news along the pike

DECEMBER 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

VOLUME 6, ISSUE 12

INSIDE . . .

PIKE'S CORNERS

CDER's Training Program Wins Deming Award

USDA Graduate School Selects Center from 10 Agencies

The Graduate School of the Department of Agriculture presented CDER with its 2000 W. Edwards Deming Outstanding Training Award. The Center placed first, ahead of nine other federal government agencies and civilian offices in the military competing for the award.

Named in honor of total quality management guru Deming (1900-1993), who taught mathematics and statistics at the Graduate School for 22 years, the 40-pound bronze eagle trophy and a plaque will eventually be displayed at the Office of Training and Communications.

Janice Newcomb, Director, Division of Training and Development, accepted the award on Dec. 14 for CDER at a ceremony in a Washington hotel as part of the school's annual Dimensions of Leadership Conference. Most DTD employees were able to attend the ceremony.

In brief remarks at the ceremony, FDA Commissioner **Jane E. Henney, M.D.,** said that the Center was setting the training standard for the whole Agency.

"CDER's training program continues to impress me," said **Nancy Smith, Ph.D.,** OTCOM Director and a former educator. "But we can't do it alone. More than 200 people from throughout the Center helped by providing scientific and technical expertise."

The award sponsors cited CDER's Competency Based Training Program (page 7) the key element that clinched the prize for CDER. Faced with a staff that grew from 1,000 in 1992

(Continued on page 8)

Two FDA Audioconferences Target Small Businesses

BY RON WILSON

FDA and the Food and Drug Law Institute held a pair of two-hour interactive audioconferences for small pharmaceutical businesses on Oct. 25 and Nov. 9. The conferences covered the FDA review process as well as assistance and incentives available to small businesses.

An audioconference is a new educational tool that provides a fast, convenient and economical vehicle for the audience to interact with an expert panel on a very focused topic. An audioconference is similar to a huge telephone conference call. Participants dial a number at a specified time and join others to discuss a topic and hear everyone else.

Either one individual or a room full of people can take part. They not only listen to the program but also have the opportunity for questions and answers in complete anonymity. Polling of the participants is another feature of an audioconference, which can also be conducted in anonymity.

(Continued on page 8)

PQRI Leveraging Collaboration Marks First Year

BY DEBBIE WERFEL

ARLINGTON, Va.—The Product Quality Research Institute—a first-ever collaborative effort between CDER, the pharmaceutical industry and academia—has identified issues related to the regulation of pharmaceuticals and is carrying out research, which is expected to have an impact on the establishment of testing standards and controls for drug products.

PQRI was established one year ago (*Pike*, November 1999) in an effort to streamline drug review and testing policies while ensuring the highest level of product quality. The institute is administratively managed by the American Association of Pharmaceutical Scientists.

In its first year, PQRI identified seven working groups to address the following regulatory issues:

- Blend uniformity.
- Manufacturing changes.
- Packaging changes.
- Bulk drug post-approval changes.

(Continued on page 8)

JOE'S NOTEBOOK

Congratulations to Pike's Authors

This is my favorite column of the year. I get to poke through all the back issues and find out just how busy CDER has been. I am always amazed at the large number of your friends and colleagues who took time from their busy schedules to share something important with you. We had contributions from a large cross-section of the Center, two student interns and two authors from outside CDER.

Here are the folks who contributed bylined articles in 2000:

Jackie Barber, R. Daniel Benz, Ph.D., Celeste Bové, Melissa Chapman, Mei-Ling Chen, Ph.D., Tony Chite, Yuan-yuan Chiu, Ph.D., Patrick Clarke, Bronwyn Collier, Joseph Contrera, Ph.D., Juliann DuBeau, Linda Emilio, Emmanuel Fadiran, Ph.D., Elaine Frost, Janet Gentry, and **Mark Goldberger, M.D.**

Erik Henrikson, Robin Huff, Ph.D., Shelly Johnson, Christine Kaibni, Deborah Kallgren, Lydia Velazquez Kieffer, Pharm.D., Kofi Kumi, Ph.D., Larry Lesko, Ph.D., David Lester, Ph.D., Sherunda Lister, Murray Lumpkin, M.D., Darek Maciasz, Nasser Mahmud, Edwin Matthews, Ph.D., Nanette McAtee, E. Jane McCarthy, Ph.D., Judy McIntyre, Edward Miracco, and **Justina Molzon, M.S.Pharm., J.D.**

Jim Morrison, Dave Moss, Sakti P. Mukherjee, M.D., D.Sc., Janice Newcomb, Chris Nguyen, Linda Papio, Maureen Pelosi, Judith Racoosin, M.D., MPH, C. Russ Rutledge, Arzu Selen, Ph.D., Tony Sims, Nancy Smith, Ph.D., John A. Spencer, Ph.D., Vaiyapuri Subramaniam, R.Ph., M.S., and **Gloria Marquez Sundaresan.**

The Communications Results Team, The RAC Representatives, Claudia R. Turner, Ph.D., Rajendra Uppoor, Ph.D., R.Ph., Debbie Werfel, Dale F. Wilcox, Ron Wilson, Janet Woodcock, M.D., Jean Yager, Robert Young and **Karen Zawalick.**

More work behind the scenes to help bring you the Pike by supplying information and checking facts.

