news along the pike

Center for Drug Evaluation and Research

October 1997

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Pike's Corners . . .

$100,000 Grant

Drug Review Innovations Win Big Event

Michael Friedman, M.D., and **Janet Woodcock, M.D.,** went to the World Series of government awards programs and hit home runs. The Lead Deputy Commissioner and CDER's Director made exceptional presentations against stiff competition and secured the FDA's position as one of only two Federal agencies awarded the Innovations in American Government Awards earlier this month.

The agency was recognized for its management and user fee innovations of the U.S. drug approval process. The award is considered to be among the nation's most prestigious public-service prizes and recognizes governmental initiatives that provide creative solutions to pressing social and economic problems.

Only 10 programs were named winners out of a pool that started with 1,540 applications. Earlier this year, the field was narrowed to 99 semifinalists and then, this summer, was culled to 25 finalists. Each finalist was the subject of a two-day site visit by a policy expert.

The award, sponsored by the Ford Foundation and Harvard University's John F. Kennedy School of Government, carries with it a $100,000 grant. The grant is intended for use in disseminating information to the American public and for sharing lessons learned with other government agencies about vital solutions to challenging public problems. The grant will be administered by the non-profit Council for Excellence in Government.

Drs. Friedman and Woodcock spoke before a national selection committee composed of experts in government services and public policy, including David Gergen, editor-at-large of *U.S. News and World Report;* Lynn Martin, former U.S. Secretary of Labor, and Vin Weber, former U.S. Representative from Minnesota.

FDA's innovation resulted in speeding the delivery of new drugs to Americans, while preserving the Agency's high standards for

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Talk About Prescriptions

Information Part of Key to Effective Drug Use

"We can't have effective drug regulation," said Center Director **Janet Woodcock, M.D.,** "unless health care professionals and consumers work together to use medicines as directed. No drug is completely safe, and the safety of a drug is attached to the information about it."

Be informed, stay healthy and talk about your prescriptions was the theme of an FDA employee kick-off to October as Prescription Drug Month. Dr. Woodcock discussed consumer concerns with prescription drugs. The Center receives thousands of questions each year from consumers about the medicines they take. Dr. Woodcock presented some of them in question and answer format:

- **How can I get access to investigational drugs?** This is important for conditions that lack adequate treatment with conventional therapy. Patients should talk to their doctors about their interest in taking part in clinical trials. Dr. Woodcock said that when she was doing clinical trials many of her patients

(Continued on page 10)

Joe's Notebook

Lessons Learned from Winners

"Much of what we do, we borrow from each other," said New York City Mayor Rudolph Giuliani in his keynote address at the Innovations in Government Awards program at the National Press Club. But if we're a Federal agency running the only program of its kind in the nation, how are other government agencies to learn from us? The answer is that the Award validates not only the specifics of the FDA and CDER drug review innovation but also the underlying principles that made the innovation succeed.

PDUFA gave us clear goals as outcomes, we've defined our mission, we've worked closely with industry, we've put more emphasis on collaboration for common purposes, we've listened intently to our public customers, we've paid attention to their risk-benefit thoughts, we've improved management practices, we've instituted project management, and we've invested heavily in improved information technology.

As I listened to a proud parade of government officials from local, state, and Federal programs describe 25 innovations that covered diverse services, from environmental renewal to crime prevention, certain common patterns and practices emerged.

Alan Altshuler, program director of the Innovations in American Government and professor of urban policy and planning at the Kennedy School of Government at Harvard University, has distilled these common patterns and practices. His list of 10 major lessons that these award-winning programs have taught us about government and innovation bears scrutiny. Here are his lessons briefly. (Be sure to visit the Innovations in Government Internet site by clicking on our 1997 winner's logo on CDER's home page or page 1 of this issue to get Altshuler's informative discussion of each lesson.)

1. **Define a mission clearly and in terms of compelling problems.** Most award-winning government programs can be traced to a clear articulation of purpose that is clearly understood both inside and outside the organization.
2. **Define challenging but achievable outcomes against which to measure performance.** Results are what matter. Are children learning more or less? Are crime rates rising or declining? Outcome targets are extremely powerful motivators, which can mobilize political support as well as administrative commitment.
3. **Collaborate with other government agencies wherever possible.**
4. **Build partnerships with the private and nonprofit sectors.** The most difficult problems facing American society cannot be solved by government working alone.
5. **Respect the talents of "front-line workers."**
6. **Identify clearly the citizens and groups who are entitled to your services and focus attention as sharply as possible on their needs.**
7. **If your tasks involve regulation, consider working with the regulated parties to meet common objectives through compliance, rather than depending entirely on traditional enforcement.** Much of the discontent with government stems from tales of capricious, adversarial actions by regulatory agencies. Recently, many agencies have adopted a more cooperative problem-solving approach. This new model requires a mutual focus on results and a sense of partnership to achieve those results.
8. **Consider how market forces may complement the provision of public goods and services.**
9. **Use information technology to improve services to citizens.**
10. **Be flexible, take risks, don't give up.**

news along the pike

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

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Ombudsman's Corner

Another Year of Ombudsing

By Jim Morrison

It doesn't seem like a year has passed since I prepared my first annual report (see October 1996 *Pike*), so that must mean that I'm having fun. This year has been busier than last, which I credit to the Ombudsman's page going up on CDER's Web site.

