment failures in clinical trials of anti-infective drugs. I also describe some exciting new methods being developed to help identify these problems and expedite the review process.

Examples of mis-presentation of efficacy data include:

1. Treatment failures that occur outside the "appropriate time windows" and are not included in the final analysis as "failures" when clinically it would be appropriate to do so.
2. Patients assessed as "cures" even after being switched to alternative treatments for the same symptoms or disorder.
3. Patients assessed as "failures" receiving in addition an "unassessable" or an "evaluable for safety" code. These additional codes exclude these failures from the "evaluable for efficacy" category, and thus undermine intent-to-treat analyses.
4. Patients who are classified as "cures" even though investigators describe them as "treatment failures" in Case Report Form notes.
5. Investigator's original outcome assessments changed by a medical monitor without documentation that the investigator agreed to the changes.

These practices can have a significant impact on the reviewer's analysis of drug efficacy, especially the timeliness of the review. Because only a select group of failures are identified, the role that concomitant factors, such as, medical conditions and medications, may have in decreasing the therapy's efficacy may be underestimated. Mis-presentations usually make it more difficult to show differences,

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About Reviewers' Corner

The purpose of this column is to allow reviewer communication of information or opinion about the process of medical and or statistical review. Articles, supplements, and letters are invited. CDER medical reviewers Grant Williams and Alexander (Zan) Fleming, and CDER statistical reviewer Steve Wilson, have agreed to share editorial responsibility.

Communication may be addressed to WilliamsG on e-mail. Documents may also be placed in a directory on the X drive (X:\MSCorner) on Pathworks. Subdirectories will be developed for various discussions. Feel free to initiate a subdirectory in the MSCorner directory. Daily, we will back up contents of those subdirectories that we have created. In addition to the MSCorner directory on the X drive, there are also Bulletin Boards in All-In-One (command = 'GPC') that may be of interest to reviewers, including the CANDA and DAREVIEW bulletin

Pediatric Corner

CDER First Year Review Finds No Misuse of Fentanyl Oralet

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equipment.

An innovative aspect of approval was a commitment made by the sponsors, Anesta Corp and Abbott Laboratories, to restrict marketing and advertising to 400 target hospitals during introduction of the formulation and to provide a mandatory educational program on the use of the product to those hospitals. FDA committed to review safety data, in particular for evidence of inappropriate off-label use, after one year of marketing and prior to wider distribution.

However, after reviewing the Phase IV studies, in December the advisory committee recommended that the marketing restrictions be relaxed in view of this good safety record to date. The panel said the company should be able to market the product to all hospitals and that it should be able to advertise in medical specialty journals. The committee further advised that the company should continue to provide its educational program to a hospital prior to introduction of the product.

The Division of Anesthetics, Critical Care and Addiction Drugs and the Division of Drug Marketing, Advertising and Communications continue to work closely with the sponsors to develop safe methods of introducing potent sedative drugs to the pediatric community.

The sponsors are to be commended for their attention to the pediatric patient as well as for the excellent educational program on pediatric sedation that they have developed to accompany this product.

The writer is a Medical Officer in the Division of Anesthetic, Critical Care, and Abuse Drugs and a representative to CDER Pediatric Subcommittee.

Reviewers' Corner

Efficacy Review Problems and Developing Possible Solutions

(Continued from page 3)

except when they differentially occur in one treatment group and not the other.

Reviews requiring the detailed examination of sponsor's assessments of "cures", "failures", and evaluability are difficult and time-consuming. If it becomes apparent that there are some good reasons to mistrust these "mis-presented" data, our faith in the sponsor's statistics and conclusions can be severely shaken -- complicating decisions on the drug.

It is possible that we may be able to detect such problems more easily. We are pilot testing a new interactive computer graphics-based system for summarizing and graphically displaying population and individual patient laboratory data. Eventually similar methods might be applied to other safety and efficacy data. We have made progress in displaying the temporal relations between treatment, laboratory findings, and adverse events, for each patient in an NDA. This has been done with small multiple graphs utilizing a common format so data can be compared. Medical conditions, signs and symptoms, concomitant and additional treatments, investigator's appraisals such as cures or failures, and evaluation codes could be added. These graphic summaries may help simplify the interpretation of clinical trial data and identify the critical factors that might be involved in reduced efficacy.

These new visualization methods should perhaps provide us with the means to efficiently work with sponsors to prevent problem areas and to correct any differences in interpretation of the data submitted.

The writer is now working as medical reviewer in the Office of Epidemiology and Biostatistics.

