news along the pike

CENTER FOR DRUG EVALUATION AND RESEARCH

APRIL 1999

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INSIDE . . .

CDER'S CORNERS

Stakeholders Meetings Focus on Science Base

Risk-Benefit Communications Top Issue in Philadelphia

BY NORMAN OLIVER

PHILADELPHIA–Ways to strengthen the Center's science base and improve communications about the risks and benefits of drugs were the top issues for the second round of FDA and CDER stakeholders' meetings held April 28. Other topics discussed included direct-to-consumer advertising, over-the-counter drugs, drug safety reporting, inspections and compliance.

Temple University's School of Pharmacy played host to the Center's meeting. About 80 people, mostly from the pharmaceutical industry, signed up for the meeting ahead of time. Bolstered by pharmacy students, the audience swelled to more than 100 at its peak.

The pharmacy school's dean, Peter H. Duokas, welcomed the FDA representatives: Center Director **Janet Woodcock, M.D.;** Mid-Atlantic Regional Director **Susan Setterberg;** New Jersey District Director **Douglas Ellsworth;** OTCOM Director **Nancy Smith, Ph.D.;** and OTCOM Associate Director **Linda Brophy.** Doukas said that bringing the industry and federal government together to discuss common issues was a first for the university.

The university's president, Peter J. Lia-

(Continued on page 12)

ICH Common Technical Document Reported on Track

BY ROGER WILLIAMS, M.D.

At a meeting in Brussels March 8 to 11, the ICH steering committee reported "substantial progress" on the Common Technical Document. The panel decided on progress milestones for the three working groups engaged in reaching consensus on separate portions of the document. A fourth working group reported on its work to specify an electronic version of the document.

The common technical document will be an information package of technical data, in the same format and with the same content, that can be submitted to the regulatory bodies in the three ICH regions: Japan, the European Union and the United States. The document will be the main focus for ICH 5, the fifth biannual meeting of the conference to take place in November 2000 in San Diego.

In other ICH developments:

- A draft guidance to define formats for the E-2B guidance, *Data Elements for Transmission of Adverse Drug Reaction Reports,* was completed. The draft defines how data can be exchanged between databases in a format independent of the software and hardware used by either the sender or re-

(Continued on page 12)

Johnson, Papio Tapped as HHS Employees of Month

BY JACKIE BARBER

Shelley Johnson and **Lynda Papio** in the Office of Management received the February HHS Employee of the Month Award. Center Director, **Janet Woodcock, M.D.,** presented the award at a ceremony to open the CDER Forum held April 13. Both Shelley and Lynda are management analysts in the Program Management Services Branch, which provides services and support on recruitment and human resources program activities for the Center.

Shelley and Lynda were recognized for their joint efforts as coordinators to make Quality of Worklife programs an enormous success throughout the Center. QWL Week is an annual Center and Agency event to show appreciation for employee contributions and to provide opportunities to learn more about balancing work and family lives.

The Center's second QWL celebration was held last fall at the various CDER offices in the local area. Last year's theme focused on health

(Continued on page 12)

JOE'S NOTEBOOK

Shaping Up the Public Health

April is the time I start getting the yard and the body back in shape for the summer. The story on orlistat (page 3) reminded me to check my own body mass index. Numbers and I don't get along very well. They don't talk to me the way they do to a friend who works in federal government budgeting.

Finding your own BMI is quite challenging if you use a pocket calculator. It's nearly impossible with paper and pencil. Technically, you get your BMI by dividing your weight in kilograms by your height in meters squared ($BMI=m/kg^2$). Great if you live in France or work on the federal budget. There are formulas for using American weights and measures, but they're just awful to look at. People with BMIs between 19 and 22 live longest. Death rates are noticeably higher for people with indexes 25 and above.

Fortunately, you can find BMI calculators that do the math for you on the Internet. A BMI calculator, charts and health risks associated with high and low BMIs can be found on Shape Up America's Web site at http://www.shapeup.org. Shape Up America is the non-profit organization founded by former Surgeon General C. Everett Koop, M.D.

BMI is only one health measure. It's correlation to the percentage of body fat is about 0.7. There are plenty more health measures to pay attention to—like blood pressure. Drugs to control hypertension have had a major impact on that public health problem. So, I thought I'd share with you comments from **Claude Lenfant, M.D.,** Director of the National Heart Lung and Blood Institute on trends in hypertension control reported from the Framingham Heart Study in the April 22 *New England Journal of Medicine.*

"New information," Lenfant writes, "indicates that a five- to 10-fold increase in use of antihypertensive medication from the 1950s through the 1980s was accompanied by striking declines in the prevalence of the highest blood pressure levels (3 and 4) down to more moderate levels (1 and 2). High blood pressure at stage 3 is systolic blood pressure of 180 to 209 mm Hg or diastolic blood pressure of 110 to 119 mm Hg. Stage 4 high blood pressure is systolic blood pressure of at least 210 mm Hg or diastolic blood pressure of at least 120 mm Hg. The study further notes that the favorable trends in hypertension treatment and control were accompanied by a decline in hypertensive target organ damage in the form of left ventricular hypertrophy which is an important risk factor for both cardiovascular disease and fatal coronary heart disease."

About 50 million U.S. adults have hypertension. Left untreated, hypertension can damage the kidneys and lead to stroke, heart attack and heart failure. Heart disease and stroke are the first and third leading causes of death, respectively, in the U.S. Hypertension is defined as systolic blood pressure averages of 140 mm Hg or greater and/or diastolic blood pressure averages of 90 mm Hg or greater.

