news along the pike

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

PIKE'S CORNERS . . .

Center has big role in 5-part strategic action plan

Plan builds on CDER efforts to protect, advance public health

The FDA document, *Protecting and Advancing America's Health: A Strategic Action Plan for the 21st Century,* establishes a framework for achieving five broad priority goals.

"The strategic plan is very ambitious but very familiar because it builds on what we in CDER were doing," said **Steve Galson, M.D.,** the Center's deputy director. During the annual State of the Center address held Sept. 10, Dr. Galson outlined how the Center's strategic direction for 2004 is based on the Agency plan's five components:

- Efficient, science-based risk management.
- Patient and consumer safety.
- Better informed consumers.
- Counterterrorism.
- A strong FDA.

Efficient, science-based risk management

We have long led the world in applying the principles of risk management—assessing public health risks, analyzing methods for reducing them and taking appropriate action. With the expanding complexity of the Agency's medical challenges and the need to reduce the health risks facing the public at the lowest cost to society, efficient risk management is more important than ever.

The Agency's approach to efficient risk management requires the use of the most current biomedical, statistical, managerial, and economic science. The plan aims to achieve quicker access to safe and effective new products and reduce public health risks without unnecessary costs by:

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Outsourcing ends for library, underway for clerical jobs

BY PATRICK E. CLARKE

Competitive outsourcing under the Office of Management and Budget Circular A-76 is continuing as planned at FDA. By June 24, all phase-1 study employees were told they had won their functional competitive bidding. Those functions were graphic arts, visual information services and library services. Since then FDA has won two more outsourcing initiatives—real property management and biological lab technicians.

"But, winning isn't always 'winning,'" said **Maddy Carolan,** a senior medical librarian at CDER.

As a result of the competitive bidding process for the library function, approximately 39 full-time employee slots at CDER will be downsized to 26, a net loss of 11 government and two contract library staff. In addition, positions will be downgraded. However, FDA has guaranteed that anyone who might lose a government job under this downsizing and who decides not to transfer to a contractor will be

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153 volunteer to help translate foreign e-mail inquiries

BY MARY KREMZNER, PHARM.D.

In CDER, we've always thought of ourselves as cosmopolitan because of our cultural diversity. This was recently confirmed when the Division of Drug Information in the Office of Training and Communications sent out an e-mail asking for help with the occasional translation of written correspondence. Within minutes, we had an overwhelmingly positive response.

Our division serves as the focal point for public correspondence in the Center. We receive and respond to thousands of inquiries each month in the form of letters, e-mails and telephone calls. Most of the correspondence we receive focuses on inquiries from the American public. The questions we answer regarding drug products range from side effects and shortages to hot topics.

Our division's 12 consumer safety officers and two consumer safety technicians make sure that everyone who calls or writes to the Center receives an acknowledgement and an answer to

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JOE'S NOTEBOOK

cGMP progress report issued

On Sept. 3—the first anniversary of launching the strategic initiative to modernize the regulation of pharmaceutical manufacturing and product quality—FDA issued a progress report (http://www.fda.gov/cder/gmp/2ndProgressRept_Plan.htm).

Highlights covered in the report include:

- A final guidance on the use of *electronic records and signatures.* The guidance clarifies the scope and application of Part 11 of the Code of Federal Regulations and provides for FDA enforcement discretion in certain areas while the Agency undertakes rulemaking to revise Part 11.
- A draft guidance on a process for *resolving disputes* arising over scientific and technical issues related to pharmaceutical current good manufacturing practices.
- A draft guidance on the *aseptic processes* used in the manufacture of sterile drugs, emphasizing current science and risk-based approaches.
- A draft guidance on preparation and use of a *comparability protocol* for assessing chemistry, manufacturing and control changes to protein drug products and biological products.
- A draft guidance for *process analytical technology*, a framework for allowing regulatory processes to adopt more readily state-of-the-art technological advances in drug development, production and quality assurance.
- A *collaboration with two universities* to identify the factors that predict manufacturing performance to further refine our pharmaceutical manufacturing risk-based assessment.
- A *collaboration* with the National Science Foundation's Center for Pharmaceutical Processing Research allowing FDA to expand its scientific foundation in the area of innovative pharmaceutical manufacturing technology.
- A *cooperative research and development agreement* with Pfizer Inc. to research chemical imaging applications in pharmaceutical manufacturing and quality assurance.
- A memorandum of understanding between the Office of Regulatory Affairs and the Center to set up the *Pharmaceutical Inspectorate.* The inspectorate will consist of a staff of highly trained individuals from the field force who will devote most of their time to conducting human drug manufacturing quality inspections on the majority of prescription drug manufacturers and other complex or high-risk pharmaceutical operations. The inspectorate will also conduct pre-approval inspections.
- An effort to *improve international standards* for drug manufacturing through global harmonization. Several scientific workshops are planned overseas later this year and early next year.

The Agency has begun the complex process of designing an integrated Agencywide, risk-based quality management system. Six organizations with expertise in quality systems and risk management approaches are providing a series of videoconference presentations to share their lessons learned. Speakers come from other government agencies, academia and a private health care facility. Copies of most of the seminars will be available in the FDA libraries; exceptions are presentations that are copyrighted by the speaker.

The seminar series is produced by **Elaine Frost,** one of my colleagues in the Office of Training and Communications. Two programs aired on Sept. 4 and 24. The others will air Oct. 2 and 16, Nov. 20 and Dec. 11 from 1:30 p.m. to 4 p.m.

