news along the pike

JULY 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

CDER'S CORNERS

Ceremony Honors 39 Individuals, 28 Groups

Entire OGD Wins Hammer Award for Streamlining Efforts

BY JACKIE BARBER

Presentation of a Hammer Award to all 147 members of the Office of Generic Drugs highlighted the Center's Spring Honor Awards ceremony June 25 at the Gaithersburg Marriott Washingtonian Center. OGD Director **Doug Sporn** accepted the award presented by Lynn Kahn from the National Partnership for Reinventing Government. Included in the award were all OGD members, including those in the immediate office, the divisions and the document room.

The award recognized OGD's streamlining efforts of the last five years to cut review times for generic drug applications from more than three years to 18 months. The award cited OGD's reengineering of the generic drug review process that has resulted in high-quality, lower-cost generic drugs being brought to the marketplace sooner. The award citation noted that scientific and regulator review of generic drug applications assures that any generic drug approved meets current FDA standards of strength, quality and purity and will have the same therapeutic effect as the brand-name drug.

The national anthem was sung by Kevin Barber, mistress of ceremonies was **Ruth Clements,** and Center Director **Janet Woodcock, M.D.,** gave the opening remarks. In addition to the Hammer, these awards were presented:

FDA Commendable Service

Patricia L. Alcock

Janine M. D'Ambrogio

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Malinowski Begins Year in Japanese Government

BY MARY-JANE ATWATER

Since September, **Henry Malinowski, Ph.D.,** has had an empty desk in Woodmont II. That's because Malinowski, associate director for biopharmaceutics and a Mike Mansfield Fellow, has been spending the last 10 months attending Japanese language classes and learning about the history, culture and economics of Japan. This full-time, intensive training has been preparing him for the next 12 months when he will work inside the Japanese government and live in Japan.

Malinowski, who was named a Mansfield Fellow in June 1998, plans to spend the second year of the fellowship examining the drug-review process in Japan, the types of drugs approved for marketing in Japan, drug dispensing processes and recommended doses. He will work at Japan's Pharmaceutical and Medical Safety Bureau, National Institute of Health Sciences and Pharmaceuticals and Medical Devices Evaluation Center, all within the Ministry of Health and Welfare. He expects that his work will be conducted in Japanese.

By attending meetings and conferences in Japan, preparing reports and participating in policy discussions, Malinowski and the other five fellows in his group will have an unparalleled professional opportunity to learn how the government of Japan works and how policy decisions are made.

"This seems to be an excellent time to study the Japanese drug regulatory system," Malinowski said, "since major changes are currently being implemented, which involve very significant revisions in the Japanese drug review process. I think we can learn from the Japanese system, if we can get a clear picture of how it works. Long-term improved communication between MHW and FDA is a major goal of my fellowship."

Those interested in Malinowski's project can contact him through his CDER e-mail account (MALINOWSKI).

The Mansfield Fellowship Program—named after Mike Mansfield, former U.S. ambassador to Japan, Senate majority leader, sen-

(Continued on page 12)

JOE'S NOTEBOOK

Arguing with Perfection

We're all likely to underestimate our chances of "becoming a statistic" when the odds of something happening are long. We draw on our personal experience of what happened before to estimate what will happen in the future. If an event is rare and hasn't happened to us before under similar circumstances, we tend to think of all long odds as being equally long and equally unlikely to occur to us personally.

Having done a stint as a sports editor in my checkered past, I was intrigued by an example of this phenomenon that came to light two weeks ago. After pitching the 14th perfect game in the history of major league baseball on July 18, an understandably ecstatic David Cone, the New York Yankee pitcher, remarked about how improbable it all was. "You probably have a better chance of winning the lottery than this happening," Cone was quoted by the Associated Press.

The next day, the American Institute of Physics, while giving "all due respects" to Cone's great achievement, noted that it is actually much more likely for big league pitcher to throw a perfect game than for someone to win the New York Lotto.

The institute explained that there have been approximately 150,000 major league baseball games played since 1901, the advent of modern baseball. Two starting pitchers per game has provided approximately 300,000 perfect game opportunities to date. So the odds have been approximately 14 in 300,000, or about 1 in 20,000, of throwing one.

On the other hand, winning the New York Lotto—guessing six numbers out of a possible 51—has a probability of 1 in 18 million.

What's more, Cone's chances were a little better than average, if you take into account the facts that he has a low lifetime earned run average of 3.14 and he has a high number of career wins at 178. You can also factor in the fact that the Montreal Expos' on-base percentage is only .321, a figure that ranks with the lowest in the major leagues.

Statistics can't tell us who will throw the next perfect game, but it can forecast the likelihood of future baseball events. "One can use prior performance to estimate the chances that someone will perform a certain way under certain conditions," said Chip Denman, manager of the statistics laboratory at the University of Maryland and quoted by the institute.

On the other hand, in a lottery, numbers are chosen at random, and every holder of a single ticket has an equal and undistinguished chance of winning. Anyone can play Lotto and win it. Whereas getting the chance to pitch a perfect game requires talent, years of dedication and a major league contract.

Lotteries and sports bring out the differences between probability, statistics and luck. "Probability deals with quantifying uncertainty, and in certain cases like a game of Lotto we can calculate precisely the chances of winning," Denman said. "In open-ended systems, like sports, all we can do is draw upon statistics to make our best estimates of future performance. We draw upon what happens so far to estimate what will happen. Luck—good or bad—is nothing more than taking probability personally."

Is your search engine letting your down? Scientists are increasingly using the Internet to locate research and forsaking libraries. Scientific editors locate reviewers on-line. Noting this, Steve Lawrence and C. Lee Giles examined how well popular search engines work. In the July 8 *Nature*, they report that search engines do not index sites equally, may not index new pages for months and no engine indexes more than about 16 percent of the Web. Moreover, the engines are biased to the more popular commercial sites in the United States and their search techniques are increasing the bias.

news along the pike

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

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OMBUDSMAN'S CORNER

Objectivity

BY JIM MORRISON

Objectivity is one of the most important words in drug regulation. CDER's primary role in society is as an objective scientific arbiter of whether a new drug should be introduced onto the market or whether a marketed drug should stay there.

Yet as important a principle as objectivity is, it is also a very elusive quality. We all have biases that affect our thinking and judgment. No matter how extensive our scientific training, we all have within us a system of values and our own a view of the world which were not scientifically derived. Added to these factors, each new endeavor contributes opportunities for additional biases.

In the drug development process, we know that certain biases exist, depending on one's role. Biases come from investment. It may be a monetary investment, such as a pharmaceutical company that has spent millions of dollars on a new product. Or it may be an emotional investment, such as a scientist who stakes his or her credibility on being right about a particular outcome.

Each stakeholder in the drug development and regulatory processes has a bias. Patients with serious diseases want to believe that a new drug will save them from agony, and they vent their frustration at anyone who seems to be standing between them and the drug. Investigators studying a new drug have a bias, since if the drug is successful, they will attain stature, publications and more funding. The news media has a bias toward whichever side of an issue will make better headlines. And consumer groups have a bias toward whatever stance will show that they are protecting the public.

