news along the pike

Center for Drug Evaluation and Research

Volume 2, Issue 9

Inside . . .

CDER Employee Survey

Focus on Communications Flow

By Norman Oliver

"We work pretty well together and get things done," said CDER Director Janet Woodcock, M.D., in her assessment of the results of the organizational effectiveness survey of Center employees. "But we have too much to do and too many demands placed on our time for our people to feel that they are adequately communicating and coordinating up and down the levels of CDER and between units."

Woodcock presented the results in a videoconference on Sept. 23 and repeated on Oct. 11. A complete copy of the survey results is available in each division, and the video presentation is available in the CDER Library. The survey, conducted in the spring of 1996, provides a benchmark of CDER's organizational climate to judge efforts at improving weaknesses.

"We got a terrific response to the questionnaire," Woodcock said. Of 1,624 CDER employees at the time, 1,123 completed and returned the questionnaire. "This is social sciences data. This isn't going to provide statistical comparisons of randomized data. This is about how it feels to work here. This is about feelings and about people's perception about how well we do in different areas, what kind of an organization we are. That's why we did it," Woodcock said.

The survey, a standard organizational effectiveness instrument, has been normalized to a variety of industrial and governmental organizations over the past three decades. Federal norms are based on data obtained from 11 non-science-based agencies and are lower than private-sector norms.

The CDER data in the survey can be compared to Federal norms or analyzed individually. Enough people taking the survey reported demographic information about themselves for data to be obtained from four levels within CDER: division directors, branch chiefs, team leaders, and non-supervisory staff.

"You can see how our people feel about working in our organization compared with other Federal organizations," Woodcock said. "You can also see the raw data on what people actually say, which gives you a somewhat different picture."

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Fall Planning Meeting Set for Oct. 29-31

3-Day Event To Highlight Center's Priorities

Top CDER officials will discuss CDER's priorities for the next six months at the Fall Planning Meeting, Oct. 29-31. The presentations will begin at 8:30 a.m. and conclude by noon.

The live presentations will take place in Conference Room G at Woodmont II. Once again, the Office of Training and Communications (OTCOM) will videoconference the event.

The remote sites are Room 13B-39 in the Parklawn Building and Videoconferencing Room at Corporate. Tapes of the meeting will be available in the Center's libraries.

Seating is on a first-come, first-served basis in all three buildings.

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Center Director Janet Woodcock kicks off the first day with a presentation of CDER's transformation goals. Highlights of the second day's schedule include presentations from the Office of Pharmaceutical Sciences, and the third day spotlights the Office of Review Management.

Joe's Notebook

Meet Your Editorial Board

Taking the pulse of an organization when you're brand new can be difficult. Your observations invariably blend in with preconceived notions of what you will find and past perceptions from similar situations. The consequences are false conclusions. Fortunately, the editor of the Pike and you, the readers of the Pike, have an expanded set of eyes, ears and minds to keep the Pike expressive of the voice of the people who work at CDER. You'll find them listed on the right, and as I get to know them better, you'll find them profiled in this space.

As I have chatted with individual members of the editorial board or heard from them by e-mail, I have been impressed by their sense of CDER as a real community and their commitment to ensuring that the Pike represents all the people in the Center and all its parts. I find it to be a distinct pleasure to edit a publication for, by and about folks who are genuinely enthusiastic about their work. I hope you find their infectious enthusiasm coming through these pages, whether you're holding them in your hand or reading them on your computer screen.

If you're reading this on your computer, you're already benefitting from the enthusiasm of board member **Margaret Stavish.** I convened, on short notice, a meeting of the board to help me plot future issues and to ensure that I was taking, as best I could, the pulse of the grassroots for this issue of the Pike. When I discovered Margaret works for the Division of Information Systems Design, I drafted her into hooking up my new computer. The old computer was behaving rather badly after its move upstairs. While Margaret was making the new computer behave, she showed me how to create electronic links within the Pike and from the Pike to other Center material on the X: drive or on the World Wide Web.

This issue starts to take advantage of the linking capacity by providing internal links. If you're reading a story and find a continuation, just click on the words "Continued on . . . " or "Continued from . . . " to move to the next section of the story or back to the previous section. You can click on the items in the index on Page 1 to go right to an item that may be of special interest to you. To encourage you to go paperless in your reading of the Pike, I've changed the typeface for the articles to one that is both slightly larger as well as being easier to read on-screen.

Is Your Name Joe or Norman?

I actually answer to both. It's an interesting experiment you can try when you see me walking down the hall. I began life with friends and family calling me by my middle name, Joe. When I got to school and found employment in large government agencies, it became much easier to go by Norman. I most likely would have been Norman here if it weren't for my wife, **Karen,** who calls me Joe to her fellow employees. What's that got to do with the price of potatoes? Well, she works in CDER, too, so there were folks here who only knew me as Joe.

Got a Question, Want Jim and Joe to Share an Answer?

If you have a question about what goes on in CDER and think the answer might be useful to everyone, **Jim Morrison,** the Center's Ombudsman, and I will tackle your questions and publish the best answers we can find. Send questions about CDER, the Pike, employee communications, the color of the rugs, to Jim (MORRISONJ) or me (OLIVERN). We'll publish the best in the Pike.

Stamp Out Mysterious Hairline, Win a Free Lunch Along the Pike

Razor blades are one of the all-but-forgotten staples of newsletter production in this electronic age. So how do I get rid of the hairline that appears in the CDER logo in the masthead, and in the upper right corner of this page? If you can solve the problem, not only do you get your name and solution published here, but I'll take you out to lunch.Warning: the electronic equivalent of correction fluid, a clear text box over the hairline, doesn't win—I've already tried that.

news along the pike

The Pike is published electronically and is available on the X: drive in Cdernews or on the World Wide Web at:

http://www.fda.gov/cder/pike.htm

Views and opinions expressed are those of the authors and do not necessarily reflect official FDA or CDER policies. All material in the Pike is in the public domain and may be freely copied or printed.

Have ideas, news, or photographs to contribute?