Correction: In the last issue, I incorrectly identified the position of contributor **Wafa Harrouk, Ph.D.** He is a pharm/tox reviewer.

news along the pike

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

Photocopies are available in the Medical Library (Parklawn Room 11B-40) and its branches (Corporate Boulevard Room S-121 and Woodmont II Room 3001).

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

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ORGANIZATIONAL DEVELOPMENT

Our next task: A culture survey; responses due Oct. 15

BY KEN WRIGHT

In my first column, I talked about how working with an organizational development consultant can assist employees to become more informed as well as higher performing, and better prepared for future changes. Three questions were asked: What can we do better? What is higher performance? How would we know if we had attained a higher performance level?

Here are additional questions that need to be asked:

- Why should we become higher performing?
- Are we doing the right "what?"
- How good are we in the work we do?
- How do we treat each other and our customers?

My work focuses on helping clients answer these questions. I have found that sharing techniques and approaches to solve problems is effective for a "learning organization." Problem-solving is achieved as we share an ongoing dialogue with our colleagues. I approach my work as an internal consultant for CDER. I do this by contracting with each organization's leadership and assessing how I can assist the organization to become more reflectively and developmentally focused.

Research shows that those leaders who were most effective at creating effective organizational change were able to integrate successfully a series of five personal leadership strategies:

- Create a compelling future.
- Let every customer drive the organization.
- Involve every mind.
- Manage collaboratively across boundaries.
- Build personal credibility.

These strategies work when coupled with the employee's desire and capacity for change. Planned organizational change is exciting when a realistic set of expectations are achieved in a realistic period of time.

A survey with instructions is being distributed this month to all employees. The survey will examine the CDER culture. Take the time to fill it out and send it back by the Oct. 15 deadline, which is a week later than listed in your survey.

Questions will be asked regarding the following:

- Your career and work place experiences at CDER.
- Workforce diversity and diversity management.
- Communication and leadership.
- CDER as a place to work
- Feedback about the survey.

We stress that the survey will be handled with the highest degree of confidentiality. The results will be returned directly to the contractor for tabulation and analysis. Once we receive the survey results, we will be scheduling meetings to share the results.

By participating in the survey and through the proper use of the results we will be ready to face the future. Call me at 594-5487 for more information.

Ken Wright is director of the Center's Organization Development and Strategic Planning Staff in OEP.

Informational campaign on hormone replacement therapy launched

BY DEBORAH KALLGREN

For a number of years women and health care professionals alike felt confident that the use of hormone therapy was appropriate treatment for symptoms of menopause and the prevention of menopause related health concerns such as cardiovascular disease and osteoporosis.

However, in July 2002 findings from the NIH Women's Health Initiative Study, brought clinical investigations to a halt due to concerns about increased risks of heart disease, stroke and breast cancer in postmenopausal women using combination (estrogens with progestins) hormone therapy. Unease about the wide use of hormone therapy in general among menopausal women began to increase.

In January, FDA responded by revising estrogen-containing product labeling to reflect the new found safety concerns. Shortly after, House Agriculture Appropriations Subcommittee Chairman, Henry Bonilla asked FDA Commissioner **Mark McClellan, M.D., Ph.D.,** to create an informational campaign to raise awareness about the recent findings on the risks and benefits of menopausal hormone therapy.

In this call for action, FDA's Office of Women's Health and CDER were asked to partner with other HHS agencies and women's health and community-based organizations to develop and disseminate targeted information to women across the nation.

Over the months that followed, the groups worked toward the development of campaign materials which included a fact sheet describing menopause, its symptoms and answers to hormone therapy treatment questions and a purse guide to serve as a tool for discussion with a health professional. Within this literature, three key messages emerged to be communicated to women:

- Become informed about menopause and hormone therapy for a better understanding of the issues.
- If currently using hormone therapy, or deciding to use hormone therapy for treatment of menopausal symptoms, make sure that it is used at the smallest dose for the shortest time necessary.
- Discuss the risks and benefits with your health care professional to make the best decision for you.

On Sept. 9, Reps. Bonilla and Rosa DeLauro and both federal and outside partnering organizations joined Dr. McClellan on Capitol Hill for a press event to roll out the Menopause and Hormones Information Campaign.

Copies of the information materials were made available in both English and Spanish translations. All materials can be obtained from the National Women's Health Information Center at http://www.4woman.gov.

The bottom line message to women is that hormone therapy, like all medications has risks and benefits.

Deborah Kallgren, a regulatory health project manager in OTCOM, recently completed a detail in FDA's OWH.

Enterprise Search full content searches; MyPortal replaces OITWeb

BY HELEN MITCHELL

Enterprise Search is the new search tool that will not only allow you to do full content searches on DFS documents if you have a DFS account, but will also allow you to search many types of "digital assets" within the CDER network including files in Word, PDF, XML, text, HTML and scanned images.

The collections of documents—or libraries—currently available include DFS, CDER guidances, Office of Generic Drugs Division Files and several Web sites.

The new search tool will also replace the current E-DocQuery search tool for access to:

- Drug Master File reviews.
- AERS reports (images only).
- Biopharm division files (prior to entry in DFS).
- Approved final printed labels (1994-2000).

Please note: Security has been put in place, so you will only be able to search those libraries you've been granted permission to access. Between the end of September and October, you'll receive an e-mail notifying you of:

- Your Enterprise Search account username (network username) and a temporary password.
- Instructions how to log on to Enterprise Search and how to change your password.
- The libraries you have been given permission to search.
- The link to the end users training manual.
- Instructions how to request additional libraries to search.

