news along the pike

Center for Drug Evaluation and Research

R1 May 15,

Volume 2 Issue 5

Point of View

Videoconferencing: The Real Wings of Modern Man

By Paul J. Motise

Videoconferencing is the way to go *and stay* for FDA speakers who must creatively cope with travel cut-backs and heavy workloads. As a veteran FDA speaker, I turned to, and now advocate, giving presentations by videoconference whenever possible. Thanks to the outstanding videoconferencing management of Angie Youngblood, I've given three such presentations: two to European audiences, and one to a Texas group. Here are my experiences and thoughts on this valuable resource.

Videoconferencing offers clear advantages to both conference sponsors and to FDA speakers. First and foremost, rather than turn down a speaking invitation due to "resource contractions," I can accept an offer and deliver the agency's message, which provides the conference with FDA participation. In fact, as was the case in Texas, we can sometimes provide more speakers by using videoconferencing than we could have provided by any other means.

Conference sponsors also benefit by using innovative high technology. Videoconferencing adds pizzazz to an otherwise routine gathering. I emphasized this benefit to help convince one association to try videoconferencing. The group's name, "Spring Innovations," made my point beautifully so they couldn't turn down the offer (you want to be "innovative," don't you?).

As a frequent traveler, videoconferencing offers me additional advantages. For example, I don't have to travel. I can give a talk in the morning and be back at my desk by the afternoon. I don't have to put

(Continued on page 2)

21st (Cyber)Century

High Tide for the Web and Flow of CDER Information

This is the first in a series of articles about the CDER home page being developed on the Internet's World Wide Web.

By Melissa M. Moncavage

The switchboard in CDER's Drug Information Branch (DIB) is pulsating. While part of the staff patiently takes questions from the public, other staff members comb through mountains of documents, finding information about drugs in response to phone or mail requests.

The previous night, a major television network news show aired an "investigative" piece on the increased chance of getting cancer by using a popular diet drug. In addition, a pharmaceutical company has just announced that it has received an FDA warning letter alleging that the firm has failed to submit adverse events reports on two of its blockbuster drugs: a heart medicine and an antidepressant.

While this chaotic scene might seem like a portrait of hell to most people -- inside or outside of government -- it's just another day at the office for this staff.

But something *is* being done about it.

In mid-1995, DIB instituted a fax-on-demand service that, while still evolving, has helped tremendously in providing fast access to valuable information and documents.

"It's a great success -- beyond what we ever anticipated," said DIB Acting Director Barry Poole. He said that about 150 documents are currently available on the system with more information being added daily.

But even bigger savings is expected to come from the arrival of a home page on the World Wide Web (WWW). The CDER home page, under development since early this year, will give consumers, industry, and the media quick and easy access to information about approved drugs,

(Continued on page 7)

Quick Index Is On-line

The "Quick Index to General Subjects of Interest Related to Drug Regulation" is now available to staff via the X drive and to the public and industry on the Internet. The Quick Index is a handy reference guide that provides general contact information about the Center for Drug Evaluation and Research (CDER). Included are commonly requested FDA phone numbers, a management phone directory (key officials/new drug evaluation division officials), an FDA attorney phone directory, and a listing of the district directors.

The revised guide also includes an alphabetized list of specific IND/NDA topics, contacts and phone numbers, standard abbreviations, organizational charts, and more. On the X drive, the path and file name are: **X:\admin\qi96.pdf.** On the World Wide Web FDA home page, the URL is **http://www.fda.gov/cder/qi96.pdf**.

Eventually, the index will be available on the CDER internal home page, also known as the Intranet, which is currently under development. A printed, 67-page version will be mailed to all CDER employees in early June.

For details, call Wanda Clabaugh in the Office of Training and Communications, 301/827-1243.

inside...

CDER Ceremony Honors Staff

By Nelson Rodriguez

One of the first things Debbie Henderson noticed about Bobbi Jones was that she couldn't keep up with the work flow.

"While all of the secretaries were very busy, there was one who always had work piled up over her head so you could hardly see her -- Bobbi," said Henderson, CDER's Director of Executive Operations. "At first I thought to myself, `Wow, this secretary must be *really* slow' but then realized that it was just that everyone kept giving Bobbi more and more work because she did such a fine job and always cheerfully."

And the hard work paid off for Jones, now a program specialist in the Office of Training and Communications. On May 10, she was one of more than 70 CDER staff members recognized for their contribution to the Center over the past year at the first CDER Honor Awards Ceremony. Henderson presented her with an Outstanding Achievement Award for her work last year in the Office of the Center Director, and added, "Bobbi is a delight to work with."