Foremost among these are the people in the Office of Information Technology who team up to bring you their monthly column. They are:

Sheila Andrew, Greg Brolund, Melissa Chapman, Don Duggan, Peter Fabry, Janet Gentry, Mary Ann Holovac, Rich Johnson, Lana Kostecka, Ralph Lillie, Mark Magee, Tim Mahoney, Jim Marshall, Linda Sigg, Mike Simms, Vali Tschirgi, David Wardrop and **Jayne Ware.**

World Aids Day was Dec. 1, and HHS always reminds us of the toll this disease takes. As of June 2000, AIDS had been reported among 753,907 persons in the United States, and 438,795 of these persons have died. An estimated 311,701 persons were reported to be living with AIDS. Although deaths from AIDS began to decline in 1996, primarily because of the use of effective combination antiretroviral therapy, AIDS deaths and AIDS incidence trends began to level by 1999. Since 1992, HIV incidence has been relatively stable. An estimated 40,000 new HIV infections are expected to occur each year. The number of persons living with HIV and AIDS at the end of 1998 ranged from 800,000 to 900,000. Among these persons, approximately one-third do not know they are infected with HIV. In addition, about four out of every 100 Americans engage in behaviors that put them at high risk for HIV infection.

If you enjoyed the essays in the *Pike* by CDER alum and former Pike editorial board member G. Alexander "Zan" Fleming, M.D., you may be interested in reading his editorial in the Dec. 21 *New England Journal of Medicine* at http://www.nejm.org/content/2000/0343/0025/1886.asp.

news along the pike

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

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).

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

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

NEWS ALONG THE PIKE
CDER Office of Training and Communications (HFD-200)
Parklawn Building, Room 12B-45

Editor: Norman "Joe" Oliver (OLIVERN)
Associate Editor: Patrick Clarke
Phone: (301) 827-1670
Fax: (301) 827-3055

OMBUDSMAN'S CORNER

A Map to the Road Ahead

BY JIM MORRISON

An important event has been lost in all the finger-pointing at FDA in the press lately. It is a quality assurance report on the processes involved with troglitazone (Rezulin). The report is available on CDER's Web site at http://www.fda.gov/cder/about/quality-assurance/default.htm.

There are two remarkable things about this report. The first is that it was done at all, because, until recently, there was no organizational process in the Center by which lessons could be learned from outcomes that didn't meet either the public's or our expectations. And the second is that it was published for all to see.

From comments in the press, it seems, sadly, that the prevailing concept of quality assurance is still to find someone to blame, execute him or her and then get on with business as usual. The problem with that approach is that we execute the one person who probably knew most about how the problem occurred and how to prevent it from happening again. Beyond that, it instills in people within an organization a fear of being wrong or of making a mistake. Put another way, it encourages people to do nothing.

As all quality assurance experts and ombudsmen know, the way to solve problems in any organization is to recognize that all humans make mistakes, to analyze the system as a whole, to identify what went wrong and to publish consensus recommendations. Then people, freed from the need to defend their actions, can learn from their own and others' mistakes.

Those of us who have been in FDA for a long time are conditioned to working in a fish bowl. It is the price we pay for doing work that is important to people. In the private sector, quality assurance reports are virtually never made public. That CDER's reports are and will continue to be posted on our Web site shows a strong commitment to our stated values, one of which is transparency.

However, publishing quality assurance reports and recommendations is but one step in a journey. The report highlights important issues. There are procedural and organizational recommendations that may be easier to implement than the scientific ones. The most difficult by far to implement will be developing a prospective plan for assessing new safety information about marketed drugs and taking action. But, as recent events have shown, such a plan is critically needed, and it can be invaluable to us in explaining to the public the reasoning behind CDER's actions.

There is not much doubt that the trend toward FDA operating in full public view will continue. The public's demand for a carefully thought out and generally understandable explanation for every action CDER takes will also intensify. I see it in the content and volume of the e-mail I get. We are rapidly moving into the information age, and there is no turning back. The road will have many curves and we will need to learn new ways of thinking and new approaches to old problems. CDER will flourish in that new age, so long as we all keep in mind the saying, "A bend in the road is not the end of the road . . . unless you fail to make the turn."