Into this maelstrom of biases are thrown the data and CDER. The data are supposed to be neutral, but they certainly do not, as is so often said, speak for themselves. If data were that talkative, we would not need statisticians. Is CDER as objective and neutral as the public expects? Alas, even regulatory agencies have biases.

It is vitally important for those of us in CDER to recognize potential sources of bias. For example, there is a danger that reviewers who work closely with sponsors from the early IND stage may start to take a proprietary interest in the drug. This is especially true if the reviewer has suggested an approach to the design of the study. The reviewer then has an intellectual investment in the success of the study. It is a rare individual who can contribute to the creation of something and then step back and take an objective view of the product.

On the other hand, if a sponsor spurns a reviewer's advice and conducts the study using an alternative design, the reviewer could have a bias against the data. This is why applicants sometimes follow CDER's advice even when they don't think it is optimal. Even identifying too closely with patients of the disease being treated by the drug may lead to a reviewer's adopting some of the patients' biases.

Post-marketing evaluation can also be subject to biases. For example, if a petition to remove a drug from the market is couched in language critical of the Agency, it is natural to respond defensively. Natural, but not objective. The public deserves better.

How can you tell if you are losing objectivity? Here are some examples I've witnessed:

- If you get emotional about a drug, either in favor of or opposed to its marketing, ask yourself: "Why am I invested in the fate of this product?"
- If you feel your blood pressure rise when you think about a drug or company, you have lost your objectivity. Even prosecuting criminal behavior should be done dispassionately.
- If you believe that all drug companies are evil and are always trying to slip one by the FDA, or if you believe that all drug companies are motivated only by humanitarianism, you have lost your objectivity. In fact, if you find yourself applying a predetermined stereotype to anyone or any group, you are biased.
- If you find yourself reanalyzing a firm's data in ways the applicant would never be permitted to do in order to prove your point, you have lost your objectivity.
- If you believe your job is to protect the consumer from any possible harm, you have lost the objectivity required to make sound risk-benefit decisions.

Trying to recognize and eliminate your biases is hard work. But we must all keep in mind that our value to CDER and to the public is directly related to our objectivity.

Jim Morrison is CDER's Ombudsman.

Consumer Information Index

An updated *Catalog of FDA Information for Consumers: Publications and Audiovisuals* is now available on the FDA's Internet site at http://www.fda.gov/opacom/catalog/decemcat.html.

The catalog lists all the Agency's currently available information materials by subject and by title and includes *FDA Consumer* reprints, backgrounders, brochures, videotapes, slide shows and exhibits. Information on how to order the materials is also included.

Roberta Boyarsky Mourned by OPS

The Office of Pharmaceutical Science announced the passing of **Roberta Boyarsky.** Boyarsky never recovered form cancer surgery on June 23 and remained in intensive care until her death on July 23. Boyarsky worked at FDA for 21 years, most recently as an administrative aide in the Quality Implementation Staff in the Office of Pharmaceutical Science. She previously held similar positions in CDER's Office of Drug Evaluation I, the Division of Human Resource Management and the Division of Personnel Management.

She will be greatly missed by her four children, five grandchildren, family in Tennessee, friends and co-workers.

Web-based Software Planned for Electronic Document Retrieval

These updates from the Office of Information Technology describe major activities, currently underway or planned. More detailed and updated information about many of these activities is available through the CDERnet's OIT site at http://oitweb/oit/. Comments or questions about any of these projects can be sent through e-mail to the OIT point of contact for each project.

RetrievalWare to Replace EFS

Since 1993 several CDER components have been using Excalibur's Electronic File System, or EFS, to search and display documents that have been scanned and stored electronically. These include adverse event reports, Drug Master File reviews, Biopharm Division Files and approved package inserts. Earlier this year OIT began a project to pilot a replacement for EFS since this software has reached the end of its life cycle.

RetrievalWare is the new, improved, upgraded and enhanced Web-based software for the search and retrieval of electronic documents and data. OIT has evaluated RetrievalWare and other products currently in use in CDER to determine the most effective replacement and most efficient migration path for CDER's EFS file rooms. The pilot determined that RetrievalWare will effectively replace EFS as well as provide a future search engine for many of the Center's electronic documents and data. Full EFS replacement is planned for the end of 1999.

Stay tuned for upcoming announcements regarding RetrievalWare user workshops and training as the date for EFS to RetrievalWare conversion nears. The OIT point of contact is **Linda Sigg** (SIGGL).

Year 2000 Activities

CDER's Y2K activities remain a top priority. The primary areas for August are desktop compliance and testing the business continuity and contingency plan.

The Desktop Team is working to ensure that all desktop computers and software are Y2K compliant. Completion of this phase of the Y2K desktop project is planned for September.

To correct the hardware problem, OIT has identified all non-Y2K compliant desktop PCs. On June 28, work began to upgrade or replace all office computers that cannot be made compliant. This is a separate initiative from the purchase of new PDUFA computers. Each computer in CDER is being visited by an OIT staff member or contractor to ensure Y2K compliance. The computer will be upgraded or replaced and certified compliant. During this time, patches will be applied to CDER core software that is not compliant.

Patches will also be applied to CDER home loaner computers to make them provide the correct date in the year 2000. Because of the size of the Y2K patches, PCs will have to be brought back to the office for upgrading. You will be contacted by an OIT desktop support person and asked to bring in your computer.

Some CDER employees have personal PCs at home configured with CDER-supplied software packages such as MS Office 97, TeamLinks and SmarTerm. To assist those users with their Y2K software compliance issues, OIT will initiate a process to have those PCs brought back to the office for upgrading and testing. However, this effort won't begin until all office PCs and CDER loaner PCs have been upgraded. Please be aware that only CDER supplied software packages on those PCs will be upgraded.

Users who have Y2K compliance issues with the operating system or the hardware in their personal PCs should contact the original PC manufacturer for instructions and assistance.

In order to address any Y2K concerns in the Center, a special year 2000 e-mail account has been established. Please e-mail any questions or comments you have to the account Y2K. Throughout this process we will strive to keep interruptions to your computing services to a minimum. Schedules and more detailed information are located on the CDER Intranet under Y2K.

The purpose of the business continuity and contingency plan is to ensure that CDER's critical business processes can continue despite any failure in supporting IT systems. The plan will be tested in document rooms, review divisions and other components between July and September. The core processes included in the test are premarket review, postmarket surveillance, compliance monitoring, and financial management.

Day One planning is progressing. Day One is a term used to describe activities the OIT staff will undertake on the weekend of Jan. 1 to demonstrate that technical operation capabilities are functional. A high-level plan was submitted to the Agency on June 30. A detailed plan is now being developed. A dry run of Day One is scheduled for August.

Several Y2K policies have been developed. These include policies covering home PCs as well as computers and software on loan from companies. These policies are on the OIT's CDERnet site under Y2K. New policies will be posted as they are developed.