In all, CDER Director Janet Woodcock, M.D. presented 42 awards in the following categories: Commendable Service Award; Equal Opportunity Achievement Award; Outstanding Achievement Award; Group Recognition Award; PHS Unit Commendation; CDER Fellowship Program Certificates; and the CDER Special Recognition Award.

The presentation ceremony was held at the Ramada Inn in Rockville, and was immediately followed by a reception for all CDER award recipients, family members, nominators, office directors and supervisors. It was held across the street in the Atrium of the DoubleTree Hotel.

It was the first time that a center-level ceremony was held under FDA's new two-tiered honor awards process. The new process gives centers the opportunity to present some agency level awards to their staff at a separate ceremony and allows greater recognition for awardees at the center level.

FDA-level awards were also presented to a number of CDER staffers during an afternoon ceremony at the DoubleTree.

The following are the CDER Honor Award recipients:

COMMENDABLE SERVICE
Karen Lechter
Jeylene Wood
Carol Assouad
Ermona B. McGoodwin
Julie Beitz, M.D.
Dianne Spillman
Robert M. White, M.D.
Maria Walsh
Paul S. Liu, Ph.D.
Maureen Dillon-Parker
Ted Sherwood
Henry J. Malinowski

CMCCC
Rashmikant M. Patel
Jane A. Axelrad
Roger L. Williams
Chi-Wan Chen
Charles Hoiberg
Yuan Yuan Chiu
Frank Holcombe
Charles Kumkumian

EEO ACHIEVEMENT
Debra L. Bowen
James D. Bona

OUTSTANDING ACHIEVEMENT
Barbara Jones
Karen Konkolewski
Robin M. Spencer

Comparative Treatments Conference Group
Louis A. Morris
Janet L. Rose
Norman A. Drezin
Leah Palmer
Sherry Danese
Diane Shnitzler
Karen J. Lechter
Warren Rumble
Nancy Ostrove.
Melissa M. Moncavage
Anne M. Reb
Jean Raymond
Lesley Frank
Russell D. Fleisher
Minnie Baylor-Henry
Thomas W. Abrams

Doxil Review Team
Anthony J. Murgo
Eva Tolgyesi
Leslie A. Vaccari
Mehul U. Mehta
Robert L. Justice
Doo Y. Lee-Ham
Dorothy W. Pease
David Hoberman
John M. Schwab
Joseph J. DeGeorge
Nam Atiqur Rahman
Clare A. Gnecco

Riluzole Clinical Team
Mohammad Hossain
Vijaya K. Tammara
Robert Z. Harris
Raman K. Baweja

Zileuton Review Team
Raymond Anthracite
John K. Jenkins
Joseph DeGeorge
James Gebert
John Leak
Mehul Mehta
Guiragos Poochikian
Venkata Ramana Uppoor

Labeling Review
Michelle Dorsey
John Grace
Norma Jean Grimes
Jacqueline D. White

OGD's Secretaries
Kimberly Crutchfield
Patricia L. Downs
Warren B. Flateau
Frank M. Foge
Eilean L. Greene

(Continued on page 4)

Point of View

Up Close & In

(Continued from page 1)

up with jet lag, wayward baggage, traveler's two-step, rubber-chicken luncheons, or mega-calorie coffee breaks. Add these to the obvious FDA savings in travel costs and attendant administrative processing and videoconferencing begins to make a lot of sense.

The Rub

On the down side, when I'm not on-site, I miss the one-on-one interaction with conference attendees; those button-hole side bars rich in news and anecdotes. Also, I don't get to listen to other speakers or to collect their reference materials. Disadvantages to conference sponsors include added logistical costs -- not every hotel is equipped properly and rentals or contracting may be needed. Conference organizers also need to account for time-zone differences when scheduling a presentation; an 8-hour time difference approaches the limitations of practicality.

Tools & Tricks of the Trade

Even though videoconference presentations are very much like the on-site variety, you'll have to adjust to some differences. For example, although you can show 35mm slides, overheads or computer generated graphics, your audience can view either you or your visuals, but not both at the same time. In addition, you can't use a light pointer for 35mm slides, but you can use a mouse pointer if you display graphics from a PC. Although you can hear your audience, you won't be able to see them unless conference managers adjust their camera to include this group. Furthermore, if the communications link is slow, you will need to slow the pace of your delivery to provide for slight transmission delays. This can be unnerving at first if, for example, the audience doesn't laugh right away at your quips -- give them time before you give up and continue!