Jim Morrison is the Center's ombudsman.

FTC Reaches Record $100M Settlement in Generic Drug Price-Fixing Case

The Federal Trade Commission on Nov. 29 announced a $100 million settlement with Mylan Laboratories Inc., the largest monetary settlement in the commission's history.

If the settlement is approved by the federal district court, Mylan will pay the money into a fund for distribution to injured consumers and state agencies. The settlement would resolve the commission's charges that four companies, including Mylan, conspired to deny Mylan's competitors ingredients necessary to manufacture two widely prescribed anti-anxiety drugs, lorazepam and clorazepate.

"This is the first time in Mylan's 39-year history that any government agency has accused us of improper conduct,'' said Milan Puskar, chairman and chief executive officer of Mylan Laboratories. "We continue to believe we acted properly.''

Anticompetitive acts in the pharmaceutical industry potentially cost consumers millions of dollars, said Richard Parker, Director of the FTC's Bureau of Competition. "This settlement serves notice of the commission's determination to pursue investigations of such behavior and to seek disgorgement of ill-gotten gains in appropriate cases."

The proposed settlement resolves a complaint that the commission filed in December 1998 charging that Mylan, Cambrex Corp., Profarmaco SRL and Gyma Laboratories of America Inc. carried out a plan intended to give Mylan the power to raise the price of generic lorazepam tablets and generic clorazepate tablets by depriving its competitors of the active pharmaceutical ingredient necessary to manufacture each product.

By early 1997, vigorous competition among generic manufacturers had driven down the prices of both lorazepam and clorazepate to very competitive levels.

In late 1997, the defendants entered into exclusive licenses that deprived Mylan's competitors of both active pharmaceutical ingredients. Pursuant to those licenses, Mylan agreed to share the profits from its sales of lorazepam and clorazepate tablets with Cambrex, Profarmaco, and Gyma.

Without access to the APIs for lorazepam or clorazepate tablets, the commission alleged, Mylan's competitors could not effectively compete for the sale of either product. Therefore, Mylan could and did raise prices approximately 2,000 percent to 3,000 percent depending on the bottle size and strength, FTC said..

For example, in January 1998, Mylan raised the wholesale price of clorazepate from $11.36 to $377 for a 500-count bottle of 7.5 mg tablets. In March 1998, Mylan raised the wholesale price of lorazepam from $7.30 to $190 for a 500-count bottle of 1 mg tablets.

For more information, see the full FTC news release at http://www.ftc.gov/opa/2000/11/mylanfin.htm and Mylan's statements at http://www.mylan.com/ftc/.

INFORMATION TECHNOLOGY CORNER

New Computer Training Room Opens Across from Parklawn

A new OIT computer training room is now open in Room 2-22 of the Park Building, directly across Parklawn Drive from the Parklawn Building.

The Park Building has been OIT's new home since February.

The training schedule (http://oitweb/training/default.htm) and online registration have been updated to include classes scheduled at both the Corporate Boulevard and the new Park locations.

The new classroom is also within a short walking distance from Twinbrook Metro station and the shuttle from WOC II.

Due to the limited parking spaces available, no visitor parking is available at the Park Building. Attendees can park in the pay lot on Fishers Lane in front of the Parklawn Building. Classes will also continue to be offered at the Corporate Boulevard location, where parking is available.

Before attending training at the Park Building, remember these important instructions:

- When registering for a class, please note which building is holding the training—Park (P) or Corporate Boulevard (C).
- Do not park your car at the Park Building. All spots are assigned, with no visitor parking. If you park in assigned spots, you may be towed.
- Remember your badge. Everyone is required to swipe his or her badge to access the building, and most doors do not have a guard to supply a visitor's pass.
- Contact **Lana Kostecka** (KOSTECKAL) prior to attending training for handicap access. Please contact OIT's Training Coordinator, Lana Kostecka (KOSTECKAL), for more information.

CDER Secure Electronic Mail

The Center's secure electronic mail system has been in operation for over one year. With this system, any CDER electronic mail user can exchange mail with participating pharmaceutical companies and be assured that the mail cannot be read by anyone else.

When you send mail to the specific e-mail address for the person in the company, your message is automatically encrypted and digitally signed by the CDER secure e-mail server.

Mail sent from the company is automatically decrypted and forwarded to your CDER e-mail account.

To use the system, all you have to do is make sure that you use one of the e-mail addresses that the server recognizes as a secure e-mail address.