While the new Framingham data clearly illustrate the positive impact of effective hypertension drugs, the majority of heart attacks and strokes still occur at lower stages of hypertension. Moreover, recent data from the National Health and Nutrition Examination Survey reveal that a national downward trend in blood pressure control rates slowed in the 1990s and actually headed slightly higher. NHLBI also noted a slight rise in the rate of stroke, increases in both end-stage renal disease and heart failure, and a leveling in the death rate for people with coronary heart disease.

NIH's Framingham study is 50 years old and still yielding critical data on the prevention and treatment of heart disease stroke. However, the study represents a predominantly white population and the new study's findings may not apply to minority groups who are more likely to suffer the most severe forms of hypertension.

news along the pike

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

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

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

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OMBUDSMAN'S CORNER

Self-Empowerment is the Only Empowerment that Counts

BY JIM MORRISON

I must be getting old, because I'm starting to sound like Andy Rooney. Don't you hate it when someone lets on they're giving you a great gift when it was yours anyway? For example, income tax refunds. It was my money in the first place; I just lent it to the government for eight or nine months interest free!

Another case in point is one of the more inane buzzwords among the recent crop of management-fads-of-the-year: empowerment. Whenever I hear that word, I get the mental image of an elf going around the workplace sprinkling magic dust on everyone, saying, "You're empowered!" Well excuse me, but I am a human being, and I was therefore born empowered. I even have an authoritative book at home that says so. I don't need someone to tell me that management has empowered me to do the job they hired me to do in the first place.

As I understand it, empowerment is supposed to make it OK for me to ask my supervisor why I have been assigned the task of moving paper clips from pile A into pile B. If I question why that task needs to be done and my supervisor tells me to shut up and just do it, I'll assume that he or she just slept through the supervisory training course. I have always felt it was not only my right but also my duty to know why I am doing whatever I do. Not only that, but it is also my duty to suggest a better way to do it if I see one. In addition, I have always believed that it was a supervisor's duty to mentor me (note the clever use of a noun as a verb) so that I understand not just my job but the reasons for doing it in a specified way, how it relates to my colleagues' jobs and how it fits into the overall mission of the organization. I have had supervisors during my career who didn't see that as part of their jobs. However, I didn't let that stop me from learning what I needed to know.

At its best, empowerment also means that everyone takes a proprietary interest in the organization and its mission. In that way, it becomes my duty to see that the organization's customers or constituents get what they legitimately need without having to be referred through an endless chain of unhelpful people.

Now, empowerment taken to the extreme is chaos. While chaos theory is the latest in management fads, it doesn't mean that people actually want chaos in the workplace. However, if everyone feels so empowered that they just go off and do whatever job they think needs doing in the way they want to do it, everything gets very complicated really fast.

With empowerment (that is, being a human) comes responsibility. Just as it is my duty to learn the purpose of my job and to apply my knowledge, skills and creativity to doing my job in the best way I can, it is also my responsibility to inform all those who need to know about my activities. I should also give them time to evaluate what I do and my methods before I do it. In that way, they can save me from doing something really stupid because I failed to factor in an important element or two.

After all this, if you still need someone to empower you, just think of me as a really large elf and that white stuff on the paper (or monitor) as magic dust. Poof—you're empowered! What you do now is up to you.

Leadership Development Programs

Speaking of self-empowerment, whether you see your future in supervision and management or just want to kick your career up a notch, watch for announcements and Forums regarding the FDA Leadership Development Program, which will be opening for applications soon. There was a Forum in Parklawn April 8, another is planned for Corporate May 24. **Janice Newcomb** and I plan to discuss the CDER Leadership and the FDA Leadership Development Programs at the CDER Forum on May 11. CDER participants in these programs will be there to give their insights and to answer questions.

Jim Morrison is the Center Ombudsman.

Fat Blocking Drug Approved for Treating Obesity

On April 26, FDA approved orlistat, the first drug in a new class of non-systemically acting anti-obesity drugs known as lipase inhibitors. Unlike other obesity drugs, orlistat prevents enzymes in the gastrointestinal tract from breaking down dietary fats into smaller molecules that can be absorbed by the body. Absorption of fat is decreased by about 30 percent. Since undigested triglycerides are not absorbed, the reduced caloric intake may have a positive effect on weight control.

The effects of orlistat on weight loss, weight maintenance, weight regain and a number of obesity-related illnesses were assessed in seven long-term multicenter, clinical trials. These studies included about 2,800 patients treated with orlistat and 1,400 patients treated with placebo. A well-balanced, reduced-calorie diet was recommended for all patient in the weight-loss and weight-maintenance study periods. The diet was intended to decrease caloric intake by 20 percent and to provide 30 percent of calories from fat. In addition, all patients were offered nutritional counseling.

Of the patients who completed one year of treatment, 57 percent of the patients treated with orlistat and 31 percent of the placebo-treated patients lost at least 5 percent of baseline body weight.

Orlistat is indicated for obese patients with a body mass index of 30 or greater, or for patients with a BMI of 27 or greater who also have high blood pressure, high cholesterol or diabetes.