What to Wear

Finally, let me share a few tips that I have learned. Wear clothing containing neutral colors; avoid stripes and small checks because they tend to "strobe" or distort the video image. Look at the camera often and resist frequent glimpses at the local monitor to see how you're doing. Vary your gaze around the room, as if you're making eye contact with a larger audience (I fooled one group into thinking we had a roomful of people here in Rockville). Allow time to correct potential link-up problems by advising your host to schedule other speakers after you; they can then reshuffle the program if troubleshooting behind the scenes becomes necessary. Also, be sure your videoconferencing coordinator performs a test link with the conference site one day or so prior to the event, especially for overseas connections.

All-in-all, I'm a believer in videoconferencing presentations and I encourage all FDA speakers to give it a try. Videoconferencing is the best way I know of to be there and here at the same time!

The writer is a consumer safety officer in the Case Management and Guidance Branch of the Office of Compliance.

Pediatrics Corner

FDA Guidance to Industry on Pediatric Use, Content, Format of NDA To Be Issued

By Kathy M. Robie-Suh, M.D., Ph.D.

The agency and industry are working together to get better pediatric use information into prescription drug and biologic product labeling. The FDA will soon issue an industry guidance document called “Content and Format For Pediatric Use Supplements.” The document will provide industry with advice about the type and the arrangement of the material to be included in pediatric supplements based on the pediatric labeling regulation published 18 months ago.

The guidance was prepared by CDER’s Pediatric Subcommittee of the Medical Policy Coordinating Committee (MPCC) in collaboration with the Center for Biologics Evaluation and Research (CBER). In some cases, the rule allows pediatric labeling to be based on efficacy studies in adults. The new guidance will provide a succinct outline of materials that should be provided in any pediatric supplement and gives a brief narrative discussion of considerations that sponsors should take into account in supporting pediatric approval under the regulation. The discussion acknowledges that the decision that a drug qualifies for pediatric use under this rule is a matter of medical judgment. Factors listed as likely to be considered in the agency decision include: "experience with a drug or similar drugs in the same disease or in other diseases, the extent of knowledge of the pathophysiology and natural history of the disease in adults and the pediatric population, knowledge of physiology, and knowledge of a drug's metabolism and mechanism of action," as well as whether the drug is to be used for brief periods of time or chronically. Specific examples for which the agency has determined that the course of the disease and the effects of the drug are similar in adults and in the pediatric population are given. These include ibuprofen, for pain (See Pediatrics Corner, News Along the Pike, June 15, 1995); ondansetron, for chemotherapy-induced nausea and vomiting; and AZT, for AIDS.

The guidance document also describes the format for the presentation of data, which is based largely on the "Guideline for the Content and Format of the Clinical and Statistical Sections of New Drug Ap-

(Continued on page 4)

Ombudsman’s Corner

To See Ourselves as We See Us, Part II

By Jim Morrison

Last month we discussed some observations gleaned from outside looking into the Center. We can also learn something about ourselves and our organizational culture by talking with people who have recently joined the Center from other organizations. That is what I have been doing in partnership with OTCOM. We conducted the first of what I hope will be a continuing series of discussions with CDER volunteers.

As you may recall, Lucy Rose, Director of the Office of Training and Communications, sent out an e-mail asking for people to join in our discussion groups. The response was good, and we plan to capture the main points and ideas generated by these groups for CDER management to review. The first session included many individuals who were relatively new to CDER, and so the discussion focused primarily on first impressions. It was so informative that I would like to share some of our observations and thoughts with you now.

That session inspired me to seek out others who were also new to the Center to obtain a broader perspective. I learned that, while we have made enormous strides in our recruitment and hiring process, primarily under the Prescription Drug User Fee Act (PDUFA), we clearly have more work to do, especially at the branch and support levels.

They value the opportunity to make a positive contribution to the health of the American public, and they enjoy the diverse and challenging work.

There is an old expression that claims that first impressions are lasting. For new employees, that first impression includes experiences at recruitment interviews, as well as interactions with personnel, administrative officers, and others throughout the first work days.

Given the importance of first impressions, it is disheartening to hear stories about new hires who had to scrounge up a chair to sit on. Others were given non-working PC's and phones, or had several days pass before their supervisor or anyone from management came by. These circumstances demonstrate a general climate of neglect and disorganization. There were many complaints about a lack of knowledge on the part of administrative and management staff regarding proper paperwork, benefits, rules regarding such things as moving expenses, or where to go for answers.