More information about CDER and FDA's Year 2000 activities can be found on the Internet at http://www.fda.gov/cder/y2k. The OIT point of contact is **Judy McIntyre** (MCINTYREJU).

Draft General Records Schedule for IT

Q: Where do you look to find out how long you should retain documents?
A: A records schedule.

Records schedules are issued by the National Archives and Records Administration to provide mandatory instructions for what to do with those records no longer needed to conduct current government business. A records schedule categorizes records into series based upon their function and use and gives instruction for how long they should be kept before being discarded.

There are two types of records schedules. An agency records schedule covers those unique records that document the specific programs and functions performed by the agency as part of its mission. In the case of FDA and CDER, that entails the drug application and review process. No other branch of the federal government performs this function. The INDs, NDAs and DMFs that CDER re-

(Continued on page 5)

Y2K Efforts Focus on Making Center's Desktops Compliant

(Continued from page 4)

ceives and reviews are considered to be "program" records because they document various aspects of the process. The Center uses the FDA Records Control Schedule, also known as "the pink book," a document that was drafted by FDA and approved by National Archives and Records Administration. That document includes the records series descriptions, their retention periods and the authority for their ultimate disposition.

Q: What if my office deals with contracts, the motor pool or some other function not directly related to drug approval?

A: In this case you would use a general records schedule.

A general records schedule covers the disposition of routine administrative or "housekeeping" records common to all agencies. A total of 23 schedules exist, each covering a specific category of administrative records. The Archives drafts them with input from specialists within the agencies who handle such records.

Recently, the Archives developed a draft general records schedule covering IT-related records. This draft was circulated within OIT, and our comments were sent to the FDA's records officer for incorporation into the Agency's response. Once revisions are made, the schedule will be issued and the retention periods made mandatory.

Retention periods, whether for "program" or "housekeeping" are not arrived at arbitrarily. They require the input of those who know and daily handle the records and who understand their value.

Like many things, records management is an increasingly collaborative effort between those who create, use and store information (see page 11).

The OIT point of contact is **Scott Zeiss** (ZEISSS).

Project Management

OIT senior staff reviewed the plan for the six-month trial of project management coordination. Comments were incorporated and the final plan posted on the CDER Intranet (http://oitweb/oit/) under PM Coordination.

Project management coordination is intended to improve senior management insight into projects, increase project accountability, facilitate project progress and ensure projects remain aligned with Center and OIT priorities. Specific success criteria for each of these goals are defined in the trial-period plan.

The six-month trial period will define new processes, such as: writing and approving project descriptions; prioritizing OIT projects; assigning project managers; and approving detailed project plans.

An OIT project coordination library will be developed with OIT senior management-approved project plans, summary reports of the status of each project and a database of OIT senior management actions related to projects. Evaluation results will be documented at the end of the six-month trial period. The OIT point of contact is **Vali Tschirgi** (TSCHIRGIV)

QA Development Project

The writing phase of the OIT improvement project continues. Development of draft guidance documents has progressed in the improvement target areas: project management coordination; project planning; project tracking and oversight; configuration management; and quality assurance. Peer reviews for 15 guidance documents are scheduled for July and August.

The planned review process has been revised to include a separate peer review meeting for each document, with combined senior staff and practitioner participation. Review of two training documents is planned for September. Information on the QA Development Project is available on the CDERnet under OIT Activities. The OIT Point of Contact is **Jerry Yokoyama** (YOKOYAMAJ).

August IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
2	**3**	**4**	**5**	**6**
9 **Word Intro** 1-4	**10** **Word Formatting** 9-12 **Word Tables** 1-4	**11** **NEST** 9-12 **File Management & Desktop Tools** 1-4	**12** **Access & Tables** 9-12 **Access Queries & Reports** 1-4	**13** **Access Form Design** 9-12 **Access Report Design** 1-4
16	**17**	**18**	**19**	**20**
23 **DFS** 9-12 **CDER Network & Web** 1-4	**24** **PPT Intro.** 9-12 **PPT Charts** 1-4	**25** **NEDAT** 9-12 **Creating Documents that meet FDA Archiving Standards** 1-4	**26** **MS Project** 9-12 **Creating Documents that meet FDA Archiving Standards** 1-4	**27** **Excel** 9-12
30	**31**			

The catalog, training materials, schedule and online registration are on OIT's intranet site.

Communications Corner: Can You Start a Memo Right?

Pick the best of these opening statements:

1. Jane and I recommend that we cancel the contract.

2. John and I met yesterday to discuss the contract.

3. Jane and I recommend that we cancel the contract for these reasons:

4. I've been asked to reply to your request for more information about the contract.

5. You'll be glad to know that we finally got the results on the contract.

Suggested answer: Your memos will rivet readers if the first line includes at least one of the "three R's":

- *Recommends* an action or choice.
- *Requests* that someone act.
- *Reveals* information.

Both 1 and 3 recommend, but 3 is better because it includes reasons and urges people to keep reading. The others are too vague and nonspecific.

Source: Communications Briefings, 7/99.

Spring Honor Awards Ceremony Recognizes Groups, Individuals

(Continued from page 1)

Elaine C. Frost

Gary M. Gensinger

Linda L. Gosey

Non-Traditional Drug Compliance Team: **A. Joel Aronson, Edward Miracco, Roma Egli** and **Vesna Stanoyevitch.** *PHS Unit Commendation:* **LCDR Jan Davis** and **LT William A. Russell, Jr.**

Stargazer Team: **Keith Ariola, Jennifer Gianan** and **Stacey Nichols**

Nolvadex Review Team: **Julie Beitz, M.D., Amy Chapman, Gang Chen, Ph.D., Gary M. Gensinger, Donna Griebel, M.D., Susan Honig, M.D., Tony Koutsoukos, Ph.D., Alison Martin, M.D.** and **Gurston Turner, Ph.D.**

Pediatric Exclusivity Training Working Group: **Jonca Bull, M.D., Maria DeCarvalho, Elaine Frost, Charlotte Henning, Khyati Roberts, R.Ph., Rosemary Roberts, M.D., Barbara Townsend** and **Leslie Wheelock.** *PHS Unit Commendation:* **CAPT Thomas Hassall.**

Rifapentine Review Team: **Funmilayo O. Ajayi, Ph.D., Brenda Atkins, Marc W. Cavaillé-Coll, M.D., Ph.D., Paul Flyer, Ph.D., Mark Goldberger, M.D., M.P.H., Linda L. Gosey, Thomas Hammerstrom, Ph.D., Ken Hastings, Dr.Ph., Joyce Korvick, M.D., Kofi A. Kumi, Ph.D., Sheryl Lard-Whiteford, Ph.D., Marianne Mann, M.D., Owen McMaster, Ph.D., Norman R. Schmuff, Ph.D.,** and **John L. Smith, Ph.D.** *PHS Unit Commendation:* **LT Lisa Hubbard.**

Course Developers and Instructors of the Regulatory Review of Investigational New Drug Applications Course: **Bronwyn E. Collier, B.S.N., Stephen P. Hayleck, M.Ed., Deborah L. Kallgren** and **Corinne P. Moody.** *PHS Unit Commendation:* **CAPT Robbin M. Nighswander** and **CAPT Cathie L. Schumaker.**

FDA Outstanding Achievement

Paul Andrews, Ph.D.