Because orlistat reduces the absorption of some fat-soluble vitamins and beta carotene, patients should take a supplement that contains fat soluble (A, D, E and K) vitamins and beta carotene. The most common side effects of orlistat are oily spotting, gas with discharge, fecal urgency, fatty or oily stools and frequent bowel movements. Orlistat is manufactured by Roche Laboratories Inc. under the trade name Xenical.

ADMINISTRATIVE MANAGEMENT CORNER

HUD Benchmarks CDER's Time Reporting System

BY RICHARD ALLEN AND PAM FAGELSON

CDER's time reporting system is developing a reputation outside the Center. In March, the Time Reporting Team hosted a Department of Housing and Urban Development delegation that came to hear about how we developed our system and how it works in practice. The HUD group is benchmarking several major time reporting systems in the public and private sectors before developing its own system. We were asked to share our experiences and resulting expertise. The delegation has also benchmarked Kodak and, at our suggestion, will contact CBER and CDRH.

The delegation, from HUD's Office of Financial Management, is planning to design and implement a departmentwide system for 9,300 people. Their main interest is unit costs, which is analogous to our interest in the cost to review an NDA. Like CDER, HUD is also interested in resource allocation and the costs associated with particular activities. The delegation found our system of having everyone report their hours directly into the database was particularly impressive. They were quite interested in the usefulness of our quarterly sampling since they hoped to avoid full-time reporting during their initial phases of development and implementation.

CDER's time reporting system is also moving into new territory with two review divisions in the Office of Review Management beginning a pilot project reporting on selected NDAs. The data from this reporting will become the basis for our estimates of how much it costs to review an application. This number has been the subject of much speculation for years both within and outside the Center. This represents a particularly complex use of the time reporting system, since every person who handles or reviews the pilot NDAs will record his or her time.

On related time reporting items, a contractor is developing a set of automated reports from the time reporting system. During April, the team tested both quality control reports and data analysis reports in preparation for automated data analysis by upper management. These reports will enhance CDER's ability to describe user-fee activities based on a variety of variables and to respond to inquiries from the Agency, Congress and other internal and external customers.

CDER's Strategic Planning Staff is using time reporting data to develop estimates of the Center's resource requirements. Objective time reporting data will give a good picture of the present situation, which is being used as the base point to plan for future resources.

Reviews don't happen in a vacuum, and every person in the Center has a contribution to make. Your continued cooperation and compliance with the time reporting resulted in a 99.3 percent compliance rate, which gives us credibility with Congress, the Agency and our other customers.

The Time Reporting Team members include **Richard Allen; John Emelio,** Branch Chief, Management Analysis Branch; **Pam Fagelson; Don Kim; Bob Linkous,** Director, Division of Planning, Evaluation, and Resource Management**;** and **Dan Luckabaugh**.

Richard Allen is team leader and Pam Fagelson is a management analyst with the Time Reporting Team.

OIT Responds to Macro Virus Attacks During Last Weekend in March

BY GREG BROLUND

Two "macro" viruses that exploit an application's programming features were unleashed at the end of March. The viruses affect Word 97 and Excel 97 files and propagate by infecting local systems and sending infected files through MS Exchange mail systems. Microsoft informed FDA of the virus attack late Friday night, March 26. The Agency then informed each center and coordinated preventive actions through the weekend and the following Monday. These actions included stopping all e-mail traffic from the Internet for part of the weekend.

In CDER, several OIT staff worked through the weekend to determine the possible impact of the macro viruses in CDER. Although CDER is not currently using the mail system that is the primary target of these viruses, the virus can infect individual systems. The virus can then be distributed to others if infected Word or Excel files are shared through e-mail, over the network or by floppy disks.

OIT obtained the latest virus detection files and distributed these files to as many desktop systems in CDER as possible before infected files could be opened. To accomplish this, the latest files were placed in an automated script that executes each time a user logs on to the network.

Unfortunately, due to the virus software's self-protection measures, the updated files could not be directly replaced on a running system. This required the development of a custom script that required each user to boot up the system twice to install the new files. Ordinarily this would occur on succeeding days; but, in this case, OIT contacted employees in each building to spread the word to reboot twice on Monday morning.

At the same time, all mail service was shut down from Sunday evening until about 12:30 p.m. Monday to help ensure that anyone receiving mail that might contain the virus would have the opportunity to have the new virus protection files loaded and avoid spreading the virus. OIT also scanned all available message log files on the CDER mail servers for messages with the suspected subject. Two messages to multiple addressees where found and deleted before they could be read. Thanks to the efforts of Agency and CDER staff, a major problem was averted.

This event reinforces the need to abide by the following virus safety practices:

- Keep macro virus protection turned on in all MS Office 97 products, including PowerPoint. In any Office 97 application toolbar, go to Tools|Options and click on the General tab and verify

(Continued on page 5)

Technical Writing Seminars for Support Staff, Non-Reviewers Added

Two new technical writing seminars have been added to the one taught for reviewers. The new seminars address the specific needs for professional staff employees who aren't reviewers and for support staff employees.

Technical Writing for Support Staff: The next seminar will be held May 5, 12 and 13 in Parklawn, Room 13B-39, from 8:30 to 11:30 a.m. The three, half-day seminars will prepare you to write internal CDER documents and help you to support other staff with their documents. This seminar teaches how to focus an audience with a purpose statement, organize thoughts and then line edit for clarity and economy. The seminar provides a refresher for word choice, grammar, punctuation and mechanics. This course is for support staff in grades GS-5 to GS-9.