It's always difficult to decide what constitutes an ombudsman's "case," because one issue or problem may generate many contacts from the client, and one client or contact may bring several issues or problems. To give you a feel for the increase in my workload, however, I can say that last year I reported 71 complaints from 59 clients. This year I was contacted by an estimated 135 clients involving many more than 200 contacts.

The mix of issues changed to some extent, however. Because of the Web site, I received many e-mails in addition to the usual phone calls and letters. Some of these e-mails presented general problems or complex issues rather than complaints about CDER's action or inaction. I hear more now from consumers and health professionals than I did last year. As you might expect from the increased business, the ratio of external to internal cases rose from FY 96's 2-to-1 to more than 3-to-1 during the fiscal year just ended.

I decided to array the analysis somewhat differently this time, following the natural grouping of cases involving complaints about CDER actions:

External	
Policy or decision challenged	41 percent
Timeliness or priorities	29 percent
Failure to respond or bad advice	30 percent
Internal	
Personnel management	59 percent
Management/administrative systems	35 percent
External interactions	6 percent

Last time I included a category of priorities or inconsistencies, which accounted for 22 percent of the complaints in the external category. However, it is often difficult to separate challenges to policies or decisions into those where inconsistency among divisions is involved and those where it is not, so I folded that category into either policy/decision challenges or timeliness/priorities, depending on the gist of each complaint.

I heard fewer complaints about timeliness in PDUFA review areas as the old application backlog was eliminated and as applicants have come to believe that goal dates will be met. I also believe that we are getting better in eliminating inconsistencies among reviewing divisions. Some non-PDUFA areas have dealt effectively with backlogs. The Office of Compliance has eliminated the backlog in issuing Certificates of Free Sale. These are now a source of user fee funds, thanks to a new law and a lot of dedicated effort. However, timeliness remains a consistent concern in other Center activities. It will continue to be of concern, requiring us to learn to work smarter and more efficiently, often with fewer resources.

Policy, decisions and priorities continue to be a major area of concern. We reduce such complaints by documenting our policies and practices better, getting more MaPPs published, including more policy documents on our Web site, making sure that we articulate our policies and decisions clearly and that we follow those policies that have been published.

Internally, management issues continue to be the primary concern, with an increased effort needed to ensure that supervisors and managers spend the time and effort necessary to improve personal interactions and the working climate. That means, among other things, providing effective positive and negative feedback to employees and foreseeing and heading off potential personnel problems. It also means improving our methods of recruitment and orientation as well as analyzing the information we are already getting from the 360-degree evaluations and satisfaction surveys.

It seems that CDER folks are complaining more about management and administrative systems that are based outside CDER. That may signify that CDER administrative systems are improving faster than FDA and HHS systems. Clearly, though, such systems in general are improving.

Finally, I received fewer alerts from CDER divisions about problematic interactions with outside contacts. Please remember that such alerts are very helpful in smoothing out problems before they become critical. And, as always, I appreciate getting feedback from inside or outside CDER about systems, problems and suggestions for making things work better. Just e-mail me (MORRISONJ) or call 4-5443.

Jim Morrison is the Center's Ombudsman.

Communications Corner: Why We Don't Hear Others

If you want to listen so you really hear what others say, make sure you're not a:

- **Mind reader.** You'll hear little or nothing as you think, "What is this person really thinking or feeling?"
- **Rehearser.** Your mental tryouts for what you'll say next tune out the speaker.
- **Filterer.** Some call this selective listening—hearing only what you want to hear.
- **Dreamer.** Drifting off can lead to an embarrassing "What did you say?"
- **Comparer.** When you get side-tracked assessing the messenger, your sure to miss the message.
- **Derailer.** Changing the subject too quickly tells others you're not interested in what they have to say.
- **Sparrer.** You hear what's said but quickly belittle it or discount it.
- **Placater.** Agreeing with everything you hear just to be nice or avoid conflict doesn't mean you're a good listener.

Source: *The Writing Lab*, Department of English, Purdue University, 1356 Heavilon Hall, West Lafayette, IN 47907 in *communications briefings.*

OTCOM's Drug Information Team Provides Timely Answers

By Mary E. Kremzner

Here's a trivia quiz for all you long-time CDER hands: What do the Advisory Opinions Branch, the Advisory Opinions Staff, the Legislative, Professional and Consumer Affairs Branch and the Executive Secretariat Staff all have in common? If you said that these are all former names of what is now known as the Drug Information Team in the Office of Training and Communications, give yourself a pat on the back.

No matter what name we've taken in the past, our responsibilities have remained constant through the years. Our mandate and our mission have always been to respond to inquiries from CDER's constituents. That is an enormous task. Our constituents are many, and their questions are as broad and varied as they are—nurses, pharmacists, doctors, consumers, insurance companies, foreign and domestic industry representatives, foreign governments, other centers and Federal agencies, as well as FDA field offices and many of you in CDER.