You can find the latest list of secure e-mail addresses on the OIT Web page. Enter OITWEB in the address line of your Web browser and click on the link to Participating Companies.

Please contact **Greg Brolund** (BROLUND) for more information.

January IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
1	2	3	4	5
8 **MS Outlook** 9:00-12:00 (C) **MS Outlook** 1:00-4:00 (C)	9 **MS Outlook** 9:00-12:00 (C) **MS Outlook** 1:00-4:00 (C)	10 **MS Outlook** 9:00-12:00 (C) **Intro. PowerPoint** 9:00-12:00 (P) **MS Outlook** 1:00-4:00 (C) **PowerPoint Charts** 1:00-4:00 (P)	11 **MS Outlook** 9:00-12:00 (C) **MS Outlook** 1:00-4:00 (C) **Intro to Excel** 1:00-4:00 (P)	12 **MS Outlook** 9:00-12:00 (C) **MS Outlook** 1:00-4:00 (C)
15	16 **MS Outlook** 9:00-12:00 (C) **MS Outlook** 1:00-4:00 (C)	17 **Pediatric Tracking System** 9:00-12:00 (C) **NEST** 9:00-12:00 (P) **MS Outlook** 1:00-4:00 (C) **NEDAT** 1:00-4:00 (P)	18 **CDER Standard Letters** 9:00-12:00 (C) **DFS** 9:00-12:00 (P) **MS Outlook** 1:00-4:00 (C) **AERS Data-Mart** 1:00-4:00 (P)	19 **MS Outlook** 9:00-12:00 (C) **Word Intro** 9:00-12:00 (P) **MS Outlook** 1:00-4:00 (C) **Word Formatting** 1:00-4:00 (P)
22 **MS Outlook** 9:00-12:00 (C) **MS Outlook** 1:00-4:00 (C)	23 **E-Doc** 9:00-12:00 (P) **E-Doc** 1:00-4:00 (P)	24 **DFS** 9:00-12:00 (P) **DFS** 1:00-4:00 (P)	25 **MS Outlook** 9:00-12:00 (C) **E-Doc** 9:00-12:00 (P) **MS Outlook** 1:00-4:00 (C) **E-Doc** 1:00-4:00 (P)	26 **Word Tables** 9:00-12:00 (P) **DFS** 1:00-4:00 (P)
29 **E-Doc** 9:00-12:00 (P) **E-Doc** 1:00-4:00 (P)	30 **E-Doc** 9:00-12:00 (P) **E-Doc** 1:00-4:00 (P)	31		

Key: Corporate Boulevard (C), Park Building (P)

The catalog, training materials, schedule and on-line registration can be found under Training at http://oitweb/.

Help Desk FAQs

Q: Where can I find information on how to buy computer hardware, software or general computer supplies.

A: Visit the IT Procurement section of the OIT Web at http://oitweb/procurements/default.htm.

OIT recently performed a procurement reengineering project in order to update the IT procurement process.

Now at the IT Procurement site, you can find out whether your purchase requisition needs OIT review.

The site has details and pricing on hardware, software and computer supplies that you can buy. There are general guidelines on when you should use an IMPAC credit card purchase or a HHS-393 purchase requisition form.

Following the guidelines on the site will enable you and OIT to expedite your IT procurements, while making sure that new purchases do not conflict with hardware and software already used in the Center.

Rx Labeling Format Proposal; New Treatments; Withdrawals

FDA on Dec. 21 proposed a new format for prescription drug labeling that will help reduce medical errors, which according to the National Academy of Sciences may be responsible for as many as 98,000 U.S. deaths annually. FDA believes that this new, user-friendly format will reduce errors in drug prescribing.

"Today's proposal is FDA's latest initiative to improve the labeling of the products it regulates," said FDA Commissioner **Jane E. Henney, M.D.** "This proposal is particularly valuable because it will make important information available in a clear, consistent and readable format that is essential to proper prescribing practices."

Prescription drug product labeling, also known as the package insert, represents a primary means of providing critical information about drugs to practitioners. As part of the drug review process, FDA reviews and approves drug product labeling that is initially proposed by manufacturers.

An FDA study showed that practitioners found drug product labeling to be lengthy, complex and hard to use. The proposed new format would provide user-friendly labeling that would allow practitioners to quickly find the most important information about the product.

One major change is inclusion of a new introductory "Highlights" section of bulleted prescribing information. This section would include the information that practitioners most commonly refer to and view as most important. It would provide the location of further details elsewhere in the labeling.

The proposed new labeling is expected to reduce practitioners' time spent looking for information, decrease the number of preventable medical errors and improve treatment effectiveness. The information will be easier to find, read and use.