Workshop Set on Rheumatoid Arthritis

By Rose Cunningham

The Intercenter Rheumatology Working Group, which has representatives from CBER, CDER, and CDRH, has been working on a draft guidance for rheumatoid arthritis (RA). This document will be discussed during a public workshop on Wednesday, March 27, 8 a.m. to 6 p.m., at the DoubleTree Hotel, 1750 Rockville Pike, Plaza 1-2. The workshop will enable experts in rheumatology clinical trials and interested representatives from industry, academia, and the public to exchange ideas on developing and assessing new treatment modalities for RA.

Participation is free but advance registration is recommended. Fax your registration to Rose Cunningham at 301/594-5493. Include your name, title, organization, address, and telephone number. After consideration of all data, information, or views submitted on the draft guidance, FDA will issue a final guidance document and announce its availability with a notice published in the Federal Register.

"Skills For Success" Workshop Set For Secretaries and Support Staff

OTCOM will conduct a pilot workshop to provide an overview of topics identified by CDER supervisors, support staff, and focus groups as having the greatest potential benefit for improving productivity and enhancing relationships between supervisors and co-workers in the Center. It will be held on Wednesday, April 17,
9 a.m. - 4 p.m., Parklawn, Conf. Room K.
Topics to be covered include:

* internal and external communication
* team building
* telephone techniques
* professional image

ELIGIBILITY: GS 1-7 secretaries and support staff who have been in CDER for 3 years or less. Limited space available.
TO APPLY: Send a completed HHS-350 Form through your first-line supervisor by Wed., April 3rd to the Div. Of Training and Development/OTCOM HFD-220, Room 9B04, Attention: Sarah Thomas
Questions? Call 443-2200.

FDA Drug Review: Faster, Quicker, Smarter

By Jeffrey Yorke

On March 13, the Division of Antiviral Drugs approved Crixivan, an AIDS drug, in a mere 42 days after Merck filed its application with FDA. The brisk review and subsequent approval broke FDA's record review of 72 days set by the same division just 12 days earlier. On March 1, the Antivirals division approved Abbott Laboratories
Ritonavir, also an AIDS therapy to battle HIV infection.

Half of the products on FDA's Top 10 list of fastest reviewed new molecular entities are drugs to treat HIV-related illnesses. (See Top 10 list below.)

Crixivan, a protease inhibitor delivered in 200mg and 400mg capsules, is approved for the treatment of HIV infection in adults when antiretroviral therapy is warranted.

For the review staff assigned to the Crixivan (indinavir sulfate) (NDA 20-685) application, it was a grueling time — "a monthus horribulus," cracked Consumer Safety Officer Deborah Kallgren. But, she added, "the superb review team held to the super accelerated review timetable with unsurpassed tenacity."

The review team worked nights and through the weekends to get the job done. The team included Stanka Kukich, Paul Liu, Ita Yuen, Nara Battula, Paul Flyer, Kellie Reynolds, Rachel Behrman, Chi-Wan Chen, Jim Farrelly, Jim Ramsey, Lisa Kammerman, Janice Jenkins, Tony DeCicco, Tony El Hage, Russ Fleischer, Nancy Sager, and David Doleski. A nod also goes to the Advisory Committee members for their preparation and application review.

The faster review times are evidence that the Prescription Drug User Fee Act (PDUFA) of 1992 has been effective in allowing the agency to hire and train seasoned health professionals to review new drug applications.

FDA's Top 10 Fastest NME Approvals

Application	Drug	Sponsor	Indication	Date Approved	Days
(1) NDA 20685	INDINAVIR	MERCK	HIV Infection	3/13/96	42
(2) NDA 20659	RITONAVIR	ABBOTT	HIV Infection	3/1/96	71
(3) NDA 19779	IOPIDINE	ALCON	Prevent Intraocular pressure	12/31/87	87
(4) NDA 20628	INVIRASE	ROCHE	HIV Infection	12/6/95	97
(5) NDA 19655	RETROVIR	GLAXO	HIV Infection	3/19/87	107
(6) NDA 20564	EPIVIR	GLAXO	HIV Infection	12/17/95	133
(7) NDA 20262	TAXOL	BMS	Mestastatic carcinoma	12/29/92	160
(8) NDA 18780	HUMULIN-R	LILLY	Diabetes	10/28/82	162
(9) NDA 20599	RILUTEK	RPR	Amyotrophic lateral sclerosis	12/12/95	166

CDER's Hot Drug Review Times Impress Hill

By Murray Lumpkin, M.D.

Even FDA's most vociferous critics had to admit during a Congressional hearing last month that the agency has shown it can deliver when resources are provided; when there is management commitment; reviewer dedication and competence; and when an accountability system in place.