Technical Writing for Non-Reviewers: This course is for professional employees in grades GS-9 to GS-15 who write reports, investigations, letters and internal memos. The two-day seminar teaches proven techniques to produce better documents in less time. You will improve your ability to analyze a document's purpose, organize information according to readers' needs and then edit for clarity, economy and readability. Check DTD's intranet site for the upcoming schedule.

Technical Writing for Reviewers: This three-day seminar for CDER reviewers will be held June 7, 8 and 10 in the Parklawn Building, Room 13B-39, from 8:30 a.m. to 3:30 p.m. The seminar shows you how to address multiple audiences, organize complex material, apply coherence devices and then edit for clarity, economy and readability. Participants analyze and critique actual CDER review documents for practice.

Preparing to Publish: This new six-hour seminar will be offered in September and will teach professionals how to write and publish scientific information in conference papers, professional journal articles and trade publication articles. You will improve your ability to decide what to publish and where; tailor writing to a target publication; produce a successful abstract, introduction, body and conclusion; submit the manuscript for publication and respond to reviewers' suggestions. This seminar does not have a prerequisite and has little overlap with the other technical writing seminars.

Writing Coaching: A private tutoring session is now available to reviewers who have completed any of the technical writing seminars. The coaching will augment other writing training. It is an effective, efficient and non-threatening way to improve your skills. This is especially important for team leaders who may need assistance in reviewing the writing of others. For more information on Writing Coaching, please contact **Bibi Jakrali** (JAKRALIB, 7-3488).

All seminars in the technical writing curriculum incorporate the elements of plain language. To register for these seminars please complete a CDER Course Registration Form found on the What's Happening page of CDERnet (http://cdernet/whappen.htm) and fax to **Sonya Armstrong,** Registrar, at 7-4575.

Word, Excell Virus Attacks Thwarted

Tips for Safer Computing Offered

(Continued from page 4)

that the Macro Virus Protection option is checked.

- Don't run macros in Office 97 files that have been mailed to you unless you have the latest virus protection software installed and running.
- Reboot your machine on a daily basis to make sure the latest virus protection software is downloaded from the server. This can be assured by turning your PC completely off at the end of each day.
- Don't change the McAfee VirusScan settings that are provided with the CDER installation. These settings include scanning of all files, compressed files and macro and program file heuristic scanning.
- Monitor the OIT intranet site at http://oitweb/oit/ for the latest virus scan software for home. This will normally be updated once a week. You can download the update to a single disk to take home.
- Check out the latest issues of the *Front Line* security newsletter at http://intranet.fda.gov/oirm/computer/frntline/cover.htm.
- Alert the CDER Help Desk (e-mail: HELP; phone: 7-0911) if you think you have a virus-infected file on your PC.

The OIT point of contact for virus issues is **Janice Ausby** (AUSBYJ).

Greg Brolund is a computer scientist in OIT.

May Information Technology Training

Monday	Tuesday	Wednesday	Thursday	Friday
3	**4** **NEDAT** 9-12 **JMP Intro (Part I)** 1-4	**5** **NEST** 9-12 **NEDAT** 1-4	**6**	**7**
10 **NEST** 9-12 **DFS** 1-4	**11** **JMP Intro (Part II)** 1-4	**12** **Word Intro** 9-12 **Word Formatting** 1-4	**13** **Access & Tables** 9-12 **Access Queries & Reports** 1-4	**14** **Access Form Design** 9-12 **Access Report Design** 1-4
17 **Excalibur Intro** 8:30-12 **Adv. Approved Drug Labels** 1:30-4:30	**18** **JMP Intro (Part III)** 1-4	**19**	**20**	**21** **LAN Resources** 1-4
24 **TeamLinks Intro** 9-12 **PowerPoint Intro** 1-4	**25** **TeamLinks Intro** 9-12 **TeamLinks Attach** 1-4	**26** **Project 98** 9-12 **TeamLinks Attach** 1-4	**27** **Calendar Manager** 9-12 **Calendar Manager** 1-4	**28**

The catalog, training materials, schedule and on-line registration are on OIT's intranet site at http://oitweb/oit/.

UNION CORNER

Unfair Labor Practices—Part 1

BY ROBERT YOUNG

The primary means by which the Federal Service Labor-Management Relations Law is enforced and employee rights protected is by way of unfair labor practice cases. For example, the law says that it is an unfair labor practice for an agency to:

- Interfere with, restrain or coerce employees in the exercise of their rights under the statute.
- Encourage or discourage membership in any labor organization by discrimination in hiring, tenure, promotion or other conditions of employment.
- Discipline or otherwise discriminate against an employee because the employee has filed a complaint, affidavit, petition or has given information or testimony covered by the statute.
- Refuse to consult or negotiate in good faith with a labor organization.
- Otherwise fail or refuse to comply with any provision of the law.

These provisions dovetail with another section of the law, employee rights. In the unfair labor practices context, these include the right to:

- Form, join or assist any labor organization freely and without fear of penalty or reprisal.
- Act for a labor organization in the capacity of a representative and, in that capacity, to present the views of the labor organization to heads of agencies and other officials of the executive branch, the Congress or other appropriate authorities.
- Engage in collective bargaining with respect to conditions of employment through representatives chosen by the employees.

Any person can charge an agency or union with an unfair labor practice. The charge sets into motion the Federal Labor Relations Authority's investigative machinery. If the charge has merit, the regional director attempts to reach a voluntary settlement to remedy the situation.