Please contact a member of the Editorial Board or:

News Along the Pike
CDER Office of Training and Communications (HFD-200)
Parklawn Building, Room 12B-45
Editor
Norman "Joe" Oliver
phone: (301) 827-1243
e-mail: OLIVERN

Ombudsman's Corner

Timeliness, Policy Emerge as Top Complaints

By Jim Morrison

I have been "ombudsing" for a year now, and I'm asked frequently about the nature of the complaints I get. Naturally, the confidential nature of my contacts makes it difficult to get very specific, but now that I have a year's worth of data, I can give you a reasonably clear picture.

This analysis is based on 71 complaints or issues in 59 contacts. I included only those involving substantive complaints or issues. The ratio of contacts from outside the Center to those from within runs roughly 2:1. That is not too surprising, since the ratio of the population of the outside world to Center employees is even larger than that (about 3,000,000:1).

The complaints can be sorted into the following categories with corresponding frequencies:

External

Timeliness	34%
Policy or decision challenged	29%
Priorities or inconsistencies	22%
Poor advice or lack of information	15%

Internal

Personnel management	57%
External interactions	23%
Management/administrative systems	20%

Timeliness is the most frequent complaint from outside. The 34% figure is really understated, because many of the complaints about priorities are aimed at speeding up our processes. This is expected. Even though we have made tremendous progress in shortening review times, expectations have also been raised. Many complaints about timeliness relate to the new drug area, but others relate to activities throughout the Center. All of us can reduce the number of timeliness complaints by not promising anything we can't deliver. A careless estimate of a completion date by us can lead a company to use it in making costly business decisions.

Next to timeliness, I hear most about disagreements with policies, actions or decisions. About a third of the time, the problem stems from miscommunication and misunderstandings. When coupled with the third category, dealing with bad or lacking information, it is clear that we can prevent many complaints by getting more and better information out. I suspect that CDER's new Web site and the anxiously awaited internal CDERnet will significantly help improve understanding of our policies and procedures. Another piece of advice I would give is to make sure you cite policies accurately, and if you think a policy doesn't make sense, don't pass it along until you understand it and find an interpretation of it that makes sense in the particular context you are working with.

It should be no surprise that over half of the internal complaints relate to poor personnel management practices. With the Federal work environment changing constantly, often not for the better, our supervisors and managers need to be aware of the impact on our people of bad press, dwindling opportunities for promotion to management positions, and the threat of downsizing. We can improve morale with honest positive and negative feedback, delegated responsibilities for meaningful work and expressions of appreciation for excellent performance.

One of the pleasant surprises of the Ombudsman's role for me has been the number of times I have been alerted by CDER staff to developing problems with external interactions. Please continue to let me know when you see a problematic interaction developing. This year I have been alerted to a systems problem in personal drug imports, multiple cases of deteriorating relations with companies and consultants, and problems with internal FDA investigations.

I also appreciate hearing about problems with administrative systems that are not serving our needs as they should. Don't assume that everyone knows about a problem you see and that no one cares. Send me an e-mail at MORRISONJ or call me at 594-5443. Together we can make CDER a better place to work.

Jim Morrison is the Center's Ombudsman.

Reviewer Mentor's Corner

Video Training Tape Available

By June Cory

CDER's Reviewer Mentoring Program now has over 40 mentors assigned to new review staff. For mentors who have been assigned proteges since the New Mentors Workshop on March 4, we have an edited videotape of the New Mentors Workshop available to loan out for viewing.

This video features Dr. Woodcock as well as other CDER staff. We will also send you the updated mentor's checklist and other information helpful for mentors.

To obtain the videotape and other information, please contact June Cory at 827-3489 or e-mail at CORYJ.

June Cory works in OTCOM's Division of Training & Development.

Project Management Corner

No Project Manager Is an Island . . .

By Susan Cusack

In a world filled with e-mail, voice mail, and many other electronic means of disseminating information, it seems that communicating with other project managers/CSOs should be a breeze.

A breeze? Hardly! For example:

- How many of you out there know that the Division of Medical Imaging has recently hired several new, talented and energetic project managers?
- How many project managers have created templates for taking minutes or managing workloads that might be worth sharing?
- How many project managers have received awards, degrees, wedding licenses, or birth certificates recently?

The Project Management Coordinating Committee (PMCC) recognizes that this kind of information should be shared. We need to have the opportunity to know what our peers are doing; become more connected, learn something new, or give someone a pat on the back.

We hope that future articles, will enable us to do this.

If you have an idea for an article, some good news, or even a little hint to share, please send it to Susan Cusack (e-mail address—CUSACKS). The only ideas that are insignificant are those you don't share.

To get this started, I am going to share a helpful hint that **Christine Kelly,** one of the new project managers in the Division of Medical Imaging, devised. Our Division holds numerous meetings with industry, and Christine heard me on the telephone, trying to give directions to a sponsor on how to get to Parklawn. She observed that it would save time to fax a street map to the sponsor. In fact, she noted that under the meeting MAPP, we must fax confirmation of their meeting, so it would be very simple to include a map with their confirmation. She pulled a small map from her orientation material, edited it a little to improve clarity, and a new meeting map was born. I thought this was brilliant. If anyone out there already does this . . . Why didn't you tell me?

Susan Cusack is a consumer safety officer in ODE III's Division of Medical Imaging and Radiopharmaceutical Drug Products.

AMF Corner

Paper Charge and History Card To Go Electronic

By David Isom and the Division of Information Systems Design

CDER's division document control rooms have historically maintained a paper "Charge and History" card for each investigational new drug (IND) and new drug application (NDA). This paper card provides a written chronological log of incoming documents, reviewer assignments, and the volume numbers where the documents are archived. The paper card also provides a place to record the dates of associated work generated during the review process such as memos, reviews, consults, and action letters. To better manage submissions, assignments, and action dates, CDER started tracking these in a COMIS database in 1986.

However, the paper Charge and History card continued to serve as the master record of an application's history because it provided a place to also record dates of other related review activities.