Richard J. Charleston

Patricia Hennighan

Frances V. LeSane

Dannette M. Locklear

Andrew Langowski

Cecelia M. Parise

Nakissa Sadrieh, Ph.D.

Chandras Sahajalla, Ph.D.

Pat Sporn

FDA Group Recognition Award

Epivir (Hepatitis B) Review Team: **James G. Farrelly, Ph.D., Paul Flyer, Ph.D., Antoine El-Hage, Ph.D., Stanka Kukich, M.D., Jay Levine, George Lunn, Ph.D., Stephen Miller, Ph.D., Prabhu Rajagopalan, Ph.D., Kellie Schoolar Reynolds, Pharm.D., Guoxing Soon, Ph.D., Barbara Styrt, M.D., M.P.H.,** and **Pritam Verma, Ph.D.** *PHS Unit Commendation:* **CDR Lauren Iacono-Connors, LCDR Terrie Crescenzi** and **LCDR Anthony Zeccola.**

Committee for Advanced Scientific Education: **Sousan Altaie, Ph.D., Nilambar Biswal, Ph.D., Debra Bowen, M.D., Sonia Castillo, Ph.D., Marc Cavaillé-Coll, M.D., Aloka Chakravarty, Ph.D., Peter Honig, M.D., Shiew-Mei Huang, Ph.D., Robin Huff, Ph.D., Mohammed Huque, M.D., Ravindra Kasliwal, Ph.D., Meyer Katzper, Ph.D., Ken Kobayashi, M.D., Joyce Korvick, M.D., Richard Lostritto, Ph.D., Pramoda Maturu, Ph.D., Thomas Permutt, Ph.D., Nakissa Sadrieh, Ph.D., Milagros Salazar-Driver, Ph.D., Genevieve A. Schechter, M.D., John E. Simmons, Ph.D., John Senior, M.D., Sidney Stolzenberg, Ph.D., William Timmer, Ph.D., C.T. Viswanathan, Ph.D., Andrea Weir, Ph.D.,** and **Alexandra Worobec, M.D.** *PHS Unit Commendation:* **CAPT William A. Hess, CAPT James E. Knoben** and **CAPT Frank D. Sistare.**

New Molecular Entity Web Page Team: **Gail Y. Chotoff, Brenda Kiliany, Pharm.D., Mary Kremzner, Pharm.D., Nancy M. Ostrove, Ph.D., Barry W. Poole, Ellen Shapiro, Paul K. Stauffer, Ellen R. Tabak, Pamela G. Winbourne** and **William B. Woodard, Jr.** *PHS Unit Commendation:* **CDR Paul Judd Andreason, CDR Gregory Dubitsky** and **LCDR James S. Williams, III.**

CDER Special Recognition

Donna Griebel, M.D.

Sam H. Haidar, Ph.D.

Ravindra K. Kasliwal, Ph.D.

Sue-Chih Lee, Ph.D.

Iftekhar Mahmood, Ph.D.

Edward S. Nevius, Ph.D.

Hasmukh B. Patel, Ph.D.

Moo Jhong Rhee, Ph.D.

Alfredo Sancho, Ph.D.

Nhan Tran, Ph.D.

Nicotine Product Group: **Debra Bowen, M.D., Cynthia McCormick, M.D.,** and **Sakineh Walther, R.N.**

Celebrex and Arava Review Teams: **Mordechai Averbuch, M.D., Vispi Bhavnagri, Ph.D., Sandra Cook, Ping Gao, Ph.D., Larry Goldkind, M.D., John Hyde, M.D., Ph.D., Kent Johnson, M.D., Sue Lee, Ph.D., Laura Hong Lu, Ph.D., Victoria Lutwak, Asoke Mukherjee, Ph.D., Lillian Patrician, Lilia Talarico, M.D., Veneeta Tandon, M.D., Douglas Throckmorton, M.D., Steve Thompson, Ph.D., Maria Lourdes Villalba, M.D., James Witter, M.D., Ph.D.,** and **Josie Yang, Ph.D.**

Center Director's Special Citation

MPCC/CPS Section Drug Interaction Working Group: **Funmilayo O. Ajayi, Ph.D., Raman Baweja, Ph.D., Jerry Collins, Ph.D., Sayed Al-Habet, Ph.D., Karen Higgins, Ph.D., Peter Honig, M.D., Shiew-Mei Huang, Ph.D., Lawrence J. Lesko, Ph.D., Patrick Marroum, Ph.D., Atiqur Rahman, Ph.D., Robert Temple, M.D., Roger Williams, M.D., Ruihua Yuan, Ph.D.** *PHS Unit Commendation:* **CAPT David Martin Green** and **CAPT Paul Hepp.**

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OGD Wins Vice President's Hammer Award for Streamlining Efforts

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CDER Administrative/Program Management Excellence Award

Susan Peters

CDER Excellence in Communication Award

Mike J. Fossler, Pharm.D., Ph.D.

Charles P. Hoiberg, Ph.D.

CAPT Yana R. Mille

CDER Information Technology Excellence Award

DPDCS IT Support Team: **CAPT Joan C. Ginetis, Howard S. Spungen** and **Naiqu Ya, Ph.D.**

DFS Keyword Working Group: **Gary K. Chikami, M.D., Elizabeth Duvall-Miller** and **Brad Leissa, M.D.**

CDER Leadership Excellence Award

Walla L. Dempsey, Ph.D.

Kenneth J. Furnkranz, Ph.D.

Nancy B. Sager

CDER Excellence in Mentoring Award

CAPT George Armstrong

Rubynell Jordan, R.N., M.P.A.

Toni Piazza-Hepp, Pharm.D.

Karen M. Templeton-Somers, Ph.D.

Bioequivalence Training Group: **Lin Whei Chuang, M.S., Barbara Davit, Ph.D., Kuldeep Dhariwal, Ph.D., Andre Jackson, Ph.D., Jahnavi Kharidia, Ph.D., R.Ph., Shriniwas Nerurkar, Ph.D., Richard Sponaugle, M.S., Nhan Tran, Ph.D.,** and **Ruth Warzala**

CDER Project Management Excellence Award

Kyong Cho, Pharm.D.