If the settlement attempt fails, the authority issues a complaint. If the facts of the case are in dispute, an administrative law judge hears the case and issues a decision that may be reviewed by the FLRA. The authority has broad powers to remedy violations through such means as retroactive bargaining orders, back pay and promotions.

Illustrations of protected activities that an agency is precluded from interfering with include:

- Joining a union.
- Assisting a labor organization as an officer, steward, representative to a congressional conferences or a member or a labor-management committee.
- Participating in formal meetings by commenting, speaking and making statements.
- Soliciting union members.
- Distributing union literature.
- Attending union meetings.
- Participating in union demonstrations.
- Participating in collective bargaining including contract negotiations and changes in working conditions.
- Assisting other employees in investigating their grievances, presenting their grievances and being a witness at a grievance hearing.
- Filing a grievance or an unfair labor practice charge.
- Complaining verbally to management as a union representative.
- Writing a union letter to the editor critical of managers and management policy.
- Using intemperate, abusive or insulting language if the rhetoric is believed to be an effective means to make a point about legitimate labor relations problems, called "robust debate."
- Requesting representation during investigations.
- Having sufficient time to secure a representative in an investigation.
- Participating in an investigation as a representative and taking an active part in the defense of an employee.

Unfair labor practices can be characterized as conduct on the part of an agency and its managers that has a coercive or chilling effect on employees' free exercise of their statutory rights. Words alone in an appropriate setting can be unfair labor practices.

The manager's intent isn't the controlling issue. What does control is whether the statement in context would be perceived as a threat, penalty or promise of a benefit. Does the statement tend to coerce or intimidate or manifest a management determination, which would be unsafe for the employee to thwart?

Ambiguous statements can be transformed into threats. When a manager is made aware that a remark is perceived as threatening and fails to dispel the threatening inference drawn and noted by the listener, then the statement has been transformed.

Examples of verbal unfair labor practices include management statements that:

- Although they supported the right of employees to join a labor organization, they did not want to see collective bargaining because it would put managers and employees "at opposite sides of the table."
- Employees who were to testify in a Federal Labor Relations Authority hearing would be watched closely by supervisors.
- An employee who was investigating a grievance he was considering filing that he would be disciplined.
- A supervisor would not select any union representative for a position that a union representative was seeking priority consideration for as a remedy to a grievance not yet filed.
- An employee had "hung himself" by going to the union.
- An employee could no longer be trusted because he had filed an unfair labor practice charge.
- A union representative had to suffer the consequences for taking too much time off for official union business.
- A performance improvement plan would be used to correct performance deficiencies that the supervisor attributed to union activities.
- A union representative would be getting better evaluations if he were not constantly questioning management's actions.
- Things would go more smoothly if

(Continued on page 7)

EEO CORNER

Awareness of Asian Pacific Americans' Contributions Blooms

BY GLORIA MARQUEZ SUNDARESAN

The month of May brings awareness of nature's beauty that has lain dormant during winter. We awake to the delight and enjoyment of the myriad blooms from pastels to bright reds, all competing for our attention. This is May's contribution every year. Likewise, May also brings the awareness of contributions of another kind—those of Asian Pacific Americans to the progress of this country.

The impact of the contributions of Asian Pacific Americans is well-documented—from the brawn and sweat of Chinese laborers who built railroads in California in the past, to the present-day talents and brains of astronauts, architects, scientists, information technologists, health professionals, business operators and educators. In sports, we have professional golfer Tiger Woods (claimed by all) and Kristi Yamaguchi, who has gathered Olympic medals for this country. I.M. Pei's architechtural talent is showcased by the East Wing of the National Gallery of Art in Washington, and David Ho was featured on the cover of *Time* magazine for his extensive research on HIV.

In public service, we have Bill Lan Lee, Department of Justice; Gary Locke, the first Asian Pacific American elected governor in Washington State. In Congress, we have Senators Daniel Akaka, Daniel Inouye and Congreswoman Patsy Mink. Norman Mineta and Robert Matsui were both detained in the during WW II; yet, despite the humiliation that their families suffered, both devoted their lives to public service in this country. Norman Mineta left Congress several years ago and now serves as chair of the Asian Pacific American Institute for Congressional Studies. World War II produced many heroes, including Senator Inouye who lost an arm defending human rights and democracy in Europe.

In the field of science, we have many Asian Pacific Americans right here in our Center—179 of them, diligently serving the public as physicians, pharmacists, pharmacologists, chemists, information technologists and consumer safety officers. Some employees do extra activities such as spearheading the formation of HHS Asian Pacific American Network, know as APANET, an umbrella APA organization for the department. These three individuals are **Min Chen,** OPDRA; **Ken Kobayashi,** ODE I; and **Gloria M. Sundaresan,** EEO Staff.

All over the country events are held to honor the contributions of Asian Pacific Americans to society. In the Center, a display, "CDER Salutes it's APA Awardees," will be in the main entrance, B Wing of the Parklawn Building during the entire month. In addition, highlights of outstanding Asian Pacific Americans will be featured occasionally by e-mail.

A commemorative program sponsored by the Public Health Service will be held May 13 in Parklawn Rooms D and E, from 11:30 a.m. to 1:15 p.m. The keynote speaker will be Deputy Surgeon General **Kenneth Moritsugu, M.D., MPH.** In addition there will be cultural presentations and Asian food sampling. Everyone is invited to participate and celebrate APA Heritage Month.