Some people wondered why there was not a booklet in the recruitment package that clearly sets forth the benefits pack-

(Continued on page 4)

Awards

CDER Ceremony Spotlights Staff's 1995

(Continued from page 2)

Patricia A. Hennighan
Linda L. Johnson
Maureen D. Majors
Eugenie S. Patrick
Michelle L. Walling
Elizabeth C. Welsh
Helen R. White
Kathleen M. Wilson
Dianne V. Woods

COMMISSIONED CORPS

Comparing Treatments

Laurie B. Burke

Zileuton Review

Stephen Wilson
Joseph Buccine
Ching-Long J. Sun
Bradley Gillespie

Labeling Review

Mark Gonitzke
Charles Hoppes
Thomas G. Phillips
Angela Payne
Adolph Vezza
Carol Zimmermann

CDER FELLOWSHIP

Stephen Goldman
Isagani M. Chico
Susan A. Maloney
Sheila R. Weiss
Barbara Styrt
Alfreda Burnett
John D. Baker
Gene Williams
Peter Zannikos

SPECIAL AWARD

Gary Hollenbeck
Judy McClone Dalby
Alice Till
Leo Lucisano
Karen A. Benard
Lloyd Tillman
Michael Theodorakis
John Simmons
Marilyn Apfel

Pediatrics Corner

Labeling Guide To Be Issued

(Continued from page 3)

plications," which has been in use since 1988 and is well-known to industry.

This guidance should enable companies to provide the FDA with focused, high-quality applications to review for pediatric use of drugs already on the market. In turn, FDA review of these applications should proceed smoothly and lead to rapid inclusion of appropriate pediatric use information in prescription drug and biologic product labeling. The document is expected to be published in the Federal Register soon.

The writer is a medical officer in the Division of Gastrointestinal and Coagulation Drug Products (HFD-180) and a Pediatric Subcommittee member.

Parklawn Classic

CDER Grabs Silver, Bronze

By Bronwyn Collier

Two hundred and sixty runners took to the hills in the 21st Parklawn Classic 5 mile run held April 26. CDER's Ray Frankewich, a chemist in the Division of Gastrointestinal and Coagulation Drug Products, took the silver medal in the men's division with a time of 31:14, only three minutes behind the first place finisher, Jeffrey Merkowitz. Erica Keys, paralegal specialist for the Regulatory Policy Staff, captured the bronze medal in the women's division in 37:08.

Congratulations also go to CDER staff who received trophies in their age categories: David Orloff, Mark Gonitzke, Barry Rothman, Dottie Pease, Russ Abbott, and Linda Carter. Center Director Janet Woodcock, M.D. led the CDER pack in the 2.5 mile walk. There were about 1,400 walkers, 550 from FDA. Happy and invigorated, walkers received their ribbons at the finish and joined the runners in the awards festivities.

Festivities following the run and walk were livened up by the Jazz Ensemble from Eastern High School. There were door prizes, which included a Cardioglide exerciser, assorted freebies from vendors, and, of course, the awards. Harry Phillips, from the guard staff, valiantly tried to make order out of the chaos of pedestrians, buses, trucks, and cars all trying to cross Fishers Lane at the same time, but nothing could dampen the spirits of the participants and volunteers-- except maybe the rain that cut the festivities a little short.

Behind the scenes, CDER volunteers helped make the Classic an event to remember. Race captain Laura West, Program Specialist in the Division of Oncology, managed to keep her shoes on this year (she's barefoot in the '95 video of the Classic, but did she run that way?). As a member of the Classic Committee, she helped shape over 260 volunteers into top-notch crews for ensuring runner and walker safety, water stops, logistics, first aid, registration, and refreshments. Special thanks to CDER staff who volunteered for Run Safety Marshall duty. They were willing to guard the runners with an attitude (stop cars with their bodies when needed) and cheer the runners on!

The writer is a special assistant ODE III.

Outside Looking In, Part II

(Continued from page 3)

ages available and provides information that newcomers need about the process during the first days and weeks here. Others complained of overselling by interviewers during recruitment, such as promises of having one day per week for professional development, only to find that such requests are denied after they get hired. There were many who cited problems and delays caused by overly bureaucratic and inconsistent rules..

Usually, we know in advance when new hires are coming. Surely, a world-class organization like CDER can create a welcoming environment for the best and the brightest that we have just selected to join us. It is a shame that the enthusiasm that people originally have about joining CDER is often dulled by our failure to provide for some basic elements upon their arrival. In recent years, there has been a trend toward decentralization of support services. With that trend comes increased responsibilities on the part of first- and second-line management to be aware of entry dates for new employees and to ensure that the needs of new employees are properly being met. It is up to all of us to do better.