Because these labeling revisions represent considerable effort and are most critical for newer and less familiar drugs, the proposal will apply only to relatively new prescription drug products.

Written comments are due to FDA by March 21. A copy of the proposed rule is available in HTML at http://www.fda.gov/ohrms/dockets/98fr/122200a.htm or in PDF at http://www.fda.gov/ohrms/dockets/98fr/122200a.pdf.

FDA on Dec. 8 approved a new treatment for atopic dermatitis (eczema)—a non-contagious skin condition that can cause redness, itching and oozing lesions. The drug is tacrolimus (Protopic), an ointment for patients with moderate to severe eczema, for whom standard eczema therapies are deemed inadvisable because of potential risks, or who are not adequately treated by or who are intolerant of standard eczema therapies.

On Nov. 28, FDA announced that Glaxo Wellcome, of Research Triangle Park, N.C., had informed the Agency that it would voluntarily withdraw alosetron (Lotronex) tablets from the market. Alosetron is a prescription medication approved to treat irritable bowel syndrome in women.

The company's action followed a meeting where the Agency discussed with Glaxo Wellcome risk management options that included restricting the distribution of the drug or marketing withdrawal.

The action followed FDA analyses of the post-marketing reports of serious adverse events, which included five reports of death in patients taking alosetron.

The Center's Lotronex information Web page (http://www.fda.gov/cder/drug/infopage/lotronex/lotronex.htm) has more information, including a letter from the Center director to consumers.

FDA on Nov. 15 announced approval of Trizivir for the treatment of HIV in adults and adolescents. Each dose of Trizivir is a fixed-dose combination of abacavir (Ziagen), zidovudine (Retrovir), and lamivudine (Epivir), three nucleoside reverse transcriptase inhibitors already approved by FDA. Because Trizivir combines a single dose of three drugs into one pill, it may be easier for some patients to comply with their medication regimen. Each component of Trizivir is also available separately.

FDA on Nov. 6 announced it is taking steps that may lead to removal phenylpropanolamine from all drug products and has requested that all drug companies discontinue marketing products containing the ingredient.

FDA issued a public health advisory concerning the risk of hemorrhagic stroke, or bleeding into the brain, associated with phenylpropanolamine, an ingredient used in many over-the-counter and prescription cough and cold medications as a decongestant and in OTC weight loss products.

Adverse events reported with these products led to concerns that this ingredient might increase the risk of hemorrhagic strokes.

Manufacturers of products containing phenylpropanolamine worked with FDA to plan a research program to clarify whether any increase in risk exists.

Scientists at Yale University School of Medicine conducted the study in which the researchers found an association between phenylpropanolamine use and stroke in women.

The increased risk of hemorrhagic stroke was detected among women using the drug for weight control, and for nasal decongestion, in the three days after starting use of the medication. Men may also be at risk. FDA believes that although the risk of hemorrhagic stroke is very low, even with phenylpropanolamine use, the conditions for which these products are used do not appear to warrant an increased risk of this serious event.

Information about the history of phenylpropanolamine, the Public Health Advisory, and the stroke study results can be found at http://www.fda.gov/cder/drug/infopage/ppa/default.htm.

Immediately after the public health advisory, the Center experienced high public interest in the subject. About 1,000 telephone calls a day were received in the Division of Drug Information, said **Barbara Daciek,** a DDI consumer safety officer. The Center's phenylpropanolamine Web pages recorded about 250,000 hits in their first two days online, according to CDER webmaster **Paul Stauffer.**

PROJECT MANAGEMENT CORNER

FDA-DIA Interactive Training Shows Benefits of Teamwork

BY JEAN YAGER AND DEBORAH KALLGREN

When was the last time you attended a professional development program that kept your interest from start to finish? An event that involved you in the action instead of making you feel like a spectator in a room full of talking heads? An experience so chock full of useful information that you could take it back to your job and apply the ideas and concepts right away?

For a number of CDER and CBER project managers, just such an event for occurred this May at the third Joint Training Workshop on the Process of Pharmaceutical Drug Development and Review sponsored by FDA and the Drug Information Association. The two-and-a-half day training event was held in Bethesda for about 250 regulatory affairs and project management professionals from industry and FDA. They learned about each other's processes, identified factors critical to successful drug development and review and strengthened their skills as team players.

Keynote speakers were Center Director **Janet Woodcock, M.D.,** and Senior Associate Commissioner **Linda Suydam.** Both underscored the importance of leveraging opportunities, such as the workshop, to improve FDA's regulatory and scientific knowledge base, reduce the risk involved with new drug and biologic products and better accomplish our shared goal of providing safe and effective drugs to the public.