During a Feb. 21 hearing on a proposed bill to reform FDA held by the Senate Committee on Labor and Human Resources, committee members were reminded that CDER had a 96 percent on-time performance on the original NDAs in the FY94 user fee cohort; it was an achievement that even beat the agreed user fee goals by three years. The committee, chaired by Sen. Nancy Kassebaum (R-Ka.), heard testimony from FDA Commissioner David A. Kessler, M.D. and Center Director Janet Woodcock, M.D. The two physicians often referred to the *present* performance level of our reviewers and it was clear that the Center's stellar performance had impact on the hearing. The faster reviews were performed without sacrificing FDA efficacy and safety standards, a fact that also did not go unnoticed at the hearing. While many issues were discussed, this is an accomplishment for which we can all be extremely proud.

The dedication and professionalism with which CDER staff has approached the user fee goals over the past several years really were key elements in keeping the hearing focused and collaborative, rather than having it become the oversight berating it could have been had we not been performing at this high level.

You should all be extremely proud. Thank you again for your dedication and professionalism. It continues to make a real difference in many, very important ways to you individually, to the agency, to industry, and, most importantly, to the American public.

Obviously, we could not have made the 96 percent on-time review performance without the dedication of reviewers in all divisions and in the areas outside the divisions that are part of the application review team. There are four very special efforts that add to the public's perception that we are a Center that is responsive, especially to the needs of those with diseases that are life-threatening and for which other therapies often do not exist. They are: the on-going efforts by Anti-Viral Drugs to review HIV therapies in very rapid time frames; Neuropharmacologic Drugs' performance on the Riluzole review; the effort by Metabolic and Endocrine Drugs on the alendronate review; and the on-going work by Oncologic Drugs, which now has no pre-PDUFA applications for cancer drugs overdue and no PDUFA FY93, 94, or 95 applications for cancer drugs overdue. In addition, no pre-PDUFA or PDUFA efficacy supplements for cancer drugs are overdue, and there are no NDAs for cancer drugs with a due date in the next two months. With that clean plate it's hard to argue that CDER is holding up cancer drugs for which Americans are waiting.

The writer is the Deputy Director for Review Management.

Good Review Practices Initiative

Pilot Mentoring Program For New Reviewers

By Ron Lieberman, M.D.

More than 75 CDER staffers nominated as mentors, along with some of their supervisors and division directors, attended the first "New Mentors Workshop" on March 4 in the Parklawn building, officially marking the start of the new CDER mentoring program. The mentors are a select group of experienced reviewers nominated by their division and office directors.

The mentors represent a broad spectrum of the multi-disciplinary review team at CDER including medical officers, CSO's, biostatisticians, epidemiologists, chemists, pharmacologists, biopharmacists, scientific investigators, etc.

In presenting her "Rationale for the Mentoring Program," Center Director Janet Woodcock, M.D., underscored the unique value of direct "hands on" one-on-one teaching. She said the mentoring program is an important link in the Good Review Practices (GRP) initiative. She called attention to the need to develop ways to recognize mentors for their valuable contributions to the review process and noted that the program will help CDER achieve its organizational and performance goals.

While praising the dedication of staffers who had begun the program, Dr. Woodcock also pledged her support to the new mentors and the new pilot program.

Office of Training and Communications Director Lucy Rose recounted the genesis of the mentoring program in the GRP Track 11-sponsored new and experienced

reviewer retreats held 11 months earlier.

Other workshop topics included an overview of the mentoring program by Nancy Smith; an overview of new reviewer training by Heidi Jolson; mentor checklists discussed by Anthony Proakis; computer access, parking space, and office space was discussed by Jack Pevenstein; and Charles Ganley, M.D. discussed, review requirements and resources. Medical reviewer Lisa Rarick, M.D. presided over an interactive panel, and I provided an overview of mentor/reviewer resources.

The mentoring program and the training workshop were developed by the Mentor Implementation Working Group (MIWG), chaired by Charles Ganley from the Division of Cardio-renal Drug Products. The program's goals are to promote the transition of new reviewers into CDER and augment the mentoring capabilities of the Center. Expected benefits include improved productivity and performance by new reviewers (proteges).

The workshop was coordinated by Lisa Rarick, chair of GRP Track 11, and me, the Mentor Coordinator for CDER from the Division of Training and Development (DTD).

As part of the process of continuous improvement and review, over the next few months a session will be held for mentors and new reviewers to share their experiences. CDER mentors could become important points of contact with academic institutions and clinical investigator training programs such as the one begun at Beth Israel/Harvard/MIT/CDERand private industry.