Gloria Sundaresan is on the EEO Staff.

Unfair Labor Practices Send Chilling Message to Those Exercising Rights

(Continued from page 6)

matters could be handled through the chain of command. There was no implication that the alternative of going through the union was not favored.

Other examples include a second-line supervisor's derogatory statement to and about a union representative's job performance for the union and a manager's inquiry about an employee's reasons for filing a grievance with the implication that the grievance would only hurt his career.

Similarly, examples of management actions that might have a chilling effect on employees or be considered a reprisal for an exercise of employee rights include:

- Attendance by managers at union organization meetings for employees. Since the employees were aware of their supervisors' presence, it could be inferred that the employees might have felt inhibited and might have been reluctant to participate in the meeting and ask questions.
- A supervisor creating the impression in a union representative's mind that his or her work and conduct were under greater surveillance because of he or she was filing an unfair labor practice charge.
- A supervisor's unnecessary presence in a union office while representation functions were being conducted.
- Inclusion in a performance appraisal of a statement critical of the agency raised through union channels.
- Placing a copy of an unfair labor practice charge in an employee's personnel file.
- Performance counseling of an employee because the employee became a union steward and engaged in protected activities.
- A supervisor's comment on a performance appraisal that a union representative spent too much time on union business.
- Lowering of a performance appraisal because of an individual's union activities.
- Determination that employee's protected activities rendered him unsuitable for transfer to a new or different position.
- Withholding of an award because of the time spent on union activities.
- Termination of a union representative under the guise of abuse of leave for taking "too much" time to pursue union business.

FDA-NTEU Contract Update

Due to a combination of events, the mediation and arbitration session scheduled for April 12 to 16 was canceled and rescheduled to April 26 to 28 and May 20 to 21. A final agreement has been delayed by a bit more than a month.

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

REVIEWER AFFAIRS CORNER

Pay Seen as Key Issue in Retaining Reviewers

BY C. RUSS RUTLEDGE AND MILTON SLOAN, PH.D.

This month's column on the Reviewer Affairs Committee features the ongoing efforts of its Comparable Pay Subcommittee.

The subcommittee was formed to address salary, promotions, tenure and related personnel topics of interest to CDER's primary reviewers. The group seeks to assist in maintaining the most competent review staff possible by remaining competitive on salary issues. According to survey results published in *Pharmaceutical Technology* last year, among the factors that are considered when changing jobs, pay is the most important factor. That hits close to home.

Turnover rates at CDER may indicate retention problems. For example, last fiscal year, CDER's review divisions lost 22 chemists, 14 regulatory scientists and eight statisticians. These were replaced by 19 chemists, five regulatory scientists and six statisticians. This is not a complete list; other review disciplines were similarly affected. It takes time to train new hires and indoctrinate them into our work culture, so the review process is affected.

What can RAC do about this situation? The Comparable Pay Subcommittee has been looking at the issue and is proceeding on the premise that pay is an important factor in retention as well. The subcommittee is fortunate to have as members, specialists from Personnel Management to help address these issues. The subcommittee has met twice this year to define the problem and has outlined three major objectives:

- Review and update special pay rate for series 1529, math statistician.
- Create a new series classification for clinical pharmacologists and biopharmaceuticists.
- Initiate special pay rate for series 1320, chemist; 0403, microbiologist; 0405, pharm-tox; and other reviewer series.

Members from the various disciplines have obtained salary survey data and internalCDER data. This may help provide the necessary justification for special pay categories and adjustments within the Washington metropolitan area. The subcommittee is in the process of collecting and analyzing data that can be presented to the Office of Personnel Management for implementation.

The subcommittee addressed the following concerns for retaining reviewers:

- OPM should, in theory, conduct annual reviews of each reviewer job series. This would be used in maintaining necessary pay adjustments.
- Other retention options that have been available for maintaining job-offer competitiveness would come directly from the Center's operating funds. Considering our present finances, there is concern that these options are seldom utilized.
- Turnover data would be important to help justify pay-setting flexibility and new pay rates. The cost of turnover should be assessed, not only in terms of pay but also to assess the nonproductive time required for training of new hires.
- Exit interview data would be helpful to give insight as to why reviewers left and also indicate what changes could be made to prevent reviewers from leaving CDER. This type of data is difficult to obtain.
- An alternative suggestion is to generate internal surveys on salary and other issues that would be important factors of retention.
- A multi-center approach would be useful and may be needed to obtain better results from OPM.

The next meeting is scheduled for May 6. The subcommittee has invited the Pay Policy Group of the Office of Human Resource Management Services to present information and discuss details of the data format needed to submit to OPM.

The subcommittee will also endeavor to establish a timeline for meeting the objectives. If you would like to contribute to this important and worthwhile issue, please contact the RAC or CPS Chair **Milton Sloan** for further details (e-mail: RAC or SLOANM, or call Milton at 7-2182).

C. Russ Rutledge is a compliance officer in the Division of Manufacturing and Product Quality. Milton Sloan, Ph.D., is CPS chair a chemistry reviewer in the Division of New Drug Chemistry III.

MAY 13 DEADLINE

CDER Leadership Fellows

CDER will once again sponsor a group of fellows in the Council for Excellence in Government's government-wide Leadership Fellows program. Applications are due to **Bibi Jakrali** in the Division of Training and Development, Parklawn Room 12B-10 (HFD-220) by Thursday, May 13. Bibi's phone number is 7-3488.