Training classes will begin in October and will be offered on an office-by-office basis. Demonstrations on how to use the tool along with highlights of new features will also be offered in the majority of the CDER buildings.

We will continue to leave the current E-Doc Query/RetrievalWare system available for your use until all offices and divisions have had an opportunity to attend a hands-on training class or demonstration of the new Enterprise Search tool features and capabilities. Stay tuned for announcements on training and demo dates.

MyPortal

BY JENNIFER WAGNER AND KATHY BRIGHT

The information available on OITWeb is being migrated to the CDER Web portal, MyPortal. Everything that was available through OITWeb is now available on MyPortal.

You should have received a password to log onto MyPortal.

If you have not received a password or do not remember your password, please e-mail the Help Desk for a new password. For security reasons, we cannot give you a password over the phone.

You will be able to browse 80 percent of MyPortal without logging on, but you will need your password to:

- See the external applications and make use of the easy sign-on feature.
- View the Discussion Forums on the Applications tab.
- Enter the Training Application, view classes offered by OIT for CDER and register for them.
- Change your assigned password.

It is a good idea to change your portal password to your network password; however, when you change your network password, you will have to change your portal password also for them to be the same.

OIT offered several demonstrations of MyPortal throughout the buildings. We hope you had a chance to attend one.

If you didn't, you can look at and print an in-depth training manual by following these steps:

- Go to http://myportal (if you are on the CBER network, you must type http://myportal.cder.fda.gov).
- Log in with your username and password.
- Click on the Training tab.
- Clicking on the link for Training Documentation.
- Scroll down to find the MyPortal link and click on that.
- Click on the Personal Portal Training Guide link to bring up a PDF version of the training manual that was distributed at the demos.

Please take the time to explore MyPortal before calling the Help Desk.

If you run into difficulty navigating the site, please e-mail the Help Desk, and we will assist you.

October OIT Training

Tuesday	Wednesday	Thursday	Friday
	1 FrontPage XP (C) 9:00-4:00	2 FrontPage XP (P) 9:00-4:00	3 FrontPage XP (P) 9:00-4:00
7 BroadBand (P) 1:00-3:00	8 FrontPage XP (C) 9:00-4:00	9 FrontPage XP (C) 9:00-4:00 Word 97—Intro (P) 9:00-12:00	10
14 FrontPage XP (C) 9:00-4:00 PowerPoint 97—Intro (P) 9:00-12:00	15 FrontPage XP (C) 9:00-4:00	16 DFS (C) 9:00-12:00	17 DSS (C) 9:00-12:00
21	22 BroadBand (P) 9:00-11:00 Word 97—Tables (P) 1:00-4:00	23	24

Key: Corporate Blvd (C), Park Building (P)
Go to http://MyPortal to access training registration and resources.

153 CDER employees volunteer to help translate foreign inquiries

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their question.

During the last two years, thanks to the Internet, we have experienced a significant increase in e-mail from abroad. These inquiries are often quite unlike those originating from the United States. The foreign e-mails tend to focus on drug development guidance, assistance with regulations, expert advice and document retrieval.

The increase in foreign inquiries and our work with **Justina A. Molzon, M.S. Pharm., J.D.,** CDER's associate director for international programs, gave us a bright idea. Why not look within the Center in a more organized manner for folks who want to help? Not only do CDER staff have the language skills, but they also understand the scientific and regulatory issues involved in many of the inquiries.

At the same time, we understand that CDER staff are certainly not in need for more tasks. As a matter of fact, we were very concerned with being sensitive to the workload and anticipated few responses to our e-mail. Nonetheless, we heard from 153 Center employees who volunteered to assist us when needed. The languages ranged from Arabic to Yoruba with 34 languages in between.

The languages or dialects and the CDER employees who have generously offered to help with translations are:

Arabic: **Sophia Abraham, Ph.D., Ali Al Hakim, Ph.D., Suliman Al-Fayoumi, Ph.D., Aisar Atrakchi, Ph.D., Sary Beidas, M.D., Ramzi Dagher, Hanan Ghantous, Ph.D., Wafa Harrouk, Ph.D., Khairy W. Malek, M.D., Ph.D., Moheb M. Nasr Ph.D., Patrick J. Marroum, Ph.D.**

Bengali: **Aloka Chakravarty Ph.D., Badrul A. Chowdhury, M.D., Ph.D., Swapan K. De, Ph.D., Mamta Gautam-Basak Ph.D., M. Atiar Rahman, Ph.D., Nam Atiqur Rahman, Ph.D.**

Burmese: **Khin Maung U, M.D.**

Catalan: **Xavier Ysern, Ph.D.**

Chinese: **Bing Cai Ph.D., Conrad H. Chen Ph.D., Shaw T. Chen, M.D., Ph.D., Xiao-Hong Chen Ph.D., Yeh-Fong Chen, Ph.D., George Chi, Ph.D., Tony Cho, Jinhui Dou, Ph.D., Guodong Fang, M.D., John Gong, Ph.D., Zi-Qiang Gu, Ph.D., Huiqing Hao, M.D., Ph.D., Ruyi He, M.D., Liang-Lii Huang Ph.D., Zei-Pao Huang, Hsien W. Ju, M.D., Sue-Chih Lee, Ning Li, M.D., Ph.D., Zili Li, M.D., Lugi Pei, Ph.D., Maria Shih, Guoping Sun, Ph.D., He Sun, Ph.D., Joseph Sun, Ph.D., Duu-Gong Wu, Ph.D., Yvonne Yang, Ph.D., Dylan Yao, M.D., Ph.D., Betsy C. Yeh, Ita Yuen, Ph.D., Jenny J. Zheng**