The workshop received very positive feedback and evaluations from the participants. The event was videotaped and is available through DTD to interested CDER staff.

The writer is the Mentor Coordinator for CDER from the Division of Training and Development (DTD).

CDER Locator To Go On-Line Next Month

By Rixie L. Scott

The Division of Management and Budget (DMB), Management Systems and Analysis Branch (MSAB) is trying to make your working life a little easier. How? By creating several on-line references that will be accessible to everyone inside and outside the Center.

> ***"These references will be periodically updated as changes occur to provide accurate and current information to users."***

MSAB staffers are creating a directory of all CDER employees that will include an organizational listing as well as an alphabetical one. Included will be organization charts, a fax directory, the key officials list, and a list of administrative functions and contacts for the Center. All this will be loaded onto the Center's Acrobat Reader which is on the LAN (local area network) and can be downloaded to every employee's personal computer. The on-line directory has been developed and is expected to be operational by the end of April.

Acrobat Reader is a program which allows these files to be read without changing their initial format and appearance. It is also possible to print a document from Acrobat if hard copies are needed. These references will be periodically updated as changes occur to provide accurate and current information to users.

MSAB staffers are also working on a project regarding the Center's system distribution lists on All-in-One. They have some ideas for new lists which will be useful Center-wide and are reviewing existing lists with management officials to ensure their accuracy and utility. The goal is to provide Center employees with useful system distribution lists that are available to everyone and that are kept up-to-date.

All of these helpful electronic references will be available soon. You will be notified by e-mail and given instructions on how to access them. If you have any suggestions, questions, or other ideas, please pass them along to MSAB. Contact Charlene Cherry (CHERRYC) 827-0517 or Rixie Scott (SCOTTRI) 827-0530.

The writer is a Management Analyst in the Management Systems and Analysis Branch,

Team-Based Project Management

Communications Are Key to A Project's

By Jean A. Yager

Team-based project management represents a shift from the traditional pyramidal form of management when one individual (the supervisor) is responsible for scheduling and control to when the responsibility is expanded to include members of multi-disciplinary teams who are directly responsible for the actual work product. This approach has several advantages. One clear advantage is that by participating in planning the activities required to complete a project and assisting in development of the project strategy, team members view themselves as integral parts of the process and accept accountability for the outcome. Another advantage is that teams provide a forum for the dynamic exchange of ideas on the content and scope of a project that ultimately results in a better work product in a shorter period of time. Additionally, a mechanism is established wherein, through team interactions, members can broaden their knowledge, understanding and appreciation of other scientific disciplines and viewpoints. As a result, team membership enhances personal and professional development.

Project management is the function that assumes responsibility for planning the project, monitoring progress, and integrating all activities critical to completion of the project on schedule. In many organizations, project managers together with team leaders organize the activities of cross-functional teams to achieve maximum efficiency in the utilization of a project's time and resources. Project managers are the "glue" that holds team members together.

In CDER, the project managers should integrate core and consult team activities to assure that they are synchronized, on track, and focused on common goals. An additional, and very important role of the project manager is that of "catalyst." Project managers must identify issues that could impede a project's success and they must also bring the appropriate people together to resolve problems. They need to be continuously vigilant in assuring and reassuring the progress of activities necessary to complete the project. The scope and reach of a project manager should be broad and complementary to that of the team leader.

The actions of the project manager, team leader, and the team members should be synergistic and mutually supportive. Communication of all significant developments regarding the project is essential to its success. Team members should inform the project manager of any and all issues related to the project. In turn, the project managers should keep the team leader and team members informed of the activities of other team members as well as any developments outside the team that could influence the project. The project manager should serve as the focal point of information and as the conduit of this information to other interested parties. In this manner, team members, team leaders, and project managers develop a collaborative working relationship for the achievement of project goals.

The writer is the Senior Project Manager for CDER.

Bob Temple Wins Presidential Meritorious

By Kevin Ropp

Robert J. Temple, M.D., has won one of the highest honors bestowed on government employees in the Senior Executive Service (SES): the Presidential Meritorious Executive Rank Award.

"It feels very good to receive the award," says Temple, a 23-year FDA veteran. "I value government service -- I've spent almost all of my working life in it. So, to be recognized within that setting is flattering and most gratifying."

Temple is associate director for medical policy and director of the Office of Drug Evaluation I (ODE I) in the Center for Drug Evaluation and Research. Temple's office is responsible for evaluating a variety of new drugs "to see if they have the evidence needed to be marketed; just as important, we watch over the drug's development," he says, "to see that it is done safely and in a way that will lead to data permitting a sound evaluation." Specifically, ODE I reviews new drugs to treat cancer, heart disease, psychiatric conditions, and neurologic disorders.