Following these presentations, the program shifted into high gear with the introduction of "key factors." Thanks to the creative talents of the CDRH studio "wizards," a football film presented a parody of the new drug approval process called the "NDA Bowl." There were jabbering commentators, a charismatic quarterback, huddles, penalty flags, crazy commercials and a live mascot who moved in and out of the video to get the crowd into the game. Participants learned about the four key elements that facilitate good FDA-industry interactions: effective communication, adherence to commitments, meaningful information exchange and clarity of expectations. Important regulatory guidance was included in the script.

Next, industry and Agency attendees learned how to work together in the fast-paced teambuilding exercise, "Gold of the Desert Kings." Teams formulated and carried out plans to survive crossing a hostile desert environment in order to mine gold. The team mining the most gold and surviving the desert won. This portion of the workshop, more than any other, had folks on their feet, rolling up their sleeves and working together to achieve a common goal. There was the thrill of victory, and the agony of defeat was clearly shown by a stuffed vulture that appeared on a team table when survival was no longer an option. Participants learned that the key factors were pivotal in winning the game and the value of team collaboration couldn't have been clearer or more enjoyable.

A three-act play that followed described the roles of regulatory affairs professionals and project managers in a pharmaceutical company and those of a regulatory project manager in CDER. Three actors carried on parallel monologues as they moved through the three phases of drug development and the NDA review. They identified areas where industry and FDA needs were similar and areas where there were differences. The messages were easy to absorb. After each act, roving reporters actively engaged the audience in the discussion. This question-and-answer session was clearly a high point for focusing on lessons learned.

Later, real life case studies were presented in a fireside chat format. The actual industry and FDA regulatory officials who worked on the product development and review presented each case. Both negative and positive aspects were disclosed to maximize the learning experience.

The program closed as participants once again teamed up to work their way through a "virtual" drug development scenario. Each table was asked to pretend that they were the development team for a new product fraught with issues. Their mission was to create an interactive plan to address these problems proactively and bring in an approvable submission. This required that each team successfully apply information and learning gained from earlier portions of the workshop.

In concluding remarks, **Mark Elengold,** CBER Deputy Director, Operations, emphasized the need to continue to work hard at improving communications between Agency and industry teams as a means of meeting joint goals. Exit polls of workshop participants and evaluations submitted to the organizers gave the program very high marks and confirmed the usefulness of the data and the effectiveness of the dynamic and highly interactive format.

Plans are underway to hold another workshop in May 2002 that will include not only project management and regulatory professionals but also FDA and industry scientists from representative disciplines. The scope of the workshop will likely expand through the diversification of the audience. However, we guarantee the same highly informative, engaging and entertaining format.

Jean Yager heads and Deborah Kallgren is a member of the Center's Project Management Staff located in OTCOM.

PIKE'S PUZZLER

Human Anatomy Scrambler

BY TONY CHITE

Unscramble the letters below to spell a part of the human body.

1. G Y A A A D M L
2. L A P L E T A
3. R E U B E M C R
4. L U N A
5. S I I R
6. T R A I N E
7. M U J J N E U
8. N E P L E S

Answer key: 1. amygdala; 2. patella; 3. cerebrum; 4. ulna; 5. iris; 6. retina; 7. jejunum; 8. spleen.

Tony Chite is a pharmacist and CSO in CDER's DFOI.

TRAINING AND DEVELOPMENT CORNER

Competency Based Training Program Key to Deming Award

BY JACK MORIN

CDER received the W. Edwards Deming Outstanding Training Award (page 1), because of its:

- Development of a model of core competencies and learning pathways.
- Training needs assessment based on the core competencies and learning pathways.
- Design and delivery of training programs that produced documented results tied to the Center's mission.

CDER's Competency Based Training Program provides an organized structure for career development. With the program, critical knowledge needed by staff is identified, prioritized and presented in a logical sequence. It also ensures that the content included in our courses, workshops and seminars focuses on the drug review process and related work requirements. This enables CDER staff to increase their productivity with a shorter learning curve. In addition, continuing education for experienced staff builds upon foundational knowledge and skills making more efficient use of Center resources.