We know we're just a few folks in this big enterprise known as CDER, but to the American people, we are the educators, the translators and the diplomats. We are the voice of the FDA, and we take that very seriously.

Today, we are a staff of nine and operate very much like our sister organization, the Exec Sec staff (see September's *Pike*). Exec Sec, however, primarily responds to written inquiries with official correspondence. On the other hand, we respond primarily to telephone inquiries with verbal answers and printed materials. Our responsibilities can be quite diverse. For example, we assist Exec Sec by responding to write-in campaigns. Currently, one involves our answering nearly 20,000 letters, and another one needs 300 answers. Our other responsibilities include maintaining consumer publications, industry guidances, over-the-counter drug monographs and fact sheets.

We handle about 200 telephone inquiries each day. Many of these are calls from consumers seeking information about the drugs they are taking. The team's six consumer safety officers meet twice a week to share knowledge and learn from each other. This helps reduce duplicate calls and ensures that callers receive a consistent answer from us if they call more than once with the same inquiry. Hot topics like the recent voluntary withdrawals of fenfluramine and dexfenfluramine led to a dramatic 50 percent increase in the number of calls we received.

And while we work hard to serve the needs of our constituents, we couldn't do it without some invaluable assistance. This help comes in many forms, but none is more vital to our success than the people in CDER. The project managers in the review divisions, compliance officers and regulatory counsels all pitch in. We know everyone is very busy, but that never prevents them from being responsive to our requests for information.

Technology plays a role in helping us meet our goals. For instance, we maintain a Fax-on-Demand system to handle many of the requests received for written documents and to reduce the amount of outgoing mail. The system contains CDER guidances, approval letters, bioequivalence guidances, protocols, labeling and FDA talk papers. The system is updated daily to include the latest information available from CDER. It is available through a toll-free call, (800) 342-2722. We also refer callers to CDER's World Wide Web site.

We are always looking for new and better ways to increase customer service, office productivity and efficiency. Our office has developed an extensive amount of information contained in file cabinets. We are involved in an effort to consolidate these files and enhance data retrieval. We are reviewing several software programs that will enable us to retrieve all this historical and current information via a database contained on a CD ROM.

As we've become more productive, we've been able to take on a broader range of activities. For example, our team provides introductory seminars for students and visiting foreign dignitaries. These provide them with an understanding of the structure and function of the Center and its mission. On the horizon is an hour-long presentation on the drug approval process designed for pharmacists. The program, approved for continuing medical education, will introduce them to the FDA and CDER and how our roles augment health care.

Mary Kremzner is a CSO on OTCOM's Drug Information Team.

CDER's Fall Honor Awards Ceremony on Tap for Nov. 21

By Jackie Barbar

The Center for Drug Evaluation and Research will hold its Fall Honor Awards Ceremony on Friday, Nov. 21, at 10 a.m., at the Gaithersburg Hilton Ballroom, 620 Perry Parkway, Gaithersburg. Proud to recognize the noteworthy accomplishments of its employees, CDER will present the following awards:

FDA Commendable Service, FDA Outstanding Achievement, FDA Equal Opportunity Achievement and FDA Group Recognition Awards.

Commissioned Officers will receive the PHS Outstanding Service Medal, PHS Outstanding Unit Citation, PHS Commendation Medals and PHS Unit Commendations.

In addition to the FDA honor awards, CDER will present Peer Honor Awards for the following categories: CDER Team Excellence, CDER Program Administrative/Management Excellence and CDER Support Staff Excellence Awards, as well as two new Peer Awards—Excellence in Communication and CDER Excellence in Leadership Awards.

The CDER Special Recognition Award will also be presented at the ceremony.

If you have any questions or if any special provisions are needed, please contact me at 4-2004 or e-mail me (BARBERJ).

Jackie Barber is CDER's incentive awards officer.

History Corner

1908 Reorganization Set Stage for Intensified Investigations

By John Swann, Ph.D.

Third of four parts

The character of the Bureau of Chemistry's Drug Laboratory work did not change immediately after passage of the 1906 Act. The laboratory, CDER's forerunner, continued to investigate drug adulteration, perfect analytical methods, examine chemical reagents and analyze patent medicines. Of course, after 1906 the Bureau could actually do something about adulterated or misbranded drugs. In 1908, the Drug Laboratory became one of two divisions within the Bureau—Foods and Drugs. The Drug Division had four laboratories to handle different functions more efficiently.

The Drug Inspection Laboratory was the component most concerned with general drug enforcement issues. Like Division Director Lyman Kebler, George Hoover, a chemist who headed this laboratory, earned an M.D. from George Washington a few years after starting at the Bureau. His laboratory examined drugs seized as adulterated or misbranded under the 1906 Act. From 1909 to 1910, the laboratory examined over 900 domestic drug samples and over 1,200 imports that had been seized by field inspectors, of which over 100 samples were violative.