The good news is that OTCOM's new employee orientation program and the new reviewers' training course designed and implemented by senior reviewers are really superb. In our discussions, recently hired staff generated an impressive list of important reasons why they like working here. They uniformly appreciate the high quality of the professional staff with whom they work (they compare our staff favorably with any in industry or academia), they value the opportunity to make a positive contribution to the health of the American public, and they enjoy the diverse and challenging work. It appears that most of the big issues are handled, but we need to pay more attention to the details.

CDER Policies

New MaPPs Show the Way

By Khyati Roberts

The Manual of Policies and Procedures (MaPPs) is becoming a way of life at CDER. It's music to our ears when someone asks, "Is there a MaPP on it?" Or sometimes, in the middle of a meeting about a policy issue, we hear, "We need a MaPP on this."

One Place To Look

MaPPs are policy and procedure guides that have replaced the old Staff Manual Guides (SMG). MaPPs are intended to provide one place where all CDER policies and procedures can be located. The manual was developed last year by the SMG Working Group, which consists of representatives from across the Center. In consultation with the authors of the original documents, the Working Group reviewed all existing SMG's and policy memoranda and considered whether the originals should be archived, revised completely, or simply reformatted as MAPPs.

What's New about MaPPs?

These guides make it easier to issue all Center policies and procedures, even some that are only temporary. A new table of contents makes specific topics easier to find, and a streamlined format provides for easier reading. The manuals also come in a new, colorful binder that makes it easy to add new MaPPs as they become available.

Access

Each division has a MaPP coordinator who maintains and updates hard copies of the manual. The MaPPs are also available via Videotex, Adobe Acrobat Reader, ORA Gold Disk, and the Internet.

Associate Director for Policy Jane Axelrad, Office of Training and Communications Director Lucy Rose, and Executive Operations Director Debbie Henderson and I (a special assistant to Axelrad), kicked-off a Center-wide campaign in January to introduce MaPPs to more than 900 CDER employees.

Benefits of Central Database

I maintain a database of MaPPs "Under Development" and assist in the development of new MaPPs. This new centralized database prevents duplicative efforts and helps to achieve quality and consistency across the Center. Suggestions for improvements should be sent to me at HFD-5, or (ROBERTSK).

The writer is a special assistant to CDER's Associate Director for Policy. Secretary Olivia Vieira also contributed to this article.

MaPPs Recently Issued by CDER

Here are some recently issued MaPPs. They are effective upon date of issuance. CDER staff are responsible for following the policies and procedures outlined in the MaPPs. If you have specific questions on a particular MaPP, please contact Associate Director for Policy Jane Axelrad, 594-6740.

4641.2 **Guide to Delegations of Authority - Travel** (4/30/96) - Redelegates certain travel authorities that were delegated to the Center Director, Deputies, and Executive Officers by the Associate Commissioner for Management, FDA.

5230.1 **Availability of Labeling Guidances** (5/1/96) - Outlines revisions to the system for announcing and attaining labeling guidances prepared by the Office of Generic Drugs (OGD) that are made available to assist the public in the preparation of package insert labeling for proposed abbreviated new drug or antibiotic applications (ANDA/AADA).

6001.1 **Special Government Employees Representing Sponsors Before CDER** (4/22/96) - Outlines current CDER policy and procedures when Special Government Employees (SGEs) seek to represent sponsors before the FDA about particular applications.

6020.3 **Priority Review Policy** (4/22/96) - Describes the review priority classification of New Drug Applications (NDAs) and effectiveness supplements.

4000.1 **Guide to Issuance of Directives in the CDER** (4/22/96) - Minor revision of old policy.

Electronic copies are available via Videotex (12-1); on the CDER common shared drive (x:\cdermapp) in pdf format (i.e., access via the Adobe Acrobat Reader), or; on the Internet.

AMF Update

June DSS Test Plans

Each month, we highlight one component of Automated Management of Files (AMF). The following is the latest news on the AMF Decision Support System (DSS).

By David Isom

The Decision Support System (DSS) provides a Windows-based interface into the existing COMIS database. COMIS contains administrative and status information related to drug company submissions. DSS is similar to the existing Online Retrieval 18 (OLR18) function in COMIS.

However, DSS includes enhanced searching capabilities, and a variety of user-friendly ways to view additional COMIS information.