> ***Temple received the Presidential Meritorious Executive Rank Award "for being a positive influence on clinical trial design and pharmaceutical development in the United States and abroad."***

Temple is also responsible for the Division of Drug Marketing, Advertising and Communication.

In a letter congratulating Temple, Health and Human Services Secretary Donna Shalala said, "Recipients of this award represent the very highest achieving career executives throughout the federal government."

His principal work interest has been in the design, conduct, and evaluation of clinical studies. "Over the years," he says, "I've been particularly interested in such questions as how to find the right dose of a drug, how to examine sub-sets of the overall population like old and young, men and women, and how to choose the right kind of control group."

Temple received the award, according to its citation, "for being a positive influence on clinical trial design and pharmaceutical

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Temple Wins Presidential

(Continued from page 7)
development in the United States and abroad."

He began his FDA career as a primary drug reviewer in 1972. Since then, he says, "I've held most of the positions that a medical person can hold in the center."

Temple is particularly proud of the work his office and the Center have done under the Prescription Drug User Fee Act (PDUFA), he says. "We've eliminated backlogs and become very prompt in doing all of our review work. PDUFA asked us to take action on applications within a certain period of time and this office, and the Center, have been well ahead of the Act's goals. We know we've maintained the quality of those reviews, too."

> ***"We've eliminated backlogs and become very prompt in doing all of our review work."***
>
> **– Robert J. Temple, M.D.**

A native of New York City, Temple received his bachelor of arts degree, *magna cum laude*, from Harvard University and his medical degree from New York University School of Medicine. He spent his internship and medical residency at Columbia Presbyterian Medical Center, New York, and completed training in internal medicine at the National Institutes of Health. He is board-certified in internal medicine and clinical pharmacology; is an honorary fellow of the College of Clinical Pharmacology; and is a past president of the Society for Clinical Trials.

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Just for Grins

Taking (Remote) Control of Your Life

Each weeknight, Chris Core of WMAL-AM's (630) "Trumbull & Core Show," wraps up the program with a humorous ditty. Here's one to consider . . .

Finally Tonight . . . I am not sure if this is just a rumor or really true but I heard that the Surgeon General wants to put warnings on exercise equipment to warn people. The warnings would say: "Caution: Failure to exercise will result in health problems."

Now this is all well and good, of course . . . But it doesn't make very good sense. I mean if somebody is buying a bicycle or a basketball or a health-rider, chances are they intend to exercise. Where these warnings would make more sense is on things used by people who don't exercise. If they really want to help, put the warnings on beer cans. And TV remote controls. And on Barca-loungers.

It's just a thought: A label which says, "Hey, lard-butt! Get up and change that channel youself or you'll be taking an early dirt nap . . . Signed, "The Surgeon General." That should do it!

A Harbinger of Spring . . .

Spring = Parklawn Classic

It's time again to begin stretching those leg muscles in preparation of the 21st Parklawn Classic set for April 26 at 11 a.m. The five-mile course for runners begins on the Rock Creek path near the soccer field on Veirs Mill Road. The starting mark for the 2.5-mile health walk is at the north parking lot off Fishers Lane. This year's run safety marshalls include Jane Axelrad, Debbie Henderson, Peggy Cunningham, and Diane B. Cave, as well as CSOs Michael Folkendt, Karen Oliver, and Lana Pauls. 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.

Troop Movements

Doug Sporn has been named director of the Office of Generic Drugs (OGD). "Doug brings an impressive record of strong leadership and management from past experience in a variety of FDA programs and functions," said Roger L. Williams, M.D., who preceded Sporn in the job. "He has extensive knowledge of the generic drugs program through his past positions as Deputy Director and Acting Director of OGD."

Sporn takes the reins of OGD on March 18 and will continue to work closely with Williams in oversight of the Office of New Drug Chemistry (ONDC) until a permanent Director for that Office is hired. He will also continue working with the Chemistry Division Directors in OGD and ONDC to assure consistent implementation of SUPAC-IR Guidance and other cross-cutting issues between OGD and ONDC.

Mike Jones, who has played a major role in billing firms and tracking funds under PDUFA, began a detail in the Detroit District Office on March 4. He is eligible for permanent assignment to the Grand Rapids, MI. resident post thereafter.

And then there's the one that got away — completely. On March 1, Consumer Affairs Branch Chief **Patrick J. Savino** found a hole in the fence and escaped to retirement bliss after 38 years of government service -- more than 32 of them with FDA. **Barry Poole** will serve as Acting Branch Chief until a permanent

news along the pike

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