The Synthetic Products Laboratory was under the direction of W.O. Emery, who had investigated food and drug adulteration in Germany for several years before coming to the Bureau of Chemistry. This laboratory was responsible for examining chemical drugs. Of major concern were the ubiquitous headache remedies and other preparations with habit-forming ingredients. Many of these remedies were actually mixtures of several drugs with rather different therapeutic actions, such as phenacetin, caffeine, heroin, acetanilid, and other compounds. Early on, this laboratory developed techniques for quantitative determination of individual ingredients in these formulations. From 1907 to 1910, the laboratory analyzed about half of the estimated 800 brands of headache, cold and influenza drugs on the market.

The Essential Oils Laboratory focused on oleaginous products that were used therapeutically or in the manufacture of other medicinal agents. E.K. Nelson, who headed this unit, worked in industry prior to coming to the Bureau, as had Kebler. This laboratory developed analyses to detect adulterations in such products, which required good, authentic samples of oils. For example, the cheap synthetic product methyl salicylate often was used to adulterate oil of wintergreen and oil of sweet birch.

Inspector John McManus described a visit to the mountains of North Carolina around 1912 to collect some authentic oil of sweet birch for reference analytical use back in Washington: "A chemist and I went up to North Carolina and arranged with one of these distillers to make several pounds of Oil of Sweet Birch. . . . I recall the chemist was kind of nervous about the mountain people. He had heard stories about them so he brought an old pistol with him and put it under his pillow. In the morning, we were awakened by a pistol shot. One of the distillers had come in, seen the handle of the pistol, pulled it out from the guy's pillow, and shot it off to wake us up."

William Salant, a founding member of the American Society of Pharmacology and Experimental Therapeutics, was in charge of the Pharmacological Laboratory. This group conducted extensive pharmacological examinations of caffeine and alcohol—both common ingredients in proprietary medicines—as well as studies of the physiological action of bleached flour, a matter of considerable Bureau interest in food regulation. Pharmacologists had been using biological assays in a systematic way to standardize ergot and other drugs since the 1890s. When the U.S. Pharmacopoeia requested the Bureau's assistance to provide manufacturers with reference standards for biologically assayed drugs, Harvey Wiley fully supported the idea. But the Secretary of Agriculture in 1910 refused to permit the Bureau to take on this responsibility, arguing that it was beyond the scope of its functions under the law. However, by the mid-1920s, the Bureau reached an agreement with the Pharmacopoeia to supply companies with specimens of drugs assayed biologically according to USP guidelines.

Thus equipped and organized, the Drug Division soon found itself overwhelmed by the magnitude of drug adulteration and misbranding in this country. The fact that the 1906 law had serious shortcomings did not help. But the Division embraced collaborative efforts with governmental and outside institutions to deal with pharmaceutical and many other problems.

John Swann is a historian in the FDA's History Office.

Combined Federal Campaign Under Way, CDER Goal $155,500

By Edward Miracco

Oct. 1 signaled the kickoff for the 1997 Combined Federal Campaign. FDA's goal this year is $620,000 with CDER's portion being $155,500. That's quite a sum of money. Clearly, this is not only a big job, but an important one. I hope you will find a charity to which you feel comfortable making a donation. They are all listed in the "1997 Catalog of Caring" which, with other required materials, can be obtained from your keyworker.

There are approximately 75 keyworkers in CDER, each with the materials and instructions needed to make a donation. If you are unsure who your keyworker is, contact me by e-mail (MIRACCOE) and I'll tell you, or, if necessary, send you the materials you need.

Remember, all the charities and non-profit organizations need your donations. These organizations improve the lives of the less fortunate including many in our own neighborhoods. So give what you can. Through your commitment and generosity the campaign will be a success and those in need will receive our support.

Edward Miracco is CDER's 1997 CFC coordinator.

Reviewers' Corner

New Virtual Journal Edition Debuts in November

By Zan Fleming

Another edition of CDER's *Virtual Journal (vJ)* is coming soon to a computer near you! Many regular and Workroom articles have accumulated since the first edition, and they will debut in November's issue. This will be the last *vJ* edition of this type. Instead, after this final bolus, we will publish articles on a continuous basis as they complete the peer review and editorial process. This means that you will get articles at a faster rate that invites regular reading. As new articles become available, you will be alerted by the e-mail and other ways.

We are striving to take full advantage of this electronic medium. For example, next month's edition will feature a superb article by **Bob Temple.** This article presents a commentary on a very lengthy treatise published in the Virginia Law Review by a University of Virginia law professor and former FDA General Counsel, **Richard Merrill.** Bob Temple's commentary, also published in that journal, sets Professor Merrill straight on a number of misconceptions in his case for "FDA reform." Temple's article by itself makes for very interesting reading, but the *vJ* can present his article in an even more useful way not possible through conventional publishing. We plan to link each of Bob Temple's comments with the relevant text in Merrill's article. Thus, the reader will be able to toggle between these two articles to experience the full sense of the debate. We will invite Professor Merrill to respond to Bob Temple's article and then give the floor to Bob Temple, *ad infinitum* or *ad exhaustum!*

We will to use a similar format for another article. This previously published paper consists of contributions from nearly a dozen FDA and outside experts to a symposium on approaches for identifying the maximum tolerated dose in early clinical studies. Instead of seeking revisions of the original published article, we have asked authors to provide a supplementary introduction and individual explanatory comments about each contribution. This added material will be electronically linked to the original text so readers can access these summary comments as well as the original article. This approach provides an updated reference that is intended to be even more valuable than the original article.