Over the past few months, staff in the Division of Pulmonary Drug Products, Oncological Drug Products, Neuropharmacological Drug Products, and Anti-Viral Drug Products participated in an alpha test of the DSS. As a result of the test groups, many exciting improvements to the system are being added. For instance, installation of a wildcard searching feature is planned, a data display area will be redesigned so that information can be easily viewed, there will be user notification if DSS is no longer attached to the network and a reconnect feature will be added, and users will have the added ability to generate printed reports, and to change DSS passwords to synchronize them with other passwords. These enhancements will probably be incorporated before DSS is available throughout the Center. The first version of DSS will be ready for installation and training in June.

The test group also wanted the capability to enter and update comments. We plan to make this feature available in subsequent versions of the DSS along with the workload graphing capability. Thanks again to all the members of our test groups who contributed to making this a better and more usable software system.

The writer is the AMF project manager.

CDER Looks Ahead

Divisions Mark Accomplishments, Unveil Plans

By Kevin L. Ropp

Speakers from throughout CDER highlighted the achievements of their organizations and set goals for the fiscal year's remaining six months during the Center's Spring Planning Meeting, April 1, 3 and 4.

In addition to the offices of Review Management, Pharmaceutical Science, and Management (See News Along the Pike, April 15), Jane Axelrad, Ralph Lillie, Jim Morrison, Debbie Henderson, and others, spoke on their respective responsibilities during the three-day videoconference.

Associate Center Director for Policy Axelrad, discussed her office's Manual of Policies and Procedures (MaPPs), rulemaking, and management initiatives. During the next six months, the office plans to:

- issue about 20 MaPPs per quarter
- publish several final rules in the Federal Register and a number of proposed rules
- resolve miscellaneous user fee billing issues, update the billing list, and begin preparing in September for the next round of billing.

Ralph Lillie, project manager for the Center's Establishment Evaluation System, or EES, gave a general overview of his program's purpose and status. A prototype system has been completed and a full-scale system should be ready for CDER use in June, he said.

Robert C. Nelson, Ph.D., Associate Director (Epidemiology) in the Office of Epidemlology and Biostatistics, outlined the status of the Center's six-month-old Adverse Event Reporting System effort. In the next six months, he plans to continue detailed design work and possibly begin testing an electronic submissions system.

On the final day of the session, the Executive Operations Director Debbie Henderson, along with CDER Ombudsman Jim Morrison, and EEO Director Margaret Bell, outlined the achievements and goals for each of their organizations.

Director of the Office of Drug Evaluation I and Associate Director for Medical Policy Robert J. Temple, M.D., highlighted the accomplishments and goals for the Division of Drug Marketing, Advertising and Communications.

Office of Training and Communications (OTCOM) Director Janet L. "Lucy" Rose, spotlighted some of that office's major accomplishments. These included:

- implementing videoconferencing,
- implementing a new CDER orientation,
- producing a live television show beamed to industry.

OTCOM's goals for the next six months include, among others, implementing a CDER home page on the World Wide Web (see story on Page One), delivering an organizational assessment, and creating a CDER visiting faculty program.

Following Rose, Office of Compliance Director Stephanie Gray introduced her management team including Deputy Director Betty L. Jones, Deputy Director of the Division of Labeling and Nonprescription Drug Compliance Jacqueline S. Leung, R.Ph., Director of the Division of Manufacturing and Product Quality Douglas I. Ellsworth, Director of the Division of Prescription Drug Compliance and Surveillance Lana Ogram, and Acting Director of the Division of Scientific Investigations Bette L. Barton. Within the next six months, the Office intends to:

- Implement GPRA principles
- Develop an Office of Compliance strategic Plan
- Establish standard operating procedures (SOPs) for the office to improve efficiency
- Automate the drug survey program
- Develop guidance and a policy on "manufacturing pharmacies"
- Prioritize Investigational Review Board inspections
- Standardize documentation sent to field investigators for routine inspections.

The planning session concluded with brief discussions of the Center's good review practice initiatives and coordinating committee accomplishments.

The Center's fall planning session is scheduled for Oct. 29 - Nov.1, 9 a.m. to noon.

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

It's Time to Wake Up and Smell the Coffee

Victor Vail is a man who shoots from the hip. Last month when he heard an editorial about Secretaries Week, aired on National Public Radio's "Morning Edition With Bob Edwards," Vail grinned and then took aim. WAMU-FM (88.5), the local member station that airs "Morning Edition," broadcast Vail's letter. Here's what it said:

Yesterday morning, while getting dressed for work, I listened to NPR's tribute to the ladies who are secretaries - and their difficult bosses. With this being Secretaries Week, your tribute was indeed timely - timely, that is, if it were 1971. There have been a lot of changes in the workplace over the past several years, one of which is the increasing number of male secretaries. Your stereotype of the female secretary is as outdated and out of place as the idea that all industry executives are male. I thought to myself as I chose my tie that it would have been nice if NPR had acknowledged all secretaries female and male without stereotyping. As your news item finished, I reached for my suitcoat, rechecked my close shave, then left for the office where I work as a secretary. And yes, I make the coffee for the office, and it is good *and strong*!