Columbian: **Edwin Ramos.**

Cuban: **Edwin Ramos.**

Czech: **Daniela Vanco, M.D.**

Dutch: **Elizabeth Chikhale, Ph.D., Gemma Kuijpers, Ph.D.**

Farsi: **Jila H. Boal, Ph.D., Kooros Mahjoob Ph.D.**

French: **Dorrie Ballmann, Eric Bastings, M.D., Siham Biade Pharm.D., Ph.D., Jila H. Boal, Ph.D., Marc W. Cavaille-Cole, M.D., Ph.D., Jennie Chang Pharm.D., Ramzi Dagher, Roman Dragos, M.D., Wafa Harrouk, Ph.D., Patrick J. Marroum, Ph.D., Owen McMaster, Ph.D., Sally Newman, Nakissa Sadrieh Ph.D.**

German: **Dorrie Ballmann, Vispi Bhavnagri, Ph.D., Marc W. Cavaille-Cole, M.D., Ph.D., Nancy E. Derr, Mamata Gokhale, Roswitha Kelly.**

Hindi: **Shukal Bala, Raj Bykadi, Ph.D., Aloka Chakravarty Ph.D., Chandra S. Chaurasia R.Ph, Ph.D., Mamta Gautam-Basak Ph.D., Mamata Gokhale, Pradeep M. Sathe, Surendra P. Shrivastava, Jyoti Zalkikar Ph.D.**

Indonesian: **Christina H. Chi Ph.D., Steve Wilson.**

Italian: **Mary Richard.**

Japanese: **Conrad H. Chen, Ph.D.**

Kannada: **Raj Bykadi, Ph.D.**

Korean: **Sang Chung, Seong H. Jang, Ph.D., Shinja Kim, Chan H. Park, Ph.D., Herman Rhee, Ph.D., Melaine Shin R.Ph, Huijeong Ashley Hahm Pharm.D., Ph.D.**

Lithuanian: **Edvardas Kaminskas, M.D., Daiva Shetty, M.D.**

Madarin: **Shiowjen Lee, Ph.D.**

Marathi: **Jyoti Zalkikar Ph.D.**

Mexican: **Edwin Ramos**

Persian: **Ladan Jafari, Sally Newman**

Polish: **Violetta Klimek, Ph.D., Dorota Matecka, Ph.D., Jean Nashed, Ph.D., Joanna K. Zawadzki, M.D.**

Portuguese: **Albert DeFelice, Ph.D., Maria Elena Ruiz, Ana Szarfman, M.D., Ph.D.**

Romanian: **Roman Dragos, M.D.**

Russian: **Valeria Freidlin, Ph.D., Elens Mishina Ph.D., Tatiana Oussiva, M.D., Ph.D., Daiva Shetty, M.D., Lyudmila Soldatova Ph.D.**

Serbian: **Svetlana Stojisavljevic.**

Slovak: **Renata Albrecht, M.D., Daniela Vanco, M.D.**

Spanish: **Silvia N. Calderon, Ph.D., Doris Ford, Marta E. Gonzalez-Pineiro, Josephine Jee, Damaris Maldonado, Judit Milstein, Rosa Motta, Juan Pelayo, M.D., Rosa E. Perez, Irene Piwowarskii, Joseph Porres, M.D., Edwin Ramos, Archana Reddy M.P.H., Maria Rivera, Ph.D., Libaniel Rodriquez, Ph.D., Lilliam Rosario, Ph.D., Maria Elena Ruiz, Milagros Salazar-Driver, Ph.D., Aida Sanchez Parm.D., Alfredo R. Sancho Ph.D., Sandra Suarez, Ana Szarfman, M.D., Ph.D., Lydia V. Velazquez Pharm.D., M. Lourdes Villalba, M.D., Maria Ysern, Xavier Ysern, Ph.D.**

Taiwanese: **Zei-Pao Huang, Betsy C. Yeh.**

Thai: **Brian Hasselbalch.**

Urdu: **Mamta Gautam-Basak Ph.D., Anwar Goheer, Ph.D., Amna Ibrahim, M.D., Daniyal Syed.**

Vietnamese: **Tan Nguyen, M.D., Nhan Tran, Ph.D.**

Yoruba: **Abimbola Adebowale, Ph.D.**

Thank you for your support.

DDI wants to remind everyone that receives letters, e-mails or telephone calls from the public that we are here to help. You can call us at x74570, or forward the e-mail to: druginfo@cder.fda.gov.

Mary Kremzner is a team leader in DDI.

LETTER FROM KUWAIT

CDER lawyer is Army Reservist facilitating humanitarian aid to Iraq

BY MAJ. KEN BORGERDING

Kuwait City (May 2003)—I am working as the legal advisor in the Humanitarian Operations Center in Kuwait City. The center was set up by the Kuwaitis and is run by a small group of Americans and British soldiers. We are responsible for facilitating the work of non-governmental organizations, or NGOs, that are providing humanitarian aid to the people of Iraq.

Essentially, what we do is act as a liaison between the Coalition Forces and the NGOs. We provide security information, border crossing paperwork and reports detailing humanitarian needs in Iraq. The NGOs take the information we provide and then acquire needed aid and expertise. They then coordinate with us for transportation and security for their convoys and shipments.

I work with the United Nations, Red Cross/Red Crescent, Physicians without Borders, Save the Children—name a humanitarian organization, and they are here. It has been interesting watching the competition among the various groups as they race to be the first one into Um Qusr, Basra, Nassiriya, all the way up to the North. My work has been about half legal and half diplomatic—dealing with other countries, our embassies across the Middle East and NGOs from every corner of the world.