If you think about it, this electronic medium provides for a completely different communication architecture from the one that the Sumerians and Chinese developed 5,000 years ago—and that we still use today. This new medium, in effect, adds a third dimension to communication. The ability to embed layers of text, graphics, data and other publications into the "surface" article enables us to build very "tall" communications. This is somewhat analogous to skyscrapers vs. low-rise buildings. Skyscrapers are built largely to economize on real estate and human walking. The electronic medium, which *vJ* strives to exploit, economizes on reading time as well as on text and graphics costs. We hope that authors will recognize and creatively use the power of this medium as they conceive articles for the *vJ*. You can access the *vJ* by typing "cdernet" in the address block of your World Wide Web browser and then clicking on the *Virtual Journal* button.

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

Vital Statistics Report Shows Significant Gains in U.S. Health

Broad gains in the nation's health, including a dramatic decline in the AIDS death rate as well as continued decline in the teen birth rate, was reported by the Centers for Disease Control and Prevention (CDC). The annual report, showing preliminary birth and death statistics for the United States in 1996, indicates that:

- HIV/AIDS mortality declined 26 percent between 1995 and 1996, falling from the leading cause of death among 25-44 year-olds to the second leading cause of death in that age group.
- The teen birth rate declined for a fifth straight year, and·a new record low was achieved in the infant mortality rate.
- The number of women obtaining early prenatal care continued to increase.

The report shows the national age-adjusted death rate from HIV/AIDS dropped an estimated 26 percent between 1995 and 1996, from 15.6 deaths per 100,000 population in 1995 to 11.6 in 1996. HIV infection, previously the leading cause of death for those 25-44, now ranks second behind accidents and adverse effects and just ahead of cancer.

Earlier this summer, preliminary findings from another CDC survey had reported a similar pattern of decline in AIDS deaths over the first nine months of 1996. HIV/AIDS mortality had increased an average of 16 percent per year between 1987 and 1994, before leveling off in 1995.

The new report, *Births and Deaths, United States: 1996*, is prepared each year by CDC's National Center for Health Statistics (NCHS). Life expectancy reached an all-time high of 76.1 years in 1996, up from 75.8 in 1995. Record high life expectancies were reached for white and black males (73.8 and 66.1 years, respectively), and for black females (74.2).

Data from this report come from birth and death certificates filed in the states and provided to the Federal government through the National Vital Statistics System.

The report can be downloaded from the NCHS home page on the Internet at:http://www.cdc.gov/nchswww/nchshome.htm.

Leadership Fellows' Corner

CDER Handbook Aims to Improve Constituent Communications

By John Emelio

When CDER embarked on the transformation process last year, one theme that rang out was the need to communicate to our constituents and the public at large the vital role that CDER fulfills in protecting and promoting the public health. The message was that we must continue to move toward an environment where information on CDER's processes and activities is communicated in an open and proactive fashion to our external customers.

During this time, the Center's first Leadership Fellows program was beginning. In considering which project I would work on during the Fellow's year, I thought about this need for communicating to our external stakeholders the many ways in which CDER contributes to the public health. Given the advantages of the Internet as a communication tool for reaching mass audiences at a low cost, I decided to lead an effort to develop a Web site on the CDER Internet site called the *CDER Handbook.* As a result of the work of many people from around the Center over the last 18 months, the *CDER Handbook* is now ready for its debut on the CDER Web site.

The purpose of the *CDER Handbook* is to provide a user-friendly resource on the Internet for obtaining information on the Center's processes and activities of interest to regulated industry, health professionals, academia and the general public. In addition, the handbook also serves to orient CDER employees to our own processes.

The Web site is arranged according to the four major activities that the Center is involved in, each accessed by its own button: New Drug Review, Generic Drug Review, Over-the-Counter Drug Review and Post Drug Approval Activities. Two other buttons, Communicating with CDER and Other Topics, are included to describe the additional activities of interest at the Center. Each selection in the handbook contains a concise description of a particular process or activity and often provides resources or links to other sites for further information.

In order to develop the Web site, we formed a *CDER Handbook* Team made up of people from around the Center (**Tim Ames, Kristin Crown, Pam Fagelson, Lori Frederick, Anne Henig, Dan Luckabaugh, Melissa Moncavage, Frank Saylor, Vanessa Starks,** and **Pam Winbourne**). In addition, there were many others, such as CDER Webmaster **Paul Stauffer**, who contributed.