Over the past three months, staff from CDER's Division of Information Systems Design (DISD) has worked closely with a team of CDER staff from various review divisions to analyze the requirements for combining the information from the paper Charge and History Card with the COMIS database. The goal is to combine this paper card information with the COMIS database so that CDER can 1) eliminate the processes required to maintain a parallel paper tracking system, and 2) provide an intuitive interface so that reviewers can access the complete history of INDs and NDAs from their desktop personal computer.

The goal: a more intuitive way of tracking review documents and viewing regulatory history

The requirements analysis is near completion, and a prototype is being developed for probable piloting this year. This new Charge and History COMIS database will be driven by a new Windows-based query interface that will allow easy on-line query of the complete history of an IND and NDA, including features such as grouping document dates that are cross-referenced. It will also provide access to related information from other existing computer systems like the Decision Support System (DSS) and the Excalibur document repositories.

Through everyone's commitment and efforts, this project will provide all CDER project managers, review staff, and division document room employees with a more intuitive way of tracking review documents and viewing regulatory history. It will also help make our document management processes more efficient by eliminating the parallel processes for maintaining a paper Charge and History card.

David Isom, the Center's AMF Project Manager, collaborated with the Division of Information Systems Design on this article.

CDER Fall Planning Meeting: Clip & Save Agenda

Date/Time	Topic	Presenter
	Tuesday, Oct. 29	
8:30 - 9:00 a.m.	CDER's Transformation Goals	Dr. Woodcock
9:00 - 9:45 a.m.	Coordinating Committees	TBA
9:45 - 10:15 a.m.	Office of Management	Mr. Abbott
10:15 - 10:45 a.m.	Break	
10:45 - 11:15 a.m.	Office of Training & Communications	Ms. Rose
11:15 - 11:30 a.m.	GRP Initiatives	TBA
	Wednesday, Oct. 30	
8:30 - 10:30 a.m.	Office of Pharmaceutical Sciences	Dr. Williams & OPS Office Directors
10:30 - 10:45 a.m.	Break	
10:45 - 11:15 a.m.	Office of Compliance	Ms. Jones
11:15 - 12:00 p.m.	OCD/Regulatory Policy	Ms. Axelrad
	Executive Operations	Ms. Henderson
	EEO	Ms. Bell
	Ombudsman	Mr. Morrison
	Thursday, Oct. 31	
8:30 - 10:30 a.m.	Office of Review Management	Dr. Lumpkin & ORM Office Directors
10:30 - 10:45 a.m.	Break	
10:45 - 11:05 a.m.	Information Technology	Mr. Isom
11:05 - 11:20 a.m.	GRP Initiatives	TBA
11:20 - 11:30 a.m.	Closing	Dr. Woodcock

Location: Conference Room G, Woodmont II
Remote sites: 13B-39 Parklawn, and videoconferencing room, Corporate

FDA, CDER Unveil New Employee Performance

The FDA dumped the old employee performance management system Sept. 1, 1996, when it implemented the new Performance Management Program (PMP).

One of the main changes with the new PMP is a switch to calendar year rating periods. In order to realign employees to the calendar year cycle, the FY96 rating period will be extended until Dec. 31, 1996, a 15-month transition year rating period (Oct. 1, 1995, to Dec. 31, 1996).

Another significant change is the switch to a "pass/fail" final rating. EPMS plans already in effect will be used along with the new Performance Evaluation Plan (PEP) in reaching a final rating of "Meets Performance Measures" or "Fails To Meet Performance Measures."

In order to use the new PEP as the rating tool for this performance cycle, the plan must have been established and signed by employees by Sept. 3, 1996, to allow for 120 days prior to the end of the rating period. Supervisors who would prefer to use the current EPMS plan rather than develop a new PEP, may identify each of the EPMS elements as a specific task or goal on the PEP form and then use the PEP process of "Exceeds," "Meets" or "Fails To Meet" in determining the final rating of record of Meets Performance Measures or Fails To Meet Performance Measures. In either case, the PEP must be established by Sept. 3.

CDER policy is to have all employees, except those listed below, on a signed PEP by close of business Sept. 16, 1996. This will allow employees to be rated for the 1996 appraisal year by the end of January 1996. Any request for exception to this date must be approved by the Office of Management.

Employees not covered under this program include:

- Senior Executive Services (SES) members.
- All employees appointed under Schedule A 213.3102 "O" (excepted appointment) authority whose appointment is limited to 1 year or less.
- Administrative law judges appointed under Section 3105 of Title 5 USC.
- Experts and consultants serving in an individual capacity and members of advisory committees.
- Senior Biomedical Research Service (SBRS) employees.
- Persons serving under an appointment in the excepted service having a time limit of less than 120 days.
- Employees in military service, e.g., PHS Commissioned Corps Officers (this does not preclude rating officials from

(Continued on page 6)

CDER Approves First CFC-Free Inhaler for Asthma

By John Jenkins

The Center for Drug Evaluation and Research's Division of Pulmonary Drug Products approved on Aug. 15 the first chlorofluorocarbon-free metered-dose inhaler for treating asthma and chronic obstructive pulmonary disease (COPD).

Minnesota Mining and Manufacturing, better known as 3M, submitted the application for a hydrofluoroalkane (HFA)-propelled albuterol sulfate metered-dose inhaler formulation. 3M will manufacture the product that will be marketed as Proventil-HFA by the Key Pharmaceuticals division of Schering-Plough.

This approval represents an important landmark in the United States' efforts to comply with the ban on CFC-containing products as mandated by the Montreal Protocol.

According to Murray Lumpkin, Deputy Center Director for Review Management: "This was a tremendous effort to work with a sponsor and help ensure that we in the U.S. are living up to our responsibilities under the Montreal Protocol on reducing fluorocarbons from our atmosphere. At the same time it ensures that Americans have access to asthma and COPD drugs that can be delivered accurately."

The approval is also an important landmark for the Center and the Division because it represents the culmination of years of hard work by a number of people within the Agency to work with sponsors to assist them in rapidly bringing these replacement products to the marketplace.