There are South Koreans, Japanese, Czech, Italians and others here everyday. Talk about language barriers, but we manage to get by with hand gestures and such. I have met some very interesting people from Sir Richard Branson, the founder of Virgin records and Virgin Atlantic Airlines, to a South African who works on a game preserve and went to Baghdad to help at the zoo.

I sleep in an air-conditioned classroom with no furniture except an Army cot and empty cardboard boxes stacked up as a dresser and a nightstand. I really can't complain given what I've heard about the living condition of the folks in Iraq and even the folks here in Kuwait that are substandard to say the least.

There are an incredible number of people over here and they have them crammed into any available space in Kuwait. There are camps here with four times the number of people they were designed to hold. Before I came here, I was sleeping in a warehouse with hundreds of people. I then moved to another camp where I was in a tent. I've been slowly moving up in the world in terms of living conditions.

In May, I made a trip into Iraq escorting a humanitarian convoy. It was an interesting experience. We left Kuwait City before dawn and reached the border at sunrise. The border with Iraq consists of two barbed wire fences and a 15-foot-tall pile of sand that stretches as far into the desert as the eye can see.

As we drove through the border town, I saw graffiti everywhere saying "Thank you US/UK" and "Mr. Bleer, Mr. Bush Yes, Saddam, No." Hopefully, as we get their schools running again, their spelling will improve.

The southern part of the country is pretty barren. It reminded me of southern Arizona without the cactuses. That part of the country used to be one of the main agricultural areas in Iraq until Saddam dammed the rivers and drained the marshes in the area to punish the people for rising up against him after Desert Storm. There is still some agricultural activity in the area. In fact, as we drove by, we saw workers bringing in the tomato harvest and saw truckloads of tomatoes headed North to Baghdad.

I talked to some other lawyers who worked in the POW camps doing screenings of the detainees before release, and they told me that one day they released some tomato farmers to return to their homes. Word soon reached the other prisoners, and everyone started to claim that he was a tomato farmer in order to be released. The week before everyone was a police officer as we were releasing police officers to return to work. I guess some of them were actually tomato farmers as they were home and taking care of business when I drove by.

Every few kilometers on the highway, we would see Iraqi military installations that had seen better days. We saw burned-out tanks and broken down-vehicles that were stripped of everything except the frame. There were also trenches and fighting positions all along the highway.

Our convoy was delivering our aid to the hospital in Nassiriya, and as we entered the town. I was surprised to see that there was economic activity everywhere, people selling everything at the side of the road—produce, gas, batteries, cigarettes and tires. I was also surprised to see that the town was in good shape. It looked no better or no worse than any town I had seen in Egypt, Jordan, Uzbekistan or Kazakhstan. Without that perspective, I would have thought: "What a mess!"

Our arrival at the hospital created quite a ruckus. I was one of two people there in uniform and instantly had Iraqis of all ages all around me. They were asking me all sorts of questions. I have a friend up around Baghdad who told me that he was questioned about drinking whiskey and Michael Jackson. In Nassiriya, I only got questions about Michael Jackson. There were about forty Iraqis around me as we discussed Michael Jackson in what is best described as "Araglish"—part Arabic and part English with plenty of hand gestures.

During the conversation about M.J., a man with a young boy pushed his way to the front. The boy had a bandage on his head covering what appeared to be a superficial wound. The man began to yell at me: "Is this freedom?" and "If this freedom, give us Saddam."

It became rather uncomfortable for a minute with a political agitator yelling in one ear and a pop music critic in the other, so I put my hand on my holster flap and backed away. The group followed me. But, as soon as the man and the boy had come, they were gone; and the conversation returned to music. It was my only unsettling moment in Iraq.

I don't know how some of these young soldiers faced with crowds carrying AK-47s do it. I kept seeing the boy with the bandage on his head throughout the day, but his "father" was nowhere to be seen. I eventually approached the boy and asked a few Iraqis with the boy where his father was. They said that the man with

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Center refines organizational structure as components move

The Center has refined its organizational structure to provide a more effective and efficient approach to information management and to integrate the review of biological therapeutics. Also, a number of groups are moving.

The Office of Information Management provides a focal point for:

- Establishing standards for regulatory and health data as well as standards for paper and electronic submissions.
- Training for use of review tools.
- Coordination of systems development projects with the Office of Information Technology.
- Reports and analysis of drug review information.
- Oversight of CDER databases.

Randy Levin, M.D., and **Cathie Schumaker** are the director and deputy directory respectively of the new office, which has three components: Business Information Staff, Division of Records Management and Review Technology Staff.

Although the laboratory and review elements of the old Office of Therapeutics Research and Review in CBER are being assigned to the appropriate major offices in CDER; the integration will preserve most of the biologics structure and practices. These will be exist as currently outlined for at least a year an a half as the Center evaluates best practices with a view to future rationalization of its organizational structure. **Sharon Risso,** who had been heading OTRR, will be a senior advisor to the Center Director.

Within the Office of Pharmaceutical Science, the Office of Biotechnology Products is home to the laboratory-based divisions that are located on the NIH campus. That office, with **Yuan-yuan Chiu, Ph.D.,** as acting director, consists of the Division of Monoclonal Antibodies and the Division of Therapeutic Proteins. (Gene therapy, which had been a part of OTRR, remains in CBER as its own office.)