Facilitated by the Division of Training and Development, the competencies and learning pathways were developed by the following CDER staff:

Tanya L. Abbott, Funmilayo O. Ajayi, Ph.D., Aisar H. Atrakchi, Ph.D., Dorothy C. Ballmann, Paula G. Bourkland, Heidi N. Burch, Sonia C. Castillo, Ph.D., Aloka G, Chakravarty, Ph.D., Tien-Mien Chen, Ph.D., Ling Chin, M.D., and **Sandra L. Coffin.**

E. Douglas Kramer, M.D., Philip M. Colangelo, Pharm.D., Ph.D., Eldridge F. Coles, Thomas A. Cunningham, Velma L. Cunningham, Joseph J. DeGeorge, Ph.D., Kuldeep R. Dhariwal, Ph.D., Angelica Dorantes, Ph.D., Patricia L. Downs, Amy L. Ellis, Ph.D., John L. Emelio, Jr., and **Emmanuel O. Fadiran, Ph.D.**

James G. Farrelly, Ph.D., Glenna G. Fitzgerald, Ph.D., Noreen A. Gomez, Alice L. Gray, Kenneth L. Hastings, Dr.P.H., Carol H. Hall, Anita G. Harrell, Devota D. Herbert, Karen M. Higgins, Sc.D., Robin A. Huff, Ph.D., Patricia F. Hughes, Ph.D., Patricia A. Johnson, Barbara M. Jones, Joyce Ann Korvick, M.D., E. Douglas Kramer, M. D., Kofi A. Kumi, Ph.D., and **See-Yan Lam, Pharm.D., Ph.D.**

Sheryl L. Lard-Whiteford, Ph.D., Sue-Chih Lee, Ph.D., Sally J. Lewis, Kooros Mahjoob, Ph.D., Iftekhar Mahmood, Ph.D., Maureen D. Majors, Frederic J. Marsik, Ph.D., Patrick J. Marroum, Ph.D., Jamie M. Metz, Veronica E. Milstead, Rebecca E. Nalley, Shriniwas G. Nerukar, Ph.D., Janice L. Newcomb, Peggy A. Noland, Carol T. Norwood, Susan H. O'Malley, William W. Oswald, Larry A. Ouderkirk, Dawn M. Reid, Charles A. Resnick, Ph.D., and **Delores A. Rhodes.**

Laura E. Riddle, Kathy A. Rios, Lawrence F. Sancilio, Ph.D., Wendelyn J. Schmidt, Ph.D., John R. Senior, M.D., Daniel A. Shames, M.D., Janice M. Sheehy, Barbara E. Shekitka, Albert T. Sheldon, Ph.D., Robert M. Shore, Pharm.D., Ronald W. Steigerwalt, Ph.D., He Sun, Ph.D., Vijaya K. Tammara, Ph.D., and **Sandra Van Buskirk.**

Victor H. Vail, Richard T. Vengazo, Vera K. Viehmann, Zakaria Wahba, Ph.D., Michelle L. Walling, Juandy S. Walston, Dan Wang, Ph.D., Andrea B. Weir, Ph.D., Karen R. Weller, Laura M. West, Leslie DeLaPena Wheelock, Grant A. Williams, M.D., Rosa L. Williams, Tonya R. Wise and **Matthew A. Zell.**

Also, about 600 CDER staff completed the training needs assessment, and more than 200 CDER staff participate in revising and developing courses annually.

Jack Morin is a writer-editor in DTD.

Medieval Adventure Game Enhances Project Management Skills

Castles, Swords and Shields may sound like something from medieval times, but it's actually an innovative and dynamic training program designed to provide a way for CDER staff to test and improve their knowledge of drug regulations, guidances, policies, basic drug development and FDA history.

The first Castle, Swords and Shields game was piloted on Nov. 16. Participants were organized into four teams with four to five members in each team. The objective was to scale the game board's castle wall by answering regulatory and development topics correctly and earning points. A correct answer won a chip. The team with the most chips captures the flag and wins the game. Teamwork is vital as the subject matter can range from the relatively easy to the more demanding. Participants found that working closely to pool their knowledge paid off in chips.

Competitive interactions intensified during "lightening rounds" when teams challenged one another to win more chips. Approximately 18 project managers from across the Center with varying levels of experience took part in this pilot. The important information gained from their evaluations will be used to refine the game play and structure.

Frequently the time spent in training doesn't provide immediate returns on the job. The strength of the Castles, Swords and Shields is that it provides participants a stimulating and entertaining means to gain valuable regulatory knowledge, strengthen existing understanding and reinforce teamwork skills all at once. Based on the enthusiastic and encouraging feedback we received from our trainees, this program delivers.