Division of Anti-Viral Drug Products Project Management Team: **Susan Cobb, LCDR Terrie Crescenzi, CAPT Tony DeCicco, Christine Kelly, R.N., M.S., M.B.A., LCDR Sylvia Lynche** and **Melissa Truffa, R.Ph.**

CDER Support Staff Excellence

Myrna-Yvette King

Joean James

CDER Team Excellence Award

Consultation Team: **Charles Cortinovis, M.D., Albinus D'Sa, Ph.D., Indira Kumar, Cynthia McCormick, M.D., David Morgan, Bob Rappaport, M.D.,** and **Michael Theodorakis, Ph.D.**

OGD Methods Validation Policy Team: **Florence S. Fang** and **Michael Smela**

Multiple Dose Bioequivalence Case Study Group: **Dale Conner, Pharm.D., CAPT Gordon Johnston, Shriniwas G. Nerurkar, Ph.D., Cecelia Parise, Rabrindra Patnaik, Ph.D., Pradeep Sathe, Ph.D.,** and **Thomas Tozer, Ph.D.**

CDER Technical Packaging Committee: **William M. Adams, Christopher S. Coughlin, Ph.D., Sonia Crisp, John J. Gibbs, Ph.D., Frank O. Holcombe, Jr., Ph.D., Ada Irizarry, Mary Ann Jarski, Robbe C. Lyon, Ph.D., Donald N. Klein, Ph.D., Sheldon B. Markofsky, Ph.D., Melissa J. Maust, Edwin Melendez Diaz, CAPT Yana R. Mille, Charles B. Parisek, Ph.D., Rashmikant M. Patel, Ph.D., Brian L. Pendleton, J.D., Radhika Rajagopalan, Ph.D., Vilayat Sayeed, Ph.D., CAPT Alan C. Schroeder, John L. Smith, Ph.D.,** and **CDR James W. Wilson, III.**

Chemistry DMF MAPP Development Team: **Robert P. Barron, Mujahid L. Shaikh, Ph.D., Arthur B. Shaw, Ph.D.,** and **Charlotte A. Yaciw, Ph.D.**

Special Products On-line Tracking System Working Group: **William K. Berlin, Ph.D., Melissa Chapman, Yuan-Yuan Chiu, Ph.D., Rose E. Cunningham, Florence S. Fang, CAPT William A. Hess, Sonya M. Hughes, Paul M. Loeback, Helen L. Mitchell, Theresa J. Monaco, Sally A. Newman, Mary C. Norris, Dorothy E. O'Brien, CAPT Thomas G. Phillips, Valerie L. Whipp, Rebecca H. Wood, Ph.D.,** and **Dianne V. Woods**

Psychological Drugs Chemistry Review Team: **Doris J. Bates, Ph.D., Wilson L. Brannon, Donald N. Klein, Ph.D., Richard T. Lostritto, Ph.D., Lorenzo Rocca, Ph.D.,** and **Robert H. Seevers, Ph.D.**

Taxol Chemistry Review Team: **Robert Barron , Li-San Hsieh, Ph.D., Yung Ao Hsieh, Ph.D., Josephine M. Jee, Sung K. Kim, Ph.D.,** and **Rebecca H. Wood, Ph.D.**

CDER Off-Label Information Dissemination Work Group: **Minnie V. Baylor-Henry, R.Ph., J.D., CDR Laurie Burke, Robert J. DeLap, M.D., Molly L. Fischer, M.P.H., Gary M. Gensinger, Joseph P. Griffin, John K. Jenkins, M.D., Heidi M. Jolson, M.D., Randy Levin, M.D., CAPT Yana R. Mille, Howard P. Muller, Jr., CDR David G. Orloff, Robert Temple, M.D.,** and **Janet Woodcock, M.D.**

DPDP Pediatric Exclusivity Work Group: **Girish Aras, Tien-Mein Chen, Badrul Chowdhury, Shan Chu, LT James L. Cobbs, James Gebert, David Hilfiker, Martin Himmel, John K. Jerkins, M.D., Miriam Pina, M.D., CAPT Cathie Schumaker, Anne Trontell, Ramana Uppoor, Ph.D.,** and **CAPT Stephen E. Wilson.**

Sustiva Review Team: **Dan Boring, Ph.D., R.Ph., Mike Elashoff, Ph.D., James G. Farrelly, Ph.D., Paul Flyer, Ph.D., Stanka Kukich, M.D., Stephen Miller, Ph.D., Kellie Schoolar Reynolds, Pharm.D., Vanitha Sekar, Ph.D., Kuei Meng Wu, Ph.D.** *PHS Unit Commendation:* **CDR Lauren Iacono-Connors, LCDR Terrie Crescenzi,** and **CAPT Harry Haverkos.**

Sunscreen Monograph Team: **Steven Aurecchia, M.D., Michael Benson, Constance Bulawka, Debra Bowen, M.D., Gloria Chang, Donald Dobbs, Katharine Freeman, Abigail Jacobs, Ph.D., Linda M. Katz, M.D., M.P.H., Michael Kennedy, Ramzy Labib, M.D., John Lipnicki, Debbie Lumpkins, Valerie Miguele, Cazemiro Martin, Gerald M. Rachanow, J.D., Nahid Mokhtari-Rejali, Albert Rothschild, Jonathan Wilkin, M.D.,** and **Mildred Wright, R.N.**

Jackie Barber is the Center's incentive awards officer.

REVIEWER AFFAIRS CORNER

Task Force to Examine Impact of New, Changed Guidances, Regs

LYDIA VELAZQUEZ KIEFFER AND KATE MEAKER

The Reviewer Affairs Committee formed a new task force to examine how reviewers are adapting to the myriad of new regulations and guidances that have stemmed from the 1997 FDA Modernization Act and the reauthorization of the Prescription Drug User Fee Act. The Guidance Issuance/Regulatory Changes Impact Task Force held is first meeting on June 22.

The task force defined its goals as providing feedback on the following questions:

What is the current status of training, communication and awareness among reviewers regarding new guidances and regulatory changes?

- The task force's initial discussions indicate that there is a wide variation across divisions and disciplines in terms of how this is done.
- There is confusion about finding the latest versions. Not all were aware of the CDER Internet site for guidances and MAPPs.
- Having too many drafts increases confusion, because it's hard to keep track of what is the most recent change.

How can training, communication and awareness be improved?

- This issue was discussed at the July RAC meeting. The committee recommended the task force contact OTCOM to see what role they are playing.
- The task force will include a request for ideas on ways to improve communication and awareness in an upcoming CDERwide survey of reviewers.

How have recent changes impacted reviewers?

- This question encompasses work load, work life and quality of work performed.
- The biggest impact seems to be deadlines and time constraints, which could impact the quality of the work.
- Guidance documents impact the advice given to sponsors and the judgements made in reviews. The key is trying to stay "on top of" the latest versions.

A recurring issue the task force will examine is whether the originators of a guidance are informed if problems arise after implementation.

Unfortunately, no medical officers or project managers were present at the first task force meeting. The task force's next step will be to explore ways to get input from a wider group of reviewers. The task force feels that it needs broader feedback on the issues and concerns before proceeding.

The current task force resulted from the merger of two other task forces: the Impact of Regulatory Changes Task Force and the Guidance Process Improvement Task Force. The RAC agreed at its April meeting to combine the two task forces because the information for both will likely be collected from the Centerwide survey of reviewers.

The organization of the original task forces was initiated after the RAC held its quarterly meeting with the Senior Management Team in August of last year. At that time, Center Director **Janet Woodcock, M.D.,** said she was very interested in learning how reviewers were functioning with all the changes that have taken place over the past several years. She noted that more than 100 guidances had been published recently and she had been hearing from reviewers that they were unhappy with the dissemination process.