Victor H. Vail, secretary to ODE 4 Director David Feigal, Jr., M.D., is currently on a detail as secretary to Randolph Wykoff, Associate Commissioner for Operations.

High Tide for the Web and Flow of CDER Information

(Continued from page 1)
recalls, shortages, and CDER programs and policies. Two Web sites will actually exist: one on the **Inter**net, which will be available to the public as well as to CDER employees. The other, on the **Intra**net,

SEARCH

will be accessible by CDER employees and will contain information that CDER uses to do its job.

Carol Assouad, Acting Director of the Center's Medical Library, and chairman of the CDER WWW Home Page Steering Committee, began laying the groundwork for the home page in February. Employees interested in developing a WWW home page for CDER met to explore the many possibilities along the information highway. Bill Rados, of FDA's Office of Public Affairs, and coordinator of the FDA home page, talked about FDA's goals and experiences with the FDA web site. The library's Paul Stauffer, CDER's "Webmaster," gave a demonstration of good and bad web sites that gave CDER employees insight into planning a site. Carol Assouad, along with Jack Pevenstein from the Office of Epidemiology and Biostatistics and Executive Director of the Steering Committee, has organized six

WHAT'S NEW

subcommittees to create and develop the page. Here's a snapshot of the groups and their activities:

Technical Subcommittee (Bill Bachman). Design, select hardware and software, load, test, implement, and maintain the system. The Committee has evaluated various server set-ups for the Internet solution and has determined that the current infrastructure, with the server in the Park Building, is the best option. The committee is looking at an Intranet solution that will be completely separate from the Internet.

Information Management (Paul Stauffer). Design home page interface, establish hierarchy and links, edit documents, preserve integrity of information, develop indexing and hypertext links, design graphics, etc. The committee is on target with the skeleton version of the CDER external home page. The group has designed and organized the home page, which has four clusters, and additional subpages. The four clusters are as follows: *About CDER, Drug Information*, *Regulatory Guidance*, and *What's Happening*. In *About CDER*, individual office and divisions will have a subpage about their organization and function. The committee has also worked with the Office of Public Affairs to begin developing graphics for the home page.

Monitoring/Evaluation (Deborah Henderson). Identify audiences and determine what they need from the home page; develop criteria for monitoring and handling feedback; and interact with the Information Management subgroup to implement feedback.

Promotion/Training (Karen Kapust). Develop internal and external training and home page promotion programs. The team has identified ways to communicate to CDER and to the outside world about the site.

Policy (Khyati Roberts). Develop policy and guidelines for home page postings. Will establish priorities for implementing, duration of posting, approvals, and frequency of updating. The policy group has completed the draft MaPP for posting documents on the WWW and will present it to the Steering Committee for approval, and then to CDER management.

Steering Committee (Carol Assouad). Monitors other subgroups and provides support and guidance. Paul Stauffer and Jack Pevenstein demonstrated the home page at an April 29 Drug Information Association meeting in Philadelphia where they received feedback from the industry.

The CDER home page is expected to be on-line by mid-summer. In July, the groups hope to develop the CDER Intranet - - a website for CDER employees only. When the site is operating at full capacity, Paul Stauffer, assisted by other library staff, will remain Webmaster and the Division of Information Systems and Design will continue to maintain hardware,

EVALUATION

software, and user training.

CDER staff is expected to be using both nets with Windows95 within the next year. Be patient please! Loading is a resource-intensive and time-consuming process.

So You Want to See the Home Page?

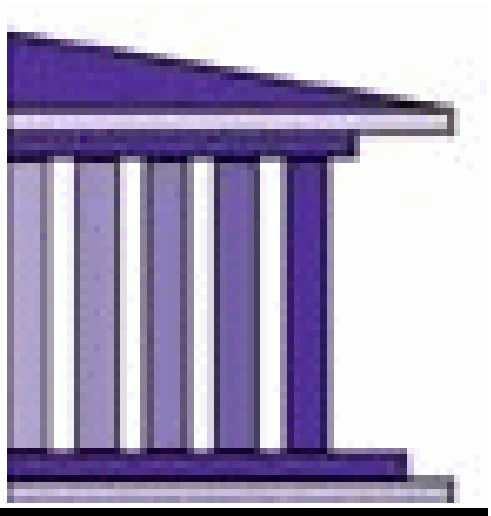
To preview the CDER home page on the WWW, go to: **http://www.fda.gov/cder**.