In the case of 3M, the Division interacted very closely with the sponsor throughout the development program and offered important advice that led to improvements in their program and their product. The review and approval were completed within one user fee review cycle (total FDA time, 14.9 months) and represent a tremendous effort on the part of the entire review team to get this product approved.

This is the second NDA for a new metered-dose inhaler product approved this year within one user fee review cycle, a remarkable achievement given the complexity of the dosage form. Each discipline has worked many long hours to identify and help the sponsor correct the deficiencies in their application so we could approve the product on the first review cycle.

The chemists completed at least three complete reviews of this NDA and the related amendments and drug master files (DMFs) during this review cycle. I would like to thank all of the members of the review team for their hard work and dedication that has resulted in this important approval. We can all be proud of this achievement.

Members of the Proventil-HFA review team include:

Sue Johnson	**Steve Wilson**
Bob Meyer	**Jim Gebert**
Misoon Chun	**Gus Turner**
Joe Sun	**Shirnette Ferguson**
John Leak	**Nancy Sager**
Rik Lostritto	**Rita Hassall**
Guirag Poochikian	**Chris Good**
Bradley Gillespie	**Shelia Keels**
Dale Conner	**Peter Cooney**
Parinda Jani	**Paul Stinavage**
Cathie Schumaker	

John Jenkins is Director of the Division of Pulmonary Drug Products, ODE II.

. . . New Performance Plan

(Continued from page 5)

establishing goals or establishing a performance plan as a supplement to the COER–"local option").

- Residents, interns, and other student employees who receive stipends under Title 5 USC 5352.
- Personnel on detail to a public international organization.
- Presidential appointees.
- Persons in positions for which employment is not reasonably expected to exceed 120 calendar days in a consecutive 12-month period.

The new policy was sent to all CDER employees via e-mail. Should you have any questions, please feel free to contact **Lynda Papio** via e-mail (PAPIO). In addition, the Office of Management recently held several Performance Management Programs.

For those unable to attend, a videotape has been forwarded to all CDER management officers for viewing. The video is approximately 40 minutes in length. If you are interested in viewing the video, please contact your management officer. There are two handouts that may be helpful when viewing the video.

Center administrative staff who can help with the program are:

Tanya Abbott, 594-6779, Office of the Center Director; **Alice Gray,** 594-1654 or **Becky Nalley,** 594-1654, Office of Management; **Bobbi Jones,** 827-1243, Office of Training and Communications ; **Anita Harrell,** 594-1058, Office of Compliance; **Toni McCannon** 594-5477, Office of Review Management.

Tammy Russell, 594-6758, Office of Drug Evaluation I; **Tom Cunningham,** 443-2544, Office of Drug Evaluation II and (temporary) Office of Drug Evaluation III; **Matt Zell,** 827-2487, Office of Drug Evaluation IV; **Sherree Lancaster,** 827-2269, Office of Drug Evaluation V; **Kathy Rios,** 827-3216, Office of Epidemiology and Biostatistics.

Rich Vengazo, 594-5476, Office of Pharmaceutical Science and Office of New Drug Chemistry; **Laurie Watson,** 594-2519, Office of Generic Drugs; **Wes Metz,** 594-5623, Office of Clinical Pharmacology and Biopharmaceutics; **Roberta Light,** 594-0510, Office of Testing and Research.

Briefly Noted

Five-day Grace Period Eliminated

The FDA's Office of Human Resources Management has revised the FDA Merit Promotion Plan regarding the five-day grace period for job applicants. The plan had allowed applicants an extra five working days in order to submit application materials in response to merit promotion vacancy announcements. The revision has eliminated the grace period. Any application material submitted within the five working days after the closing date will continue to be accepted until Sept. 30. Beginning Oct. 1, 1996, all application material must be postmarked or received on or before the closing date of the vacancy announcement.

Questions concerning this change may be directed to Kimberly Carter, personnel staffing specialist in the Division of Recruitment and Staffing at (301) 827-4070.

New Small Business Guide to FDA Available

The 3rd Edition of A *Small Business Guide to FDA* was published in the Spring of 1996 by the Office of External Affairs, Industry and Small Business Liaison Staff. It has been disseminated widely to industry and offices within FDA, with principal distribution to the Regional Small Business Representatives and to the Centers' industry outreach offices. FDA printed a limited number; however, the guide is available on FDA's World Wide Web homepage at:

http://www.fda.gov/opacom/morechoices/moreindu.html

Trust Established for Commerce Families

The Federal Government recently established a Commerce Employees Fund, a charitable trust, to provide help to the families of Department of Commerce employees who died in the plane crash near Dubrovnik, Croatia, last April. According to Health and Human Services Secretary Donna Shalala: "While the nation experienced a great loss that day, the families and children of those on the plane suffered an even greater loss. The Fund will help provide for the children's education, funeral expenses, and other needs of the families."

To contribute to the fund, employees can send a donation to the Federal Employee Assistance and Education Fund (FEEA) which will administer the Fund. Checks should be earmarked for the "Commerce Employees Fund" and mailed to the FEEA, Suite 200, 8441 West Bowles, Littleton, Co. 80123.

Epidemiology Branch Mourns Nasis-Ravitz

By Tom Conrad

Public Health Service Commander Anastasia Nasis-Ravitz, Pharm.D., from CDER's Office of Epidemiology and Biostatistics, Epidemiology Branch, died Aug. 22 of breast cancer.

While working in the Epidemiology Branch, Nasis-Ravitz was instrumental in drug use research and the development of FDA's Post-Marketing Safety Assessment for new prescription drugs. She took medical retirement on Aug. 1, 1996.

Nasis-Ravitz was a Pharmacy Commander in the Commissioned Corps for 17 years and had earned a doctorate in pharmacy. Her Federal career began in 1976 as a Staff Pharmacist at the National Institutes of Health's Clinical Center. She worked her way up through Assistant Supervisor to Supervisory Pharmacist before transferring to FDA in 1984 as a Lexicographer and later Section Chief of Drug Information Services.