Most of the non-laboratory elements form the Office of Drug Evaluation VI in the Office of New Drugs with an indication-based structure. ODE VI, with **Karen Weiss, M.D.,** as director, consists of the Division of Therapeutic Biological Oncology Products, the Division of Therapeutic Biological Internal Medicine Products and the Division of Review Management and Policy. The biologics statistical reviewers and advertising and marketing reviewers are integrated into other existing offices.

A number of moves are taking place to accommodate our new colleagues from CBER, our PDUFA expansion and the availability of facilities at White Oak.

- ODE VI will relocate from Woodmont I into Woodmont II.
- The Office of the Center Director will move from Woodmont II to Rockwall, across from White Flint.
- Tentatively, ODE V is slated to move from Corporate to a nearby office building, and the Office of Counter-Terrorism and Pediatric Drug Development will backfill that space.
- The CDER laboratories, except for St. Louis and the two biologics divisions on the NIH campus, are moving into new lab buildings on the White Oak campus in October.

ORP lawyer on the road in Iraq

(Continued from page 6)

the boy was not his father, but rather worked for Saddam Hussein.

Along with crime, members of the old regime who are trying to stir up trouble seem to be the biggest problem here. They are digging up highways to stop aid shipments and trying to start riots around soldiers.

As they unloaded the convoy, I walked into the hospital pharmacy and wandered among the shelves of drugs manufactured in Iraq. I'm not sure how comfortable I would be taking some of these products.

I talked with the pharmacist who spoke some English. When I asked: "How are you," he replied that he was tired. I asked if he worked long hours. He said no and repeated that he was tired. I said he should take a nap, and he said that he was not sleepy rather that he was tired of Saddam. He said he had lived for 25 of his 40 years under Saddam and that he was tired.

I told him that I hoped his next 40 years would be better, and he said that he hoped so too. It was a sad moment as I thought of all the people who had lived in an oil-rich nation like Iraq and had so little, not to mention the lack of freedom and the threat that at any time you or a family member could be taken away at any time never to return. We heard some horrible stories from the Iraqis about life under Saddam.

The rest of the day was pretty uneventful. Incidentally, the hospital where we unloaded was the hospital where Pfc. Jessica Lynch was held before being rescued. On the way back to Kuwait, we saw an Army convoy of tractor trailers carrying supplies north go by. I almost drove off the road laughing (which would have been a bad thing given our training on land mine awareness prior to leaving the States) when I saw a truck with two soldiers wearing wrap-around sunglasses and full Arab headdress drive by.

Ken Borgerding, a regulatory counsel in the Office of Regulatory Policy, is an Army Reserve major on active duty.

PIKE'S PUZZLER

Famous pairs

BY TONY CHITE

1. The *carapace* and the *plastron* are the names of the:
a. Upper and lower shells of a turtle
b. Dorsal and ventral sides of a shark
c. Posterior and anterior sides of the vena cava
d. Left and right side of an incisor

2. The *obverse* and *reverse* most commonly refer to the:
a. Inside and outside of the ear
b. Heads or tails of a coin
c. Front and back of a fingernail
d. Top and bottom of a hair

3. *Estrogen* and *progesterone* are secreted by the:
a. Leydig's cells
b. Anterior pituitary
c. Ovary
d. Adrenal cortex

4. The two predominant proteins found in skeletal muscle tissue are:
a. Fibrinogen and fibrillin
b. Lysine and choline
c. Guanine and cytosine
d. Actin and myosin

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PROJECT MANAGEMENT CORNER

Biologics project managers adjust to new CDER family

BY DEBORAH KALLGREN

When CBER's Office of Therapeutics Research and Review staff became CDER's newest ODE VI and Office of Biotechnology Products this summer, they knew that there would be significant challenges in making the changeover between centers.

The task of sorting out organizational, procedural and cultural differences while staying "on track" with review timelines would not be easy. So how have they done so far? To find out, I caught up with Wendy Aaronson, director of ODE VI's Division of Application Review . . .

"They haven't missed a beat! These really are an extraordinarily committed group—reviewers and project managers alike," says Wendy. Clearly there have been some "bumps in the road" for all making the transition, but for OTRR's 14 project managers and two branch chiefs (equivalent to CDER's chief PMs), the biggest is the fact that their product-based review structure will, by Oct. 1, be restructured to mirror CDER's indication-based model.

"Our PMs are assigned to work with a particular product and they know the status of every IND, BLA or supplement for that product, regardless of the clinical indication. Because they consistently deal with the same regulatory affairs industry contact, it is also very conducive to building solid working relationships with Industry counterparts," says Wendy.

Biologics PMs are also responsible for assessing review team comments and monitoring for overlaps or inconsistencies in topic areas.

This organizational change from that of product-based to indication-based strongly impacts another key PM responsibility—communications. "Having the same PM for a product ensures that the various review disciplines and groups stay informed of new issues and changes for that product," Wendy said. She describes communications now as appearing to have many added layers.

Because of the size of CDER vs. that of CBER, there are many more people and expert groups in other areas of the Center to keep in the loop such as pediatrics, labeling and counterterrorism. She says that understanding when to get them involved is still confusing, but that they have created checklists of contacts to help them sort out the uncertainty. Project managers are asked not to make any assumptions, but always refer to these lists.

A compounding glitch in internal communications is the fact that CDER and CBER have vastly different databases that are on different platforms. These cannot "talk" to one another and even accessing the database from another center is an issue. Furthermore, there is no simple way to migrate the data from the CBER databases to CDER's COMIS.