If you would like to preview the *CDER Handbook*, you can find it on the CDERnet. Simply type "cdernet" in the address block in your Web browser and then click on "About CDER." Then click on the Handbook button. If you have any questions or comments regarding the *CDER Handbook,* you can contact me by phone (7-0519) or via e-mail (EMELIO). We welcome your thoughts and suggestions on how we can improve this product before we move it to the Internet within the next month.

John Emelio is a management analyst in the Management Analysis Branch.

Information Technology Corner

AMF Division Files System Pilot Leads to Enhancements

By Sarah Coburn and Sue Makoff

In the May issue of the *Pike,* we discussed the pilot for the first phase of the Division Files System (DFS) in the Division of Oncologic Drug Products. DFS, a key component of CDER's Administrative Management of Files (AMF) initiative, provides CDER staff with the ability to import final review documents that are ready for signoff, route the documents for signature, automatically store them in an electronic repository, search for documents stored in the repository, and view the documents online.

The pilot in Oncology concluded successfully in July. Thanks to the invaluable feedback from pilot users, the DFS Development Team added 30 new features and improved many standard features. Some of the enhancements include: improved performance, a more intuitive check-in process that closely follows the business process, e-mail notification when a review document arrives in your DFS inbox, redesigned screens and a toolbar that provides quick access to DFS functions.

Rollout of the enhanced DFS to the Division of Pulmonary Drug Products is underway. Division staff attended training Sept. 26 through Oct. 3. DFS was installed in the division on Oct. 3, and the DFS Development Team will be providing on-site user support for several weeks. By the end of the calendar year, DFS will be deployed in the Divisions of Metabolic and Endocrine Drug Products and Reproductive and Urologic Drug Products.

We are excited to report that while the first phase of DFS is being rolled out, the CDER DFS Working Group will be meeting to begin phase two. The second phase will include real-time updating of assignments in the Center-wide ORACLE Management Information System (COMIS) directly from DFS, as well as automatic distribution of completed documents and full text searching. Plans for DFS also include a DFS homepage on CDER's internal web site where current DFS information will be published.

Sarah Coburn and Sue Makoff are members of the DFS Development Team.

Project Management Corner

Project Managers Work in Multiple Roles for Generic Drugs

By Kassandra Sherrod

Project managers serve in only one division in the Office of Generic Drugs (OGD)—the Division of Labeling and Program Support. In the interest of building a community of project managers within CDER, this article highlights the responsibilities of this unique group of people.

In OGD, project managers work in both the Regulatory Support and Review Support branches of the division. In addition to specific duties, all project managers serve as the liaisons between the OGD and regulated industry, the public and other FDA offices.

Project managers in the Review Support Branch work with the scientific team leaders for chemistry and bioequivalence. The primary job for the project managers is to coordinate the review process among all disciplines within OGD. They monitor the overall application review process and provide daily oral or written reports to management. The project managers also enter this information into a designated database.

All applications that have been recommended for approval are placed onto an "approvals matrix" by the project manager who prepares the approval package, monitors its progress and reports this activity to management during a biweekly meeting.

Project managers are the primary contact for interactions with the Office of Compliance, Office of Review Management (ORM) review divisions, Drug Master File holders or their agents. Memoranda of telephone conversations regarding specific applications are prepared by the project managers.

Project managers also track overdue applications, process all "Special Supplement—Changes Being Effected," bundled supplements, "Expedited Review Requested," SUPAC supplements, supplemental withdrawal letters, transfer of ownership letters and second major not-approvable letters. Special projects are also assigned to these project managers.

The project managers in the Regulatory Support Branch serve as the front line for regulatory issues. They audit applications for acceptability for filing. Several other routine responsibilities include tracking drug shortages, application integrity policy issues, suitability petitions, issues involving General Counsel and various monthly reports. Project managers often interact with ORM on formulation issues, products of questionable review jurisdiction (whether they are NDAs or ANDAs), consults and other matters.

Kassandra Sherrod is a project manager in OGD's Division of Labeling and Program Support.

Informative "Supplement Facts" Panel Due

FDA Publishes Final Dietary Supplement Rules

FDA last month published final rules that will give consumers more complete information in the labeling of dietary supplement products.

These rules implement some of the major provisions of the Dietary Supplement Health and Education Act of 1994. The Act requires FDA to develop labeling requirements specifically designed for products containing ingredients such as vitamins, minerals, herbs or amino acids intended to supplement the diet.

The new rules require these products to be labeled as a dietary supplement (for example "Vitamin C Dietary Supplement") and to carry a "Supplement Facts" panel with information similar to the "Nutrition Facts" panels that appear on most processed foods.

The rules also set parameters for use of the terms "high potency" and "antioxidant" when used in the labeling of dietary supplements.

Required information on the "Supplement Facts" panel will include information on:

- An appropriate serving size.
- Fourteen specific nutrients, when present at significant levels, including sodium, vitamin A, vitamin C, calcium and iron.
- Other vitamins and minerals if they are added or are part of a nutritional claim on the label.
- Dietary ingredients for which no Reference Daily Intakes (RDIs) have been established.

If the product contains a proprietary blend of ingredients, the rule requires the total amount of the blend and the identity of each dietary ingredient in the blend (although amounts of individual ingredients in the blend are not required).