In 1988, she returned to NIH, working in the National Cancer Institute's Division of Cancer Treatment. Then, in 1990, Nasis-Ravitz separated from the PHS to complete her doctorate. After completing her doctorate and working at Good Samaritan Hospital, she returned to FDA in 1993 as a Senior Regulatory Research Officer in the Office of Epidemiology and Biostatistics, Epidemiology Branch.

During her career in the Commissioned Corps, her awards included the Commendation Medal, Achievement Medal, three Unit Commendations, Hazardous Duty Award, National Emergency Preparedness Award, Special Assignment Award, and Regular Corps Ribbon.

Nasis-Ravitz is survived by her husband, Dr. Bernard Ravitz and her 4-year-old son Sean, both of White Hall, Md. Donations or memorials may be made to the American Cancer Society for Breast Cancer Research at 8219 Town Center Drive, P.O. Box 43026, Baltimore, Md. 21236.

Many remember Nasis-Ravitz as a hard-driving, motivated professional. She kept this poster in her office that I believe reflected her inner self not seen by many:

How To Be an Artist

Stay loose. Learn to watch snails. Plant impossible gardens. Invite someone dangerous to tea. Make little signs that say yes! and post them all over the house. Make friends with freedom & uncertainty. Look forward to dreams. Cry during movies. Swing as high as you can on a swing set, by moonlight. Cultivate moods. Refuse to "be responsible."

Do it for love. Take lots of naps. Give money away. Do it now. The money will follow. Believe in magic. Laugh a lot. Celebrate every gorgeous moment. Take moonbaths. Have wild imaginings, transformative dreams, and perfect calm. Draw on the walls. Read everyday.

Imagine yourself magic. Giggle with children. Listen to old people. Open up. Dive in. Be free. Bless yourself. Drive away fear. Play with everything. Entertain your inner child. You are innocent. Build a fort with blankets. Get wet. Hug trees. Write love letters.

Tom Conrad works in the Office of Epidemiology and Biostatistics, Epidemiology Branch.

CDER Outreach to Field

Small Business Reps Call for Enhanced Links

As part of the Center's communications outreach program, the Office of Training and Communications held a CDER orientation with the Office of Regulatory Affairs' Small Business Representatives from the FDA's regional offices. During the meeting, coordinated by OTCOM's **Rita Hoffman,** the field representatives expressed a need for improved communication flow between CDER and the field.

Representing the regional offices were **George Walden,** Northeast Region, **Joseph Phillips**, Mid-Atlantic Region, **Barbara Ward-Groves,** Southeast Region, **Joseph Petty,** Midwest Region, **Marie Falcone,** Southwest Region, and **Mark Roh,** Pacific Region. The representatives asked that new mechanisms be set up to help keep abreast of emerging developments such as speeches to be given by key Center officials in their areas, new publications, and guidance documents.

Lucy Rose, OTCOM Director, provided an overall welcome; and **Jean Yager,** the Center's Senior Project Manager, brought the representatives up to date on project management initiatives to improve review times. OTCOM staff briefed them on communications initiatives to bolster accessibility to information about CDER and its policies. **Paul Stauffer,** CDER's webmaster from the Medical Library, gave a hands-on demonstration of the CDER homepage and the guidance documents now available on the World Wide Web. **Angie Youngblood** discussed how they can take advantage of the Center's video-conferencing capabilities. **Janice Newcomb,** Director of the Division of Training and Development, provided an overview of the Center's ongoing training program.

OTCOM Moves, Thanks DISD, Facilities Management

Linda Brophy, Special Assistant to OTCOM Director **Lucy Rose,** reported that renovations to the 12th floor of the B Wing in the Parklawn Building are complete and that OTCOM relocated and consolidated over the weekend of Sept. 21-22.

Linda, Lucy, and their immediate staff are in Room 12B-45, Freedom of Information is in 12B-05, the Division of Communications Management, including the Drug Information Branch, is in 12B-31, and the Division of Training and Development is in 12B-10.

Other teams of CDER professionals making sure OTCOM was up to speed on Monday were: **Ruth Clements, Jim Cockran, Anne Beckmeyer, Craig Thomas, Jamey Henneberger,** and **Mary Hawthorne** of the Facilities Management group. Rose also praised the efforts of the **Division of Information Systems Design** to make a smooth transfer of the computer system."Both groups' commitment to service was exceptional," Rose said.

"Special recognition is extended to **Bobbi Jones,** OTCOM Program Specialist, whose endless coordination and direction made the move smooth and efficient," Brophy said. "Additional thanks and appreciation are extended to all OTCOM office coordinators including **Katie O'Donnell, Charlotte Henning, Rynetta Little, Pamela Winbourne, Wanda Blackston, Amy Mason,** and **Sonya Armstrong,"** Brophy added.

36th ICAAC Convention

Project Managers Take Message to New Orleans

OTCOM's **Rita Hoffman** pointed out there was another highly successful CDER move of a different sort. OTCOM and the Project Managers Communications Committee took their popular show minus the display (see Page 9) to New Orleans for the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Sept. 16-18.

In New Orleans, they joined forces with the FDA's Office of Health Affairs to staff the FDA booth at the 36th ICAAC conference sponsored by the American Society for Microbiology and attended by 14,000 physicians and scientists from all over the world along with representatives from the pharmaceutical industry.

Joining Hoffman at the three-day FDA exhibit was CDER project manager **Susan Cusack.** The project managers had a side area of the FDA display area and were able to demonstrate the World Wide Web site as well. FDA recruiters were also out in force.

"There were a variety of publications there in addition to CDER's," Hoffman said, "including how to obtain information on devices, biologics, and foods."

Also helping out was the public affairs specialist from the FDA's regional office in New Orleans, **Darlene Tollestoup.**

This is like the car show for drugs," Hoffman said.. "It's humongous. It's an international program with industry, microbiologists, and virologists from all over the world."