If you have any concerns or would like certain issues addressed, please contact **Kate Meaker,** chair of the Guidance Issuance/Regulatory Changes Impact Task Force by e-mail or phone (MEAKERK, 7-4257).

Lydia Velazquez Kieffer, Ph.D., is RAC chair and a clinical pharmacology and biopharmaceutics reviewer in DPE I. Kate Meaker, Ph.D., is chair of the task force and a biometrics reviewer in DB II.

TRAINING AND DEVELOPMENT CORNER

CDER Training Catalog, Course Schedule Due in September

BY IRIS KHALAF

This year, for the first time since 1996, an all-inclusive CDER Training Catalog is scheduled for distribution Centerwide by the first week in September. The catalog includes:

- A message from the center director
- Current and future training opportunities.
- The CDER-recommended core and discipline specific competencies and learning pathways.
- Certain FDA leadership and management programs.
- Satellite broadcasts.
- CDER training under development.

An explanation about the CDER core and discipline specific competencies and how to use the learning pathways is included.

The catalog is intended to provide a useful resource in planning current and future professional growth and development.

As stated in the center director's message: "The many courses, programs, and workshops listed help to ensure that people in CDER have the knowledge and skills necessary to do their jobs well."

In conjunction with the *CDER Training Catalog*, the fall 1999 CDER course schedule will be posted online at DTD's intranet site at http://CDERnet/DTD/index.htm.

The CDER course schedule is a virtual document that will provide detailed information about the courses that offered during the 1999 fall semester.

As soon it is posted online, during the first week of September, you may begin to register for the fall semester. Registration instructions are provided in the schedule.

We encourage you to carefully review both the catalog and the course schedule and use these resources in planning your training for the coming year.

If you have any questions, you may contact the Division of Training and Development at 7-4580.

Iris Khalaf is an education specialist in DTD.

EEO CORNER

High School/High Tech Program Benefits Students, Center

BY GLORIA MARQUEZ SUNDARESAN

For the second summer in a row, CDER's partnership with the United Cerebral Palsy Association has brought students with disabilities to work in our Center. This year, the offices and divisions paid $1,000 for each student hired. Also, the Prince George's Workforce Services Corp. presented an award on July 30 to the Center for participating in the program. **Roger Williams, M.D.,** Deputy Center Director (Pharmaceutical Science) was instrumental in encouraging OPS divisions to participate. As a result, OPS was able to hire three of this summer's four students. The students are:

- **Lillian Cavin,** Office of Pharmaceutical Science.
- **Tiffany Rogers**, EEO Staff.
- **Casey O'Rourke**, Office of Generic Drugs.
- **Samuel Mather,** Division of Applied Pharmacology.

Talking to the students' supervisors and mentors has revealed several shared concepts. These supervisors and administrative officers were willing to make the sacrifice of squeezing one more activity in their already tight schedules. They had the patience to help an individual and look at the future benefits both for the individual and the Center. Comments from some of the supervisors and mentors are:

- "Sam does a good job working with cells. As a matter of fact, he is very careful, and I let him do the part where he does a better job than I do. This gives me more time to do other things. These students may get experience that will have an impact on their future life."

  —**Adjordan Aszalos,** Division of Applied Pharmacology Research.
- "Although, I'm not in the laboratory often, I like to help Sam."

  —**Safaa Ibrahim,** OCPB.
- "We gave Lillian several tasks to find out what she does well. She works on the computer and prepares some tables for us. I'm happy with her performance."

  —Bill Myers, Office of Pharmaceutical Science.
- "We found out more about Lillian, what she is capable of and made sure that her assigned tasks would not frustrate her."

  —**Carol Hall,** Office of Pharmaceutical Science.
- "Casey is a big help to us. **Dr. Paul Schwartz** and I try to expose him to the different areas in what we do."

  —**Allen Rudman, Ph.D.,** Division of Drug Chemistry I.
- "It is an opportunity to show what we do here and maybe help the students consider an FDA career in the future. Not only do we teach them, but we also learn from them."

  —**Rashmikant Patel, Ph.D.,** Division of Drug Chemistry I.
- "Tiffany may have a disability, but she's OK. She can do anything."

  —**Diane M. Smith,** EEO Staff.

One of the future benefits that our Center can get from the HS/HT Program is to consider it as a part of the Center's long-range diversity strategic plan where we include qualified students with disabilities in the potential recruitment pool for our Center's workforce.

Gloria Marquez Sundaresan is a CDER EEO specialist

PIKE'S PUZZLER

Travel Daze

BY PAUL MOTISE

Across

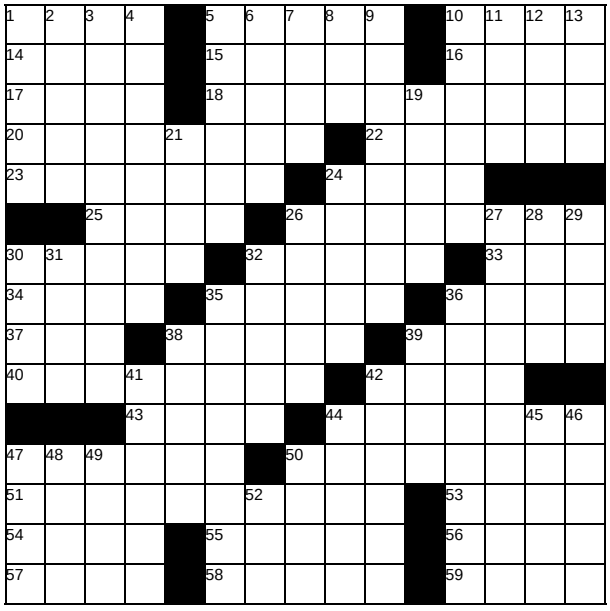
1 "___ In The USA"
5 Globe trotters pay it, for a change
10 Caspian feeder
14 Yes!
15 Hotel tab action, sometimes
16 Pleasant French resort
17 Traveler's need, often
18 Lapel or podium follower
20 Foamflower
22 Pontificates
23 Angered
24 Minor pest
25 Step ___! (Move!)
26 Lobby feature, usually
30 Soot particles
32 Hotel entertainment, sometimes
33 MD grp.
34 Pit sound
35 I-95 Inn
36 Vegas machine
37 Poem
38 Singer Bob
39 English novelist, Daniel
40 Petroleum conveyances
42 Blended, var.
43 Scores high
44 Dumbo's secret energizer
47 Hi Fi Successor
50 Spanish opera
51 CDER's standard image maker
53 Darn!
54 Arabian gulf
55 Product code, briefly
56 Middle Age guitar
57 Type
58 Ruhr city
59 Chemical suffix

Down

1 Photo finish
2 Greatly, arch.
3 Remove slides, perhaps
4 Competitors
5 Biceps band
6 Trade group
7 South American empire, once
8 Yours and mine
9 Table or tea follower
10 Doffs
11 Alice to Ralph, sometimes
12 50 down, formally
13 Wine sediment
19 Babble
21 Support
24 Assumption
26 Japanese clogs
27 Getting there
28 Melville novel
29 Chopped liver, in 16 across
30 Scram!
31 Skirt type
32 Parts
35 "Let ___ go!"
36 Beer quantity, formally
38 Kitchen utensil
39 Mexican president, 1877-80
41 Ma or Pa
42 London borough
44 One time Tidal Basin swimmer, Ms. Foxe
45 Wash out, chemically
46 Emits beams, ME
47 Resorts
48 Tourist's list
49 Pitcher
50 12 down, informally
52 Failing condition, briefly

Paul J. Motise is a consumer safety officer in the Division of Manufacturing and Product Quality.