The rule also specifies a minimum type size and flexible formats. The rule requires that the labels of products containing botanical ingredients identify the part of the plant used to make the products.

In addition, the source of the dietary ingredient may either follow the name or be listed in the ingredient statement below the "Supplement Facts" panel.

"High potency" may be used to describe a nutrient when it is present in a food product, including dietary supplements, at 100 percent or more of the RDI established for that vitamin or mineral.

"High potency" may also be used with multi-ingredient products if two-thirds of the nutrients that are in the product are present at levels that are more than 100 percent of the RDI.

"Antioxidant" may be used in conjunction with currently defined claims for "good source" and "high" to describe a nutrient where scientific evidence shows that following absorption of a sufficient quantity, the nutrient (such as vitamin C) will inactivate free radicals or prevent free radical-initiated chemical reactions in the body.

EEO Corner

CDER Program Marks October as Disability Awareness Month

By Gloria Marquez Sundaresan

October is National Disability Awareness Month, a time of the year for all of us to raise our consciousness of what persons with disabilities can contribute to the workplace and to society in general. The consciousness raised in October should not last just for a month but for the entire year. This is especially true for those of us who are in a position to hire highly qualified individuals to improve the representation of employees with disabilities in the CDER workforce.

Making an effort toward this goal will help the Center comply with the Rehabilitation Act of 1973, which prohibits discrimination against qualified persons with disabilities on the basis of physical and mental handicaps. Moreover, this act also requires that the Federal Government take positive steps in the hiring, placement and advancement of persons with disabilities and to provide reasonable accommodation where appropriate. Compliance with this law is helping millions of capable persons with disabilities contribute their talents and boost the country's economy.

One outstanding person with a disability who secured his niche in history and in the hearts of his fellow citizens was one of the great leaders both in this country and abroad—Franklin Delano Roosevelt, statesman, President and world leader. It was FDR who steered this country through the dark and troubled times of World War II and brought it into the light of peace. His polio-afflicted legs were no barrier to achieving what he did for the nation and the international community because his courage, will and determination were all in his mind, heart and soul. Without opportunity, a person with a disability will not be able to share his or her talents with the rest of the community.

October is filled with activities and programs to observe the National Disability Awareness Month. For our part, the CDER EEO Information and Sharing Satellites (CEISATS) conducted a videoconference, "Hear Our Voices," Oct. 29., in the Parklawn Building and in Corporate Boulevard. **Roger Williams, M.D.,** Deputy Director (Pharmaceutical Science), delivered the keynote address. **Charles McNelly, M.D.,** Executive Director, United Cerebral Palsy, w as the guest speaker. **Dorothy Menelas** form the Office of Testing and Research sang "One Moment in Time."

The program featured two panel discussions in which a volunteer secretary and a newly hired chemist in the Office of New Drug Chemistry shared their experiences to inspire and give courage to others in similar situations. The secretary, **Maureen A. Sey,** is involved in the Unpaid Work Experience Program, a partnership between the CDER EEO Staff and the Division of Rehabilitation Services of the State of Maryland.

Panel A represented the Division of Rehabilitation Services and included Ms. Sey and her counselor, **Kim Trebel.** Panel B represented the Office of New Drug Chemistry and included the chemist, **Li-Shan Hsieh,** and the selecting officials **Rebecca H. Wood,** team leader, and **Josephine Jee,** chemist.

This program was made possible with assistance from **Angela Youngblood, Wendy Stanfield, Wanda Claybaugh,** OTCOM; **William Myers,** OPS; and **Kathy Abel,** OCPB.

If you have questions, please call me at 4-5427 or e-mail (SUNDARESAN).

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

Epidemiology Branch Mourns Loss of Frank Rosa

Franz Rosa, M.D., MPH, epidemiologist and teratologist in the Epidemiology Branch, Division of Pharmacovigilance and Epidemiology, CDER, passed away on Friday, October 3, at his home in Rockville. He had prostate cancer diagnosed in 1986.

Dr. Rosa worked for the FDA since 1979 and "retired" in 1996. He was the quintessential public servant, and was devoted to the worldwide promotion of maternal and child health. After retirement he became a special government employee and continued to walk and bicycle to FDA to consult on reproductive and teratologic issues.

Dr. Rosa had over 50 years of government service. He served in the Navy in the '40s and '50s and was a veteran of the Korean War. From 1958 to 1976, he worked in the Commissioned Corps of the Public Health Service at posts in the United States, Asia, Africa and Europe.

He served as director of the American University's School of Public Health in Beirut and director of Ethiopia's School of Public Health. His last assignment in the Commissioned Corps was maternal and child health chief at the World Health Organization in Geneva, Switzerland. He was medical director of the Peace Corps from 1976 to 1978.