Additional information on this and another leadership development program will be announced at the CDER Forum on May 11 at noon.

FDA Approves New Protease Inhibitor for HIV

FDA on April 16 granted accelerated approval to amprenavir, a new protease inhibitor. The drug is approved for use in children 4 years old and older and in adults in combination with other antiretrovirals for HIV infection.

FDA based its approval on 24-week data from two ongoing well-controlled clinical studies involving more than 700 patients. Results from these trials showed a decrease in viral load and an increase in CD4 cell counts in patients taking amprenavir. These results were shown in previously untreated patients and in patients who had previously received reverse transcriptase inhibitors.

Amprenavir was studied in 118 pediatric patients 4 or more years old and is available as capsules or liquid. It must be used in combination with other antiretroviral agents. The most frequently reported adverse events among patients in the studies were nausea, diarrhea, vomiting and rash. Amprenavir is manufactured by Glaxo Wellcome Inc. under the trade name Agenerase.

Regulatory, Project Management Certification Program Explained

For CDER's project managers, keeping up with need-to-know information has never been more important. With the increasingly rapid pace of drug review and the expanding complexity of the review management process, new project managers must acquire the knowledge and skills necessary to become proficient at their jobs as quickly as possible and experienced project managers must continually enhance their skills.

The Regulatory and Project Management Certification Program provides a comprehensive training program to enable project managers with varying degrees of experience to meet or exceed these expectations. Participation isn't mandatory. The program exits solely to benefit project managers in their professional development and serve as a venue for continued learning.

Curriculum. To support the specific educational needs of project managers, core competencies were identified. From these competencies, a four-level program was created to focus on project management, regulatory affairs, science and computer skills. Program courses are currently offered through the Office of Training and Communications, Office of Information Technology, independent contractors and training partnerships with outside nonprofit professional organizations.

Except for the novice project manager with six or fewer months experience, classes may be taken in any order. However, the course schedule is arranged with more basic courses suggested for completion first. The program is self-paced, and there are no compulsory time frames for attaining certification.

You should make every effort to enroll in courses as soon as they become available because not all courses are offered in both spring and fall semesters, and availability is dependent upon funding.

The Individual Development Plan. The first step to certification is to complete and submit an individual development plan—a check-box listing of all courses as they appear within the various levels of the curriculum. The plan is customizable and designed to take your prior knowledge into account so that you can devise a program that will best meet your individual training needs. A copy of the most current IDP can be found by selecting Training on the PMCC intranet site at http://cdsmlweb1/pmcc/index.htm.

To enrollment in the Regulatory and Project Management Certification Program, you should assemble all the documents needed to support your IDP such as certificates of completed courses, requests for waivers and justifications for substitutions.

Waivers: Key course requirements may be waived if you have relevant substitute job experience and have demonstrated proficiency in the subject matter. Attach a separate sheet to your plan listing all courses for which you are requesting a waiver and a justification specific to each course. Your supervisor's concurrence must be included on the course waiver request.

Substitutions: If you have previously completed courses comparable to those specified under the certification program, you may request that these classes be considered as substitutions. You should attach separate sheets to your plan listing all course substitution requests, associated course descriptions and documentation of completion.

For the second step, you should present your plan and supporting documentation to your division's chief regulatory project manager. You should discuss courses that have been completed, those which should be completed for certification and those which may be waived or substituted. Place a check mark or a "C" next to courses you need to complete, a "W" by courses for which you are requesting a waiver and an "S" by those for which you are requesting a substitution. You and your supervisor should sign and date the plan at the bottom of the form.

Next, make two copies of your plan and any supplemental documentation. Provide one copy to your supervisor and retain the other for your own records. Your supervisor will forward the signed original plan and attachments to Center Project Management Staff, WOC II, HFD-009, for review and concurrence by the Certification Board.

Once the board issues its concurrence, the signed IDP will serve as your final plan for certification. Future revisions to the certification program's requirements won't obligate you to modify your plan unless you choose to do so.

Once you have completed all certification course requirements in your plan, you and your supervisor must sign the final IDP and forward it to the Center Project Management Staff. The completed package will then go to Personnel and become part of your permanent record.

The Center Project Management Staff will issue a certificate of completion for Regulatory and Project Management Certification Program. We welcome your comments, questions and suggestions. Please contact the Center Project Management Staff at 4-6596.

OGD Meets with Generic Industry Trade Groups

The Office of Generic Drugs occasionally holds meetings with the three generic drug trade associations to facilitate communication. These groups are the Generic Pharmaceutical Manufacturers Association, the National Association of Pharmaceutical Manufacturers and the National Pharmaceutical Alliance.

Last month, the office met with the groups to discuss organizational and personnel changes within OGD, review performance, a guidance on improving the content and format of abbreviated new drug applications, the impact of recent regulations regarding financial disclosure for investigators on studies and guidances being prepared by Office of Pharmaceutical Science coordinating committees.

These meetings provide a more informal atmosphere for trade association representatives and OGD managers to discuss issues related to generic drugs which are not generally covered in OPS meetings with all the drug industry associations. The meetings also provide a face-to-face forum for introducing new staff members to the generic drug industry.