Project Management Exhibit Scores Hit at RAPS

The CDER exhibit on project management had a highly successful first appearance at the 20th annual convention of the Regulatory Affairs Professionals Society (RAPS) Sept. 9-10 at the Sheraton Washington Hotel. **Rita Hoffman,** a consumer safety officer with OTCOM's Drug Information Branch, spearheaded the coordination effort required for the display which was co-sponsored by the Center's Project Management Coordinating Committee.

"We were the biggest draw of all the exhibitors," said Hoffman who fielded questions from industry representatives about regulatory affairs, new drug applications, and other details about CDER's operations for the two days the exhibit booth was on display. Project managers **Susan Cusack** and **Kevin-Daryl White,** answered many questions about the day-to-day operations of project management. The CDER webmaster, **Paul Stauffer,** developed a program to support demonstrations of the Center's Web site. Hoffman reported that she received a great deal of support for coordinating and setting up the display from **Jean Yager,** the Center's senior project manager; Drug Information Branch's **Pamela Winbourne;** and **Mary Lambert,** Division of Anesthetic, Critical Care, and Addiction Drug Products. "We also had assistance in the technical aspects of setting up the hookups for the World Wide Web from the Division of Information Systems Design," Hoffman said.

The booth highlights CDER's highly interactive team-based project management initiative designed to reduce the amount of time it takes for the Center to review a new drug application (NDA). The booth displays the NDA review template and highlights the improved review times achieved with project management under the user fee program.

The theme of the RAPS convention was "Solve the Regulatory Puzzle." More than 150 government and industry expert speakers discussed the state of the FDA and regulatory affairs. RAPS is a processional association with about 6,000 members working as regulatory affairs professionals in the health care industry. They are employed in pharmaceutical, medical device, biological, and biotechnology areas.

The CDER booth introduced communication outreach efforts on the part of the Center's project managers and OTCOM.

"This exhibit played a dual role. We introduced the project management concept at CDER to the outside world and showed them how open CDER is becoming through the World Wide Web," Hoffman said. "It was outstanding, just phenomenal. Industry now understands that CDER isn't a black hole, that the divisions are ready to work with them from the onset, and that the resources and guidance documents are available. We also introduced videoconferencing, so that industry doesn't have to travel to Rockville."

Distributed at the booth were the new *Small Business Guide to the FDA* and the special report of the *FDA Consumer*, "New Drug Development in the United States."

Posing at CDER's booth on display for the first time at the RAPS convention are (from left) Rita Hoffman, Jean Yager, Sharon Schmidt, Debbie Kallgren, Janet Woodcock, and Patricia Desantis.

Kevin-Daryl White (left) demonstrates the CDER Web site to industry representatives.

Photos by Linda Brophy (top) and Rita Hoffman

People Along the Pike

When I was much younger, I always liked to write about the Army's high-speed units. You know who they are—those teams doing difficult and dangerous work under impossible conditions with world peace hanging in the balance. What made those units high-speed? The best equipment? Yes, but that was only part of the equation. People make things happen. That's why I seized the opportunity to come to CDER. Now I wouldn't have to traipse off to the woods to find teams of people doing difficult and dangerous work under impossible conditions with world health hanging in the balance. The People Along the Pike do that everyday. I thought that some of them would walk through my door if I left it open.

Indeed they did. One of the first was **Gowraganahalli Jagadeesh,** from the Division of Cardio-Renal Drug Products. Gowra stopped by with his own copy of a book for which he was editor. Editing the Pike is a piece of cake compared to *Pharmacology of Receptors and Ion Transporters: Proceedings of the International Seminar on Recent Trends in Pharmaceutical Sciences, February 19, 1995, India.* Not all of you might think this is bed time reading, but I remember the time when receptors were no more than hypotheses. Now, as Gowra points out in his preface, more than 400 have been cloned and sequenced. Gowra has asked the CDER library in Parklawn and Woodmont to order copies, but in the meantime you can borrow his if you e-mail him (JAGADEESHG).

Ron Goodman, the WOC II mail carrier, stopped by the other day to thank the team responsible for the Division of Management Services' picnic. "September 20th was my division's picnic for the year," Ron noted in an e-mail report. "This was one of my best picnics I ever had since coming to FDA, such a bright and warm day being outdoors, having a marvelous time, and just being filled with high spirits. Hope this is nice and concise." Yes it is, Ron, and you can bet your thoughts are appreciated by the picnic's steering committee. **Yolanda Reeves** reports that team included **Craig Thomas, Lynda Papio,** and **Ruth Clements.**

Now that my first issue of the Pike has been put to bed, I'll be out and about to see you. I'll be asking questions, doing interviews, and whatever else I can think of to find out what you're doing, what you're thinking, and how the Pike can help brighten your day and enlighten your outlook on CDER's People Along the Pike. But remember, my door is open, and the phone and e-mail are just a moment out of your schedule. I have fat-free pretzels, and we can always scare up some high-test coffee. In the meantime, I've gleaned some People Along the Pike changes from the e-mail that deserve a home here before they get filed in cyberspace.

Roger L. Williams, Deputy Director, Pharmaceutical Science, announced that the Office of Pharmaceutical Science selected **Eric B. Sheinin,** as the Director of the Office of New Drug Chemistry (ONDC). Eric received his Ph.D. in organic chemistry from the University of Illinois at the Medical Center in Chicago, after which he joined the FDA. "He brings an impressive record of leadership and management from 25 years of work at the Agency, all of which have been spent in CDER or its predecessor organizations. Eric has held positions in new drug divisions covering the fields of medical imaging, surgical and dental drug products, oncology, and radiopharmaceutical drug products," Williams writes.

Williams took advantage of his position as the departing Acting Director of ONDC to congratulate the People Along the Pike in ONDC for a highly successful first year of operation. "The success of the Office has been evident not only in the extraordinary performance record of the Office in meeting PDUFA goals but also in many activities that work to achieve the mission, vision, values, and goals, which have been articulated by Center leadership as part of the change process," Williams writes. "In addition to the **review staff,** I would like to thank especially **Eric, Dr. Charles Hoiberg, Dr. Yuan-Yuan Chiu,** and the **ONDC team leaders** for providing leadership to ONDC during its first year of operation." Williams wrote that he would also like to thank the many People Along the Pike who have worked so hard on the policy documents that will clarify what information should be provided in applications and that will promote consistency in reviews.