Solution on page 10



Contract Preview

BY ROBERT YOUNG

The expected effective date of the contract is now early September. By law, only bargaining unit employees are covered by the contract. Members of the Commissioned Corps, supervisors and managers are not covered. They have no rights, benefits, duties or responsibilities under the contract. If you are a bargaining unit employee, you should read the contract carefully when you receive it. Here are a few contract provisions which may have major consequences for you on the effective date of the contract or which might profit from prior preparation:

- Transit subsidies. Public transportation subsidies for bargaining unit employees will be available up to $65 per month actual cost beginning Oct. 1. If the program is not implemented by then, subsidies will be retroactive to that date.
- Employee rights. When there will be more than one representative of the Agency at a bargaining unit employee counseling session, the employee may request a union representative to accompany him or her. Employer representatives include supervisors, managers and employee and labor relation specialists.
- Details. Bargaining unit employees detailed to a higher graded position for more than 30 days will be temporarily promoted. Merit promotion procedures will apply to details over 120 days.
- Travel. Meetings controlled by FDA will be scheduled so that bargaining unit employees are not required to travel during non-work time.
- Leave. If a supervisor rescinds previously approved annual leave, bargaining unit employees can be reimbursed for funds already advanced and not refundable, such as unrefundable airline tickets, cruise deposits or hotel deposits.

Employee Rights

The professional differences of opinion of bargaining unit employees will be protected under the contract.

- A bargaining unit employee who disagrees professionally with an action the Agency is taking and would ordinarily be asked to concur in the action, may decline to concur.
- A bargaining unit employee who has a professional difference of opinion can ask that the difference be documented in the administrative file and may ask for Agency review of the difference up to the commissioner.
- If a person outside the Agency has a professional difference of opinion and requests review of an FDA bargaining unit employees' decision, finding or recommendation, the FDA employee will be told where to find the outside request for review. At the bargaining unit employee's option, the employee may then proceed as above. Magic words are not required to request a review. Complaints, for example, either in writing or oral and reduced to writing will be treated as requests for review.
- There will be no reprisals against bargaining unit employees who exercise their rights in accordance with this article.

The above procedures are consistent with and mandated in large part by FDA regulations.

Peer Review

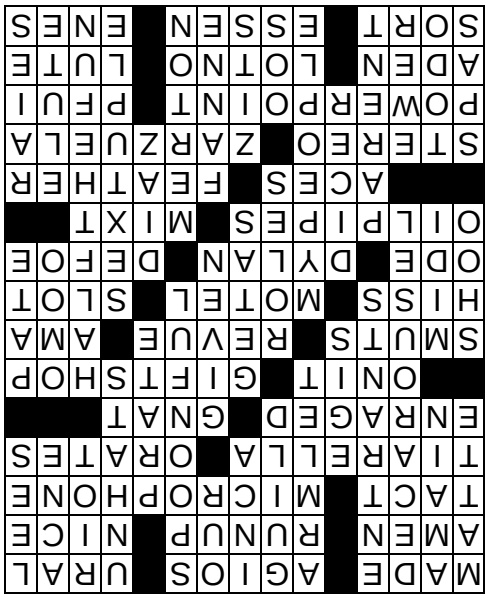
The Agency will administer peer review programs. The following procedures and rights are superimposed on all peer review programs:

- So long as a bargaining unit employee has the minimum qualifications necessary to be peer reviewed, he or she can self-nominate. Supervisory concurrence or approval will no longer be necessary.
- A bargaining unit employee may nominate up to three members for a peer review committee. Absent just cause, at least one nominee will be appointed to the committee so long as he or she is a qualified and appropriate peer.
- A bargaining unit employee must submit the documents required, but may submit additional material, within reason, for the committee to consider.
- A bargaining unit employee will be given an opportunity to appear before the committee to answer questions and make summary statements.
- A record will be kept of the proceedings, and it will show, among other things, how the bargaining unit employee's activities measured up to qualification standards and factors.
- Bargaining unit employees whose work is successfully peer reviewed will be promoted in a timely manner.

Committees

Bargaining unit employees will be needed to serve on the many labor-management committees that the contract creates. Most of the committees will be formed at the various levels of organization, from the FDA nationwide level down to appropriate local levels such as divisions, branches and teams. Among these committees will be partnership committees, award committees, parking committee, health and safety committees, alternative work schedule committees and flexible work place committees. Official time will be available for those bargaining unit employees serving on committees. Appointment to committees will be made by the chapter. Ordinarily, only chapter members will be appointed.

Robert Young, M.D., Ph.D., is president of the local chapter of NTEU.



New Federal Umbrella Group Formed for Records Management

By Scott E. Zeiss

The discipline of records and information management is a fragmented one. The records manager deals with what should be saved or destroyed. The information technologist handles the planning and implementation of computer hardware and software. The archivist attempts to preserve those documents deemed to be of permanent historical value. The historian sifts through a myriad of older documents, meeting notes, memoranda of conversations and other data to interpret their meaning. Each toils alone in his or her own vineyard.

Various support organizations have sprung up over the years to assist one specialty or another. Some are oriented towards the private sector, others deal in highly technical aspects. Sometimes they will jointly host a conference or meeting to exchange ideas or papers. But often in this world of rapidly changing ideas and technologies, information fails to get to those who need it. Best practices aren't quickly identified and shared. New ways of simplifying a task aren't learned. A good idea dies because nobody hears about it.

So it has been with federal records and information management—until now. Recently, members of such disparate organizations as the Electronic Records Management Work Group, the Small Agency Council Records Officers' Committee and the Association of Government Records Management Professionals joined together to create the Federal Information and Records Managers Council.

The council's purpose is to improve the efficiency and effectiveness of federal information and records management functions in all agencies by providing a forum for exchanging knowledge, resources and methodologies about the implementation and evaluation of systems and practices. The council will create partnerships with archivists, librarians, IT staffs, the information industry, professional associations and other information management professionals to better manage the life-cycle of federal information and protect the nation's documentary heritage. Additionally, the council will provide advice and assistance to the National Archives, Office of Management and Budget, Government Accounting Office and other agencies that oversee information and records management. Finally, the council will disseminate professional knowledge and techniques via educational seminars, workshops and the sharing of experiences related to the records profession.