12 CDER Directors Named Leadership Fellows

A dozen of the Center's leaders have been selected to take part in CDER's first Directors' Leadership Fellows Program. They are: **Minnie Baylor-Henry, George Chi, Yuan-yuan Chiu, Ruth Clements, John Jenkins, David LePay, Patricia Love, Jim MacGregor, Janice Newcomb, Lisa Rarick, Ellen Shapiro,** and **Solomon Sobel.**

They will take part in a rigorous development program designed and administered by the Council for Excellence in Government. "The program is about leading," said Ron Redman from the Council. "To get there, we will examine how we think, how we perform certain leadership skills and how we deal with leadership issues such as change, power and resistance. We will learn from leaders in other organizations. The end point is leading in new ways to get greater results for CDER."

Drug Review Innovations Win in Ford Foundation Awards

(Continued from page 1)

quality, efficacy and safety. The agency has cut new drug approval times nearly in half, while the number of new drugs approved in a year has doubled.

"We are very gratified that FDA's revolutionary innovations in the drug review process have been selected for this honor," Friedman said. "These improvements were made possible through a collaborative partnership of government and private industry. Patients in the United States now have much earlier access to safe and effective medicines as a result of FDA's streamlined drug review process and expanded access programs."

To accomplish this feat, FDA implemented a number of initiatives to speed the review of—and access to—new medicines.

First, FDA, Congress and the pharmaceutical industry negotiated the Prescription Drug User Fee Act of 1992. Under this program, the pharmaceutical industry pays user fees that enhance FDA resources for drug review.

Second, a new procedure, called accelerated approval, was developed to bring new drugs for serious and life-threatening diseases to market more quickly. This program allows for the development, review and approval of drugs for diseases like AIDS and cancer much faster than was previously possible. These drugs are now routinely approved in less than 6 months; some have been approved in a matter of weeks.

Third, a system of ranking new drugs based on their medical benefits was linked to even faster review goals, to ensure the greatest attention to breakthrough drugs for serious conditions.

The results far exceeded expectations. U.S. drug approval times decreased dramatically and are now among the fastest in the world. Americans have access to new therapies faster and suffer less, recover more rapidly, are often cured completely and live longer lives, or enjoy an improved quality of life.

Consumer Information Part of Effective-Use Equation

(Continued from page 1)

obtained satisfaction from helping advance scientific knowledge about their disease and helping others. Patient support groups are sources of information about trials.

- **How can I be sure the drugs I am taking are safe?** No drug is completely safe. Consumers need to be informed and keep their physicians informed of all their signs and symptoms. Physicians need to listen to what their patients tell them and not prescribe drugs that may treat one condition but be inappropriate for another coexisting condition. She cited the example of doctors who prescribe drugs that cause ulcers to patients who have already complained of ulcer pain.
- **How can I get reliable information about prescription drugs?** Read the label, pay attention to warnings and be aware of interactions. Dr. Woodcock noted that the current labeling isn't easy for consumers to read.
- **Are generic drugs just as good as their brand name equivalents?** Dr. Woodcock said that the Center won't approve a generic unless the Center is sure that the generic is bioequivalent to the brand-name product.

Dr. Woodcock was joined by senior FDA officials and former Congressman **Paul G. Rogers,** chairman of the non-profit National Council on Patient Information and Education (NCPIE). **Charles Gaylord,** Acting Associate Commissioner for Consumer Affairs, introduced the program and served as master of ceremonies.

Sharon Smith-Holston, Deputy Commissioner for External Affairs, discussed the history of the patient information movement that led to the Action Plan for the Provision of Useful Prescription Medicine Information earlier this year (see February's *Pike).* Originally, drug information was intentionally written just for doctors and not intended to be read or understood by patients. The movement always enjoyed support from consumer groups but was opposed by industry and trade association groups for both practical reasons and the fear that it would lead to self-medication when a doctor's advice was required.

The serious consequences caused by the lack of information and the ready availability of information technology have tipped the balance in favor of the patient information program. Noncompliance and human error cause major suffering and economic loss. Medication mishaps cost $20 billion to $75 billion a year. Computer technology has undermined objections to storing and filing thousands of information leaflets in each pharmacy in the country. The plan is available on the Internet at http://library.nyam.org/keystone.

Lead Deputy Commissioner **Michael Friedman, M.D.,** reiterated the FDA's commitment to ensuring that patient information developed by third-parties is scientifically accurate, unbiased, sufficiently specific and comprehensive, current, easily understood and useful. He said that while the program is voluntary, it has clear and serious goals set in law. The FDA wants the industry to succeed and will watch carefully to ensure that the goals are met—75 percent of consumers receiving useful prescription information by 2000 and 95 percent by 2006. Brochures and leaflets, he pointed out, are an important backup to the wisdom and expertise supplied by physicians, pharmacists and other health care professionals. As patients take responsibility for their own health, he said, they need to understand how the medicines they take can be helpful or harmful and how they interact with other medicines, foods and dietary supplements. American consumers expect and deserve useful patient information, and Friedman expects the spirit of cooperation to deliver on the goals of the plan.

Rogers praised FDA employees for being the guardians of the public health and presented Associate Commissioner for Health Affairs **Stuart Nightingale** with a plaque for 15 years of service on NCPIE's board.