Shortly after **Eric Sheinin** assumed his new duties as office director, he tapped **Yuan-yuan Chiu,** Ph.D., to serve as Deputy Director, Office of New Drug Chemistry. Yuan-yuan received her B.S. degree in chemical engineering from Cheng Kung University in Taiwan and her Ph.D. in chemistry from Harvard University. Yuan-yuan has been with the FDA since 1980 and has served as a review chemist and a supervisory chemist in the Division of Metabolism and Endocrine Drug Products and, most recently, as the Director of the Division of New Drug Chemistry II.

Yuan-yuan is the recognized Center expert in the area of biotechnology and has served as the chair of the Center's biotechnology committee and the Center's bovine spongiform encephalopathy (BSE) working group. (BSE is known popularly as mad cow disease.) She also serves as the leader of the Center's working group on chemistry, manufacturing, and controls of botanical products. Yuan-yuan also conducted the preapproval inspections of the facilities used for the first two biotechnology products approved the Center. She has published nearly 50 articles in scientific journals and has edited a book, *Drug Biotechnology Regulations, Scientific Basis and Practices.* Immediately prior to joining the FDA she studied the chemical and genetic structure of human immunoglobulins in the Department of Biophysics at Johns Hopkins Medical School.

Center Director **Janet Woodcock** and Office of Compliance Director **Stephanie Gray** announced that

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People Along the Pike

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David A. Lepay has taken over as Director, Division of Scientific Investigations, replacing **Frances Kelsey**, now the Deputy for Scientific and Medical Affairs in the Office of Compliance. Dave received a B.S. from Yale College in 1978; M.D. from Cornell Medical College in 1986 and Ph.D. from the Rockefeller University in 1985. He completed a research fellowship in viral pathogenesis at the Scripps Clinic and Research Foundation in LaJolla, Calif., in 1992. He was a pathology resident and clinical fellow at Brigham and Women's Hospital, Department of Pathology in Boston, Mass. He began his FDA career with CDER's Division of Anti-Viral Drug Products as a reviewer in 1992. He reviewed Pre-IND, IND, and NDA submissions for primary HIV therapies (including botanical and alternate therapies), treatment and prophylaxis of HIV-related opportunistic infections, and immune modulatory drugs. He was the clinical representative of HFD-530's Pre-IND team. He also was the FDA Representative to national protocol committees on AIDS-related diarrheal illness. He is board certified in clinical pathology.

Deputy Center Director (Review Management) **Murray M. Lumpkin,** and ODE II Director **James Bilstad,** wrote to announce that **Lisa Rarick,** accepted the position of Director of the Division of Reproductive and Urologic Drug Products. Lisa received her B.S. and M.D. from the Loma Linda University School of Medicine in Loma Linda, Calif., and completed her Ob/Gyn Residency at Georgetown University. She was board certified by the American Board of Obstetrics and Gynecology in 1990 and is a Fellow of the American College of Obstetricians and Gynecologists. Outside her FDA responsibilities, she serves as a volunteer at the Zacchaeus Free Clinic in Washington, D.C. In addition, she has been an officer in the Washington Gynecological Society, in which she has been a member since 1989. Lisa joined FDA in December of 1988 as a medical officer in the Division of Metabolism and Endocrine Drug Products where she had extensive experience in overseeing the development and review of many drug products associated with human reproduction. At FDA, she received the Award of Merit in May of this year.

Murray Lumpkin also announced that Diane Cave, his secretary in the Office of Review Management, retired after 31 years of dedicated service to FDA.

Office of Management Director **Russell J. Abbott** announced that **Greg Warzala** accepted the position of Director, Division of Database Management. "As you may remember from our six-month planning goals from the Spring session," Abbott wrote, "we were to establish a new division to consolidate the management and facilitate the integration of database management functions and resources in the Office of Management. This included the reorganization of branches from within the Division of Planning, Evaluation and Resources Management and the abolishment of the Division of Drug Information Resources." Previously, Greg was the Branch Chief for the Computer Services Branch in the Division of Applied Information Technology in the Center for Biologics Evaluation and Research. In this position he was responsible for the divisions programming, budgeting and execution plan related to Information Technology and Infrastructure Architecture. He also served as the Acting Director, Division for Scientific and Management Information Systems where he was responsible for the overall coordination and development of the Computer Assisted Product License Application Review Program (CAPLAR). Greg has held a variety of positions in the Defense Department and the Army, and served in the Army from 1970 to 1972.