Membership is free and open to all federal records managers and chief information officers, including their staffs, along with anyone who works with government information and federal records. This allows archivists, librarians, historians, Freedom of Information staff, information technology specialists, webmasters and other public access providers to participate and share the perspectives of their specialties.

Among the professional organizations assisting the council are the Association for Federal Information Resources Management, the Association for Imaging and Information Management, National Association of Government Archivists and Records Administrators, Organization of American Historians, Professional Records Information Services Management and the Society of American Archivists.

The council's inaugural meeting was held on June 15 at the National Archives. Representatives from many federal agencies and the professional organizations attended. The group unveiled and discussed many of the issues it would like to address and solicited volunteers and input for the workgroups they need to assemble. Among them are:

- The development of standards for the retention, retirement and archival preservation of all Federal electronic records, including Websites and databases.
- A new definition of what is a record.
- What all federal employees should know about records management
- Training standards for records management.

If you would like to know more or have any questions or comments regarding CDER's records management, please contact me by e-mail (ZEISSS).

Scott Zeiss is an information manager in OIT's Division of Data Management and Services.

FDA Approves Pioglitazone to Treat Type 2 Diabetes

FDA on July 16 approved pioglitazone (Actos), a new drug in the thiazolidinedione class of drugs to treat type 2 diabetes. Pioglitazone is approved as monotherapy for patients with type 2 or adult-onset diabetes who are not adequately controlled by diet and exercise alone.

Pioglitazone is also approved for use in combination with sulfonylureas, metformin or insulin in patients who are not adequately controlled on these agents alone. Patients taking this drug should also maintain appropriate weight and follow a careful diet.

The new drug improves a condition that seems to be an important underlying cause of type 2 diabetes: resistance of the body to insulin. In clinical trials involving more than 2,300 patients in the United States, pioglitazone was shown to improve patients' ability to use insulin.

In general, pioglitazone was well-tolerated in clinical studies. Adverse events commonly reported included headache, upper respiratory infections, and muscle pain.

Another drug of the thiazolidinedione class, troglitazone (Rezulin), has been associated with idiosyncratic hepatotoxicity, or liver failure. In clinical studies of patients treated with pioglitazone, by contrast, there was no evidence of drug-induced hepatotoxicity.

Nevertheless, because of the liver toxicity associated with troglitazone, FDA is recommending that liver enzymes should be checked at the start of pioglitazone therapy and every two months during the first year. After the first year, testing should continue periodically.

The drug will be manufactured by Takeda Pharmaceuticals America Inc., and marketed in the United States by Eli Lilly and Co.

Office of Commissioner Reorganization Adds Functions to CDER

The reorganization of the Office of the Commissioner announced last month resulted in reassignment of about 110 employees to the Centers and the Office of Regulatory Affairs.

The changes included moving some functions to CDER, including MedWatch, PDUFA waivers, patent term restorations, the scheduling of controlled substances and personnel operations that directly support the Center.

The Immediate Office of the Commissioner was reduced from 20 to about 10 employees. The ombudsman function was reassigned to the new Senior Associate Commissioner. Some of the science functions from the Office of Operations were added to the OC, including coordination of the Science Forum, support for the FDA Science Board and coordination of start-up science innovation projects.

Center directors and the associate commissioner for regulatory affairs now report directly to the commissioner, and the Office of Operations was abolished.

The Office of the Chief Counsel and the Administrative Law Judge was unchanged. The Office of Equal Opportunity is the new name for the Office of Equal Employment and Civil Rights.

The new Office of the Senior Associate Commissioner incorporates the public affairs function, the tobacco program, the orphan products program, the ombudsman and executive secretariat functions and the new advisory committee oversight function.

The Office of External Affairs and the subordinate Office of Health Affairs were abolished.

A new Office of International and Constituent Relations incorporates responsibilities for women's health issues, special health issues, most consumer affairs functions and international functions.

The Office of Policy was abolished. A new Office of Policy, Planning and Legislation incorporates regulation and policy functions; legislative affairs; both the planning, evaluation, and economic function and the management initiatives function formerly in the Office of Management and Systems.

The Office of Management and Systems will be streamlined by having some of its functions transferred. The office will retain its core finance, personnel, information technology, acquisitions and facilities functions.

More details can be found on the FDA Website at http://www.fda.gov/oc/reorg/june1999.html.

Malinowski to Use Japanese in Daily Work With Japan's Regulators

(Continued from page 1)

ator and congressman—enables federal government employees with a strong career interest in the issues of importance to the U.S.-Japan relationship to learn Japanese and gain a substantial personal knowledge about the government of Japan.

With proficiency in Japanese, a network of contacts in Japan in their professional fields and an understanding of how the Japanese government makes policy decisions, the fellows will serve as a resources for their U.S. agencies and strengthen their agencies' Japan-related policies and programs.

The fellowship program was established by Congress in 1994 and is administered by the Mansfield Center for Pacific Affairs (http://www.mcpa.org).

Mary-Jane Atwater is communications director for the Mansfield Center.

FDA Approves Zanamivir For Inhalation For Influenza Treatment

FDA on July 27 approved zanamivir for inhalation (Relenza), an inhaled anti-viral drug, for adults and adolescents aged 12 years and older for the treatment of uncomplicated influenza virus. This product is approved to treat type A and B influenza; though the principal trials enrolled over 1,000 patients with type A influenza, a much smaller number (approximately 120) had type B influenza. Zanamivir is the first approved drug for the treatment of influenza since the approval of rimantadine (Flumadine) in 1993.

Clinical studies determined that patients with influenza receiving zanamivir had shorter times to improvement in influenza symptoms. Part of the evidence for efficacy was provided by studies in the Southern Hemisphere and Europe. Efficacy treatment studies enrolled more than 1,500 patients with influenza-like illness, for example, fever, headache, muscle aches, cough and sore throat.

Effectiveness was demonstrated only in patients who started treatment within two days of symptoms. Zanamivir appears less effective in patients who do not have elevated temperature or severe symptoms.

Safety and effectiveness have not been established for the drug's use in preventing influenza.

This product has not been shown to be effective, and may carry risk, in patients with severe or decompensated asthma or chronic obstructive pulmonary disease. Bronchospasm was documented in some patients with mild or moderate asthma following administration of zanamivir. Any patient who develops bronchospasm should stop the drug and call their health care provider. Patients with underlying respiratory disease should be instructed to have a fast-acting inhaled bronchodilator available when they are being treated with zanamivir.

Zanamivir is taken twice daily for five days using a breath- activated plastic inhaler device called a Diskhaler. The device holds a Rotodisk, which is a blister package containing a powder mixture of zanamivir and lactose.

After a Rotadisk is loaded into the Diskhaler, a blister is pierced and the drug treatment is released into the air stream created when the patient inhales through the mouthpiece.

Before using this product, patients should be instructed by their health care provider in the proper use of the inhaler—including a demonstration whenever possible.

Zanamivir will be marketed by Glaxo Wellcome, headquartered in Research Triangle Park, N.C.