> "It's like getting married and meeting the entire family from out of town for the first time and then being quizzed a week later on relationships four generations removed. It doesn't sink in until you are forced to spend a weekend together in a cabin without running water or electricity!"
>
> —Wendy Aaronson

This would not be a significant hurdle if the databases just captured important information about submissions. The issue is that these databases populate other databases, document management systems and the electronic document rooms.

"CDER enters all reviews, telecons, and letters into DFS." Wendy said. "The document room even prints and then mails the letter that was entered in DFS, so DFS is integral to the CDER review process. CBER cannot use DFS because we are not using COMIS. CBER still has a paper archive of internal communications; however, we are beginning to use the CBER electronic document room as a repository for all internal communications. After digital signatures are rolled out, we intend to use the CBER EDR as the archive for all internal communications in the same way as CDER uses DFS. CDER is working hard to iron out the IT issues that are causing access problems. In the interim, we just do what we can to try and minimize the information disconnect."

She credits much of the positive progress to steps taken by CBER and CDER senior managers to understand overall similarities and differences between the groups. This identification process has been particularly helpful because people can vent their frustrations, but also focus on problem solving and identifying best practices of OTRR and CDER.

"It's good to acknowledge that we use the same IND regulations, that we must meet the same PDUFA goals, but seeing the obstacles and getting stuck in frustration mode is not productive. Staying focused on leveraging our strengths is the best approach to go forward." That is why most OTRR staff consider the "Biologics Orientation to CDER" provided in July by OTCOM to be a highly positive experience.

"It really gave people here the opportunity to learn about the organization and the various groups within the Center. Acronyms like ODS and OPS meant nothing to us before, but hearing a presentation and matching a face to a name for these areas was a tremendous help—processing all the new information and being able to remember how the pieces fit together is the key and that may not happen until you just jump in, network, and interact."

Finally, she added: "It's like getting married and meeting the entire family from out of town for the first time and then being quizzed a week later on relationships four generations removed. It doesn't sink in until you are forced to spend a weekend together in a cabin without running water or electricity!"

Deborah Kallgren is a regulatory health project manager in OTCOM.

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PUZZLER ANSWER

Key 1a; 2b; 3c; 4d

Tony Chite is a CSO and pharmacist in the Division of Information Disclosure Policy.

Libraries to consolidate under CDER management with fewer staff

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offered another job in the Agency and retrained if necessary at the Agency's expense.

Also as a result of the study, all FDA libraries will consolidate into one system operated by CDER. This approach ensures minimal customer impact because it allows all the physical libraries, including those in other centers, to stay open for research purposes while centralizing behind-the-scenes technical processes such as procurement, cataloging, periodical management and acquisitions.

The centralization should eliminate redundancy and make the library system stronger and able to provide more efficient service, Carolan said. But the A-76 effort has taken its toll. "We've spent the last 18 months in limbo. It's been terrible for morale," Carolan said. "Still, we all pulled together and continued to provide excellent service to all of FDA."

By the time the library staff went through the bidding process, they were emotionally drained, said **Carol Cavanaugh,** the director of the Division of Library and Information Services and the functional coordinator for the library A-76 study. "It is difficult to keep up services and motivation while the A-76 work and the transition is going on," she said. "I think we all went through stages of grief. It was hard to manage a team. Some staff felt threatened and became defensive.

"If I had to do it over again, I would have involved our customers more and enlist their support," Cavanaugh said. "People who don't use the libraries' research services frequently don't understand the depth of knowledge required to do our jobs and how specialized the library profession has become. To be a librarian requires a master's degree in library and information science. In addition, all FDA librarians have extensive knowledge and expertise in specific scientific and medical areas. Some of our staff have or are working on doctorates, a number are credentialed medical librarians and a few are credentialed in other scientific and medical areas, such as pharmacy."

A-76 process path in libraries

At the beginning of the process, two groups were formed, one to prepare a description of the work and another to prepare the government's proposal. In order for the competition to be open and fair to all potential bidders, people in one group could not speak to those from the other group about the A-76 work they were doing.

The first group consisted of representative library personnel, a union representative and the contractor hired by FDA to help conduct the A-76 process—Management Analysis Inc. This group created a performance work statement, which included a description of the tasks, workload statistics, turnaround timeframes required to complete tasks, quality standards associated with the tasks, the volume and frequency of the tasks and types of interactions with other customers. The completed statement with supporting documents and appendices was more than 400 pages long.

The second group created the "most efficient organization" proposal—the government's offer, minus the costing. Known as the MEO, this is the government's proposal to perform a commercially defined activity. It may include a mix of federal employees and contract support. It is the basis for calculating the government's cost bid. The second group also had to try to factor in special initiatives. "We may get FDA or Center requests for extensive, long-term work on a particular project, such as the tobacco initiative," Cavanaugh explained. This type of work outside the lines had to be accounted for in the government's proposal.

"Once the MEO was submitted, we went into a personnel freeze, and attrition in a few of the Center libraries was rather high," Cavanaugh said. "People have retired or gone on to other positions, and we have been unable to fill the vacancies."

The contractor worked extensively with both groups, including interviewing each employee about his or her work. The contractor has an 80 percent success rate in terms of government employees winning their A-76 bids.

However, most of the contractor's experience had been working with the Department of Defense, Cavanaugh said. "The contractor was used to working with DoD libraries where they could do things like reduce the number of hours the library is open or the number of books purchased to come up with a lower-cost bid. A lot of what we do is used in Agency decision-making, and it's critical that we continue to provide full research services."

Based on the performance statement, a proposal request was advertised, and Cavanaugh conducted site visits for potential bidders. A project advisory committee evaluated bidders' proposals to see that minimum requirements were met and that they had the ability to perform all the required tasks. The advisory committee never saw prices, just technical specifications. This committee, too, could not discuss issues with members of the other two teams.