The developers of this game were **Tawni Brice, Rita Hoffman, Lisa Hubbard, Deborah Kallgren, Diane Moore, Matthew Tarosky** and **Jean Yager.**

They would like to extend their appreciation to CDER staff who participated in this first premier of this training program: **Julieann DuBeau, Walter Ellenberg, Laura Governale, Anna Marie Homonnay, Alice Kacuba, Dan Keravich, Crystal King, Melodi McNeil, Karen Oliver, Maureen Pelosi, Dianne Spillman, Brian Strongin, Leslie Vaccari, Melissa Truffa** and **Debra Vause.**

—Jean Yager and Deborah Kallgren

USDA Graduate School Selects CDER Training for Deming Award

(Continued from page 1)

to about 1,800 currently because of user fees, the Center needed a systematic training program based in science, policy and job-related skills to standardize orientation and shorten the learning curve for employees.

Based on competencies, learning pathways and individual development plans, the training program grew from seven courses in 1997 to 20 courses in 1999. Existing courses were also revised.

Reviewer participants increased sixfold, from 258 in 1997 to 1,542 in 1999. Reviewer training hours quadrupled from 4,148 to 15,982 hours.

Training costs were reduced through partnerships with pharmaceutical firms, associations, academic institutions and foreign governments.

Intangible results from the training program included increased communication and teamwork throughout CDER, improved direction for new employees and a sense of accomplishment within OTCOM's Division of Training and Development.

The identification of training requirements through needs assessments will allow CDER to maintain current knowledge and skills and prepare for future scientific training.

The result is a systematic training program that supports the Center's mission and is flexible and proactive in developing staff skills in areas of future need.

The Graduate School noted that competency-based training provided an organized structure for the career development of employees with advanced degrees and was well-integrated with the Center's public health responsibilities.

FDA, FDLI Sponsor Interactive Audioconference for Small Businesses

(Continued from page 1)

The first part of the program was held Oct. 25 in an FDLI conference room. Panelists included CDER, CBER and industry representatives. The moderators were **Ron Wilson,** Director of CDER's Small Business Assistance and Frank Sasinowksi, an attorney specializing in food and drug law. CDER panel members were **Linda Carter, John Friel, Mark Goldberger, M.D.,** and **Donald Hare.**

The audioconference focused on the FDA review process and the mechanisms for economic assistance and incentives. Two hypothetical cases of drug products moving through the new drug development and review process were used for discussion on the following questions:

- What types of applications are available for the small pharmaceutical business?
- What are the pros and cons to consider when deciding which type of application to file?
- How does a small business expedite approval of an application?
- When is expanded access used in the approval process?

The panel also focused on the types of pre- and post-approval economic assistance and incentives available to small pharmaceutical businesses including:

- Patent extension.
- New drug product exclusivity.
- Orphan drug exclusivity and tax credits.
- Pediatric exclusivity.
- The Small Business Innovative Research Program.
- Solicited and unsolicited grants.

The program for Nov. 9, determined by polling the participants at the end of the Oct. 25 audioconference, discussed three hypothetical cases involving:

- An orphan drug application.
- A 505(b)(2) application involving a new dosage form of an existing drug.
- An application requiring expedited review.

Each case also included multiple choice questions. The participants were polled for the correct answer.

Time at the end of each audioconference was provided for questions from the participants. The responses indicated a significant need among the small pharmaceutical and biologic business community to learn about the various routes to FDA approval and the assistance and incentives available to them as they develop their products. There was interest in having a similar program in the future and possibly using the materials for the program in another arena.

Ron Wilson is director of CDER's Small Business Assistance Staff.

FDA, Industry, Academia Find Success in Tackling Regulatory Issues

(Continued from page 1)

- Drug substance impurity testing.
- Drug substance particle size analysis.
- Topical and aerosol forms.

"Based upon our first experience with the Blend Uniformity Working Group, the PQRI process is working," said Tobias Massa, Ph.D., a representative from industry who is chair of the institute's steering committee.

"It shows that this process can indeed be successful in addressing regulatory issues. The key is that, for the first time, we have FDA, academia and regulated pharmaceutical manufacturers collectively working together."

The Blend Uniformity Working Group is expected to make recommendations to FDA in early 2001 on science-based changes to regulations for blend uniformity testing. These recommendations will ensure that there is thorough mixing of the drug within the blend and dosage unit.

PQRI will collaborate with the International Pharmaceutical Aerosol Consortium to address several issues associated with the chemistry, manufacturing and control requirements for oral and nasal inhalation products defined in draft FDA guidance. The specific issues to be studied are currently being identified.

PQRI is also considering an FDA request for help in addressing several issues associated with drug counterfeiting.

"FDA is extremely supportive of PQRI," said **Helen Winkle,** Acting Director, Office of Pharmaceutical Sciences, FDA.

"FDA sees PQRI as an excellent means for leveraging intellectual and laboratory resources and promoting regulatory research programs to enhance our science base."

Debbie Werfel works in media relations for AAPS.