Division Files System Upgraded; Y2K Task Force Survey on Tap

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

Division Files System

DFS Version 1.4 was released into production on Feb. 27. This release included:

- Check-in of PDF documents.
- Expanded definitions of the recommendation codes on the check-in screen.
- View Signatures screen includes each signer's discipline and task instructions.
- New searches which query documents by author as well as for all documents created by a specific author or narrow search by date and document type.
- The Create/Modify Signature Lists function has been simplified. It is no longer necessary to highlight an existing list on the Create/Modify Route Slip screen to edit the list. All editing and creation of lists are done from the Create/Modify Signature Lists screen.

Preliminary work has started for DFS Version 2.0. One of the main requirements driving DFS Version 2.0 is the reduction of document room costs associated with the filing, data entry, reproduction and distribution of final form copies of internally generated documents..

Currently, **Randy Levin, M.D.,** ORM's Associate Director for Electronic Review, is holding meetings to standardize the business process of document flow through review divisions. Once this standardization is complete, the requirements for Version 2.0 will be finalized, and regular working group meetings will be conducted. The OIT point of contact is **Janet Gentry** (GENTRY).

Year 2000 Activities

CDER's Y2K efforts continue at a rapid pace. As reported in March, all CDER mission-critical applications systems and infrastructure components have been certified as Y2K compliant.

The next focus will be personal computers. On March 23, the Agency announced that OMB had provided funding to replace non-compliant PCs in the Agency. The priority is to replace mission-critical PCs. CDER has identified 500 non-compliant PCs. This number includes only in-office PCs, not home-based PCs. The new machines will arrive between mid-May and late June. **Margaret Cates** is OIT project manager for this effort and will assemble a team to develop a plan for deploying the new equipment.

Final testing of non-mission critical CDER application systems is scheduled for April 12 through May 31. The Y2K server will then be made available to local application developers to test their own ORACLE applications that reside on the CDER VMS Cluster or to test a download process from CDER corporate databases. A testing schedule is being developed for all those who requested time on the Y2K server to do their own testing. Please contact **Judy McIntyre** for more information.

The CDER Y2K Task Force led by **Mark Goldberger, M.D.,** developed a letter and survey to the pharmaceutical industry regarding to help assess the industry's Y2K readiness. The letter requests industry assistance in assuring the Agency and the American public that individual firms have addressed the Y2K problem as it affects the adequate supply of safe and effective drugs to Americans.

The survey was sent to new drug and generic drug manufacturers, bulk suppliers, distributors, repackagers and wholesalers. Planning is underway for posting survey information on CDER's Y2K Web site at http://www.fda.gov/cder/y2k. This may include aggregate data as well as a list of companies who have confirmed that they have taken all the necessary steps regarding Y2K compliance. Additional work is being done to complete a rapid response plan to deal with potential drug shortages.

HHS required each of its operational divisions to develop "Day One" plans by March 31. This plan defines the steps the Agency and centers will take on Saturday, Jan. 1, to demonstrate that key technologies will work on Monday, Jan. 3. The OIT Day One team consists of 14 people who will conduct the tests and correct any non-functioning components. Results will be reported to FDA's chief information officer who will report to HHS by noon, Jan. 1.

More information about year 2000 activities can be found on the FDA Web site http://www.fda.gov and CDER's Y2K Web site at http://www.fda.gov/cder/y2k. The OIT point of contact is J**udy McIntyre** (MCINTYREJU)

AERS Datamart Prototype

The Adverse Event Reporting System provides a repository for and access to post-market reports of adverse health events that are suspected to be caused by prescription or over-the-counter drugs. CDER released AERS for production in late 1997.

AERS has a highly normalized relational database structure. Each type of data is stored in its own table and linked to related data in other tables. In addition, it contains tables of reference values used to ensure data validity and integrity during data entry. This structure promotes accurate data entry and storage, but it contributes to slow performance when querying against the database. The structure helps ensure that everything is in the correct place and conforms to predefined rules, but it hinders access.

FDA recognized early on the need for a companion datamart to support end users with timely query and report response. OPDRA and OIT have contracted with ORACLE Corp. to solve this data access problem by creating the AERS datamart.

A datamart is a specialized database whose structure facilitates data access—all other design considerations are secondary. A datamart uses the same core data as a typical relational database, but the data is repackaged and stored in a structure that favors quick query response.

(Continued on page 11)

Contractor to Design Datamart for Timely AERS Queries, Reports

(Continued from page 10)

A datamart differs from a data warehouse primarily in terms of scale and scope. A data warehouse typically crosses databases.

OIT determined an AERS datamart effort should be developed using a phased approach with the following objectives: provide CDER users with a datamart capability quickly, include all AERS data and be designed in such a way that functionality could easily be expanded. With these goals in mind, a 90-day project was designed and planned to culminate in the rollout of a production-ready set of screens that will efficiently query the AERS datamart. This project is currently on schedule and under budget. The entire AERS dataset has been migrated to the datamart structure. Preliminary tests indicate a great improvement in query performance.

The goal of the AERS datamart and its companion user application is to provide quick access to the AERS data. The AERS datamart prototype will be rolled out in May. ORACLE based the initial design on the business requirements of the medical review staff from the Division of Pulmonary Drug Products as they use postmarket AERS reports. However, the design is sufficiently flexible that it can be modified to accommodate the needs of other divisions. Not only will it provide easy access to AERS data, but it will reduce the medical officers' reliance on hard copy reports and the attendant shuffling of reports to and from the document room. The OIT point of contact is **Melissa Chapman** (CHAPMANM).