After the final decision, a transition team was formed to transition to the government proposal. "We've requested the use of early outs and buyouts, but haven't gotten word yet on approval," Cavanaugh said. The library is scheduled to operate with the new organization beginning Dec. 5.

That may not be the end. A-76 is a continual process with all contracts and MEOs subject to renewal every five years.

Clerical positions face A-76 next

In fiscal years 2004 through 2006, all clerical jobs at FDA will be competed. These positions are file clerk (305 job series), secretary (318 series) and office automation clerk (326 series). This will affect about 156 CDER clerical employees, including summer hires, according to **Devota Herbert,** administrative assistant to the center director and chairperson of the Support Staff Coordinating Committee.

A functional assessment of all CDER clerical staff positions has already been completed, according to Herbert. This is not a formal part of an A-76 study, but a precursor to developing specific A-76 studies. "The contractor worked closely with us to get the interviews completed in time," Herbert said. "They worked with our schedules and agreed to interview in groups of up to six people at a time."

The SSCC, along with selected members from the Office of Management, Hu-

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CDER plays important role in achieving FDA's strategic initiatives

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- Employing principles and technologies that can reduce avoidable delays and costs in product approvals.
- Overhauling and updating the way medical products are manufactured.
- Implementing an enforcement strategy that combines clear communications to industry backed up by effective civil and criminal enforcement.

Patient and consumer safety

Too many American's suffer from preventable adverse events related to medical products resulting in human suffering and avoidable medical costs.

Consequently, we are enhancing our post-market monitoring, communication and regulatory activities. In addition, one of the most promising new ways the FDA can improve its system for reporting safety problems is to have direct and secure access to relevant modern electronic health information.

By supplementing the current passive reporting systems and partnering with healthcare providers and other government agencies, we will develop more innovative and effective information on the risks associated with FDA-regulated products.

We will help speed the implementation of safer systems for medical care through steps such as:

- Bar coding medications in hospitals.
- Implementing 21st-century methods for communicating with health professionals to reduce adverse events.

Better informed consumers

Informed consumers represent our nation's greatest public health asset, because the choices that people make every day can have a great impact on their own health and the health of the nation.

We are undertaking major new efforts to ensure consumers have the most up-to-date, truthful information on the benefits and risks of FDA regulated products. In this arena, we fulfill two complementary roles:

- Ensuring the information that sponsors provide about products is accurate and allows for their safe use.
- Communicating directly with the public concerning benefits and risks of products we regulate.

The strategic plan calls for the Agency to learn more about how to communicate with consumers more effectively about risks and benefits.

The goal is a well-informed public, empowered to make better choices to improve their health.

Counterterrorism

We are working harder and more creatively than ever to speed the availability of the next generation of safer, more effective countermeasures to protect Americans against biological, chemical, nuclear and radiological agents of terrorism. We have two complementary but necessarily separate roles in this effort:

- We will help get products developed.
- We will then review marketing approval data on the same products.

A strong FDA

Our continued ability to carry out our mission of protecting and advancing America's health rests squarely on its most important resource: a talented and dedicated staff. Unlike other HHS agencies that provide grants or fund programs, our contribution to the public health is through our professional services.

Additional information about FDA's strategic plan, including a list of key action items and objectives, is available online at http://www.fda.gov/oc/mcclellan/strategic.html.

Slides from the State of the Center address are available to FDA employees only on the Center's intranet at http://cdernet.cder.fda.gov/dtd/SEMINARS/Fall03/State%20of%20CDER2003.ppt.

A-76 study of clerical functions underway affects 156 positions in CDER

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man Resource and the NTEU, sponsored a workshop for CDER's clerical staff to help prepare and inform them of the functional assessment interviews and the A-76 process. "Before the workshop, a template was sent to employees to help them think about all the various functions that make up their jobs," Herbert said. We emphasized that they think beyond the four functions targeted in the assessment:

- Mail, correspondence and reports.
- Office automation.
- Travel.
- Office supplies and equipment.

The workshop, held June 18, drew approximately 135 members of the Center's clerical staff. "It went very well," Herbert said, "and everyone seemed to leave with a more positive attitude and a more confident feeling with regard to the interview process.

"We were so very pleased with all the support throughout the Center. Many supervisors we called offered their assistance and expressed their concerns. Many even sat in on the interviews. CDER management is very committed to the clerical support."

The workshop would not have been held without the support of Center Director **Janet Woodcock, M.D.**

"Dr. Woodcock places a very high value on the support staff at the Center," said **Doug Hamilton,** deputy director, Office of Management. "She is very committed to lessening any negative impact of A-76 on the staff and the Center."

However, **Rick Rohdenburg,** A-76 coordinator for FDA, sounded a cautionary note. "It's not expected that FDA will be able to guarantee jobs in the upcoming studies," he said of the process involving clerical jobs.

"In fiscal year 2004 through fiscal year 2006, FDA must review more than 500 positions for possible outsourcing. Contractor wins on these studies would make it extremely difficult to place this number of employees in other FDA jobs," he said.

"Additionally, FDA has been directed to reduce administrative positions by 15 percent—7.5 percent in fiscal year 2004 and 7.5 percent in fiscal year 2005. Reductions generated by A-76 initiatives would be credited toward meeting the 15 percent reduction goal."

For more detailed information on the A-76 initiative, go to: http://intranet.fda.gov/oms/change/a76/.

Patrick Clarke is a public affairs specialist in OTCOM.