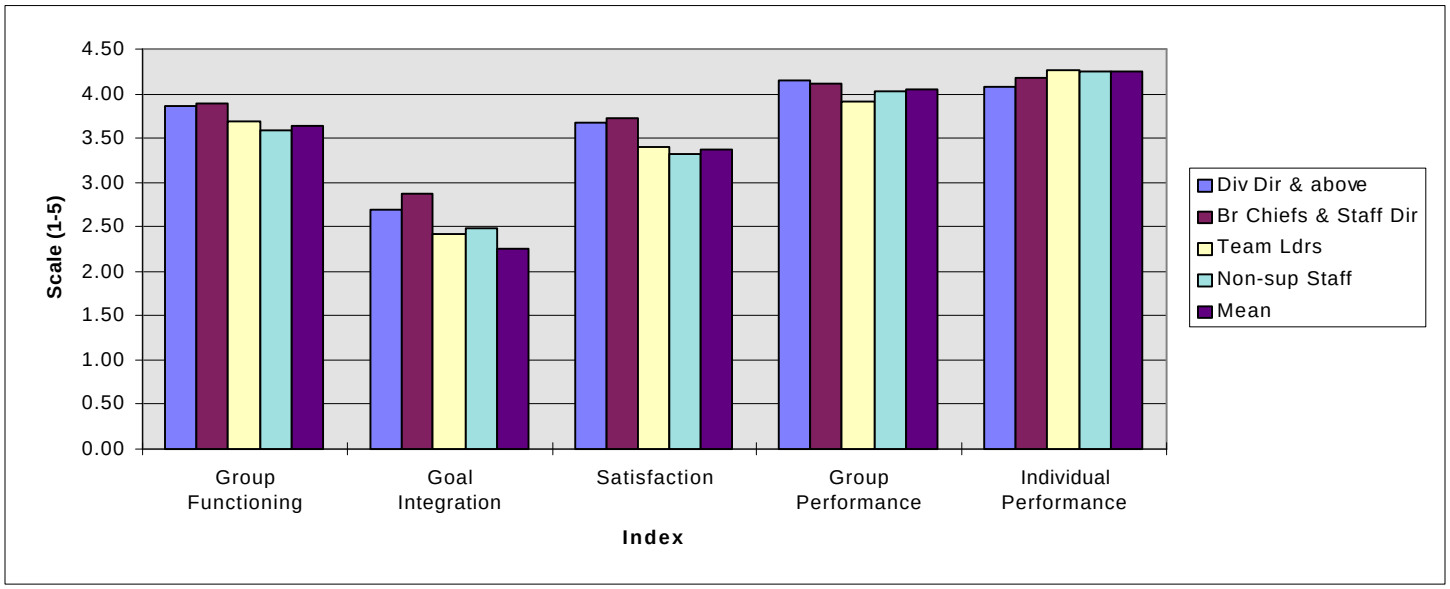
Russell J. Abbott also announced **Judith M. McIntyre** returned to CDER as Deputy Director, Division of Database Management. Judy has been in the Federal Government since 1980 where she began her career as a Computer Specialist/Section Chief in CDER/DISD and served as a supervisor of two development database teams. Prior to accepting the position as Deputy Director, Division of Database Management in CDER, Judy was a Computer Specialist for CBER in the Division for Applied Information Technology. Her duties included the full life cycle development of the automated technical information database systems as well as serving as the CBER Computer Safety Officer. Judy has received seven different awards since joining the government including the FDA Commendable Service Award and the FDA Commissioner's Special Citation.

Are you bothered by phone calls at the dinner table asking for contributions? **Satya Dubey,** from the Office of Epidemiology and Biostatistics, and a team of more than 100 People Along the Pike will be presenting you with a golden opportunity to be able tell those folks that you gave at the office and not have your nose grow as long as a breadstick. Satya is spearheading this year's Combined Federal Campaign for the Center and has been busy soliciting coordinators and key workers. I'm quite sure that among the 2,500 non-profit organizations in this year's campaign, you can find a local, national, or international group that's doing its level best to improve someone else's quality of life in a way that's important to you, either personally or professionally.

If you've read this far, remember I want to see many more **Names in Boldface** in this column. People Along the Pike are working hard. Tell me about those winning teams and notable accomplishments. It doesn't take long to whip off an e-mail, drop by the office, or call on the telephone.

The word processor is always turned on, and I can type almost as fast as you can talk. That's a promise. See you Along the Pike.

—Joe Oliver



END RESULTS: The chart displays a breakdown of CDER employee responses to elements of the category, "end results." On this 1-5 scale, a score of 3 represents an average response.

Employee Survey Data Pinpoint Communications Flow

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Woodcock said these actual responses will be used to address important employee concerns in key areas such as communications flow that aren't revealed in comparative data. Within CDER, there were many significant differences among responses based on role within a work group or membership in an academic discipline. The highly positive comparative data can be found in the report prepared by the firm that conducted the survey, Rensis Likert Associates, Inc. The report, the definitions of the elements measured, and the raw data broken down by supervisory subgroup have been released publicly and are available in each division.

The firm, in its report on the comparative data, said that there are 27 key individual indexes the survey measured. With four reporting levels, there are 108 additional "readings" of the data that can be examined as a cross section of CDER in addition to the averages for the Center. "By our own criterion of 60th percentile and above representing a strength and 39th percentile or below representing a potential problem, the results are extremely positive," the firm said. "Only three of the 108 index values fall in the potential problem band, while 74 are clear strengths." To obtain an overall glimpse of how it feels to work at CDER, the assessment focuses on four major areas: organizational climate, supervisory leadership, peer relationships, and end results. Each area is made up of elements, and each element is a composite drawn from several responses.

Organizational Climate

Organizational climate, which describes the Center's policies, procedures, practices and conditions, was a clear strong point in Federal comparative data, with seven of 11 elements scoring as strengths, and the remaining as typical. Five of the elements were placed in the top one-third.

As an example of how the actual employee responses can be used to identify a CDER problem area that scores well in comparison to other Federal agencies, Woodcock discussed communications flow. Managers at the division director or branch chief level estimated the quality of CDER's communications flow as about average.

Team leaders and non-supervisory persons estimated communications flow below average. All CDER employees said they would prefer better communication.

Supervisory Leadership

This category measures how the supervisor interacts with the subordinates as people. Seven of the eight elements in this area scored typical among Federal agencies. Employees tagged support and participation as areas needing attention.

Peer Relationships

How co-workers interact with each other was another strong area in CDER's effectiveness survey. Three of its four elements exceeded the Federal norm, and one was clearly at the high end of typical responses. Goal emphasis was a strength in the peer relationship area compared to its typical score in the supervisory leadership area, emphasizing the overall perception of peer relationships as one of CDER's best assets. Goal integration scored well in comparative data; however, employees want to see improvement.

End Results

End results is a category that takes a bottom-line view of what occurs in an organization: how effectively and efficiently its employees rate their ability to perform the organization's mission and meet its goals. As the employee response chart above shows, CDER employees find a high degree of satisfaction working hard in a high-performing organization.

Woodcock emphasized that CDER was a special organization with a special trust for the health of Americans and that Center employees were holding themselves and the Center to a higher standard. She said the survey would likely be repeated in about a year.