Want To Know More?

U.S. Food and Drug Administration

The CDER Medical Library has books about the Internet and WWW. How about: "The World Wide Web Complete Reference;" "Web Weaving - Designing and Managing an Effective Web Site;" "The Web Server Book;" "The Internet Passport;" "The Mac Internet Tour Guide," 5th Ed; and "The Internet Companion," 2nd Ed.

The writer is a Public Health Advisor and the Internet contact in the Division of Drug Marketing, Advertising and Communications.



Pike to Form Editoral Board of Advisors

The staff of News Along the Pike is inviting participation on an editorial board to help shape and guide the monthly, employee-generated publication. Board members will meet monthly to discuss FDA and CDER news, information, and policies and to discuss story ideas, writers, and editorials. Members will also be encouraged to write opinion pieces. The purpose of the board is to give Center staff a broader representation of Center issues that are featured in The Pike. Participation will be on a voluntary basis and appointments will be for one year. Interested parties should e-mail Jeffrey Yorke (YORKEJ), or fax 301/827-3055.

Eugenie Triantas Dies at 75

Joined FDA in 1973 as Chemist

Eugenie T. Triantas, a medical officer in the Division of Gastro-intestinal and Coagulation Drug Products, died of leukemia on April 14 at her home in Potomac, Md. Dr. Triantas was 75 years old. She started her exemplary 23-year career with the FDA in 1973 as a chemist in the division then known as "Surgical Dental Drug Products." Dr. Triantas was promoted to Medical Officer in 1976 and was later nominated for a Commendable Service Award for "extraordinary effort in the development and approval of new hematologic drugs." Dr. Triantas was at the forefront of developments in the use of new antithrombotic drugs to treat cardiovascular diseases, many of which are life threatening. Her authoritative evaluations brought great credit to FDA and provided the pharmaceutical industry with perceptive advice regarding appropriate clinical trial designs for these drugs.

Dr. Triantas was a very kind and caring person. One colleague said, "she was always telling me I was working too hard. When she would see me in the office in the late hours, she was always telling me to go home and get some rest." She was a wonderful person and a dedicated employee and she will be greatly missed.

She is survived by two sisters and a niece.

Needed: Organ and Tissue Donors

Nine Americans die every day waiting for organs to become available, according to the Health Resources and Services Administration (HRSA) Division of Transplantation. If you want to be an organ donor, you must be sure to take the three essential steps: first, sign an organ donor card; second, indicate your intentions on your driver's license; and third, tell your family. If you would like more information, dial 800-355-SHARE (7427).

Just for Grins

3 Doctors Go to Heaven . . .

Three doctors arrived at the Pearly Gates at the same time. Saint Peter asked the first one, "What did you do with your life?"

"I was an obstetrician and I brought many beautiful babies into the world."

"That's wonderful. Come in and welcome to heaven," St. Peter said warmly. "And you?"

"I was a pediatrician. I made thousands of sick babies better."

"That's great. A marvelous contribution. Please come in," St. Peter said. "And you?"

The third doctor stepped up and said, "I ran an HMO. I provided thousands of doctors like these the money to do their work."

"Hmmm." St. Peter thought for a minute. "Okay. You can come in too, but only for 24 hours!"

Communiqué

Consumer Affairs Becomes Drug Information Branch

CDER's former Executive Secretariat group, recently referred to as the Consumer Affairs Branch, has been renamed the Drug Information Branch. The staff collectively decided that the new name more accurately reflects the work it does and that it will be easier for constituents to understand. The branch, which is part of the Division of

Office of Training & Communications
OTCOM
...A Commitment to Excellence

Communications Management, in the Office of Training and Communications, is directed by Acting Branch Chief Barry Poole, and can be reached at 301/594-1012; fax: 594-3302.

A separate group in the Office of the Director and directed by Lee Zwanziger, currently serves as CDER's Executive Secretariat. It can be reached at 594-5461, fax: 594-6197.

– Lucy Rose

news along the pike

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

Jeffrey Yorke, Editor
301/827-1669 fax: 301/827-3055

Copy Editors
Rose Cunningham
Lori A. Frederick
Elaine Frost
Kevin L. Ropp
Marcia Trenter

Layout & Design
Margaret Stavish

Distribution Manager
Donald Carrington 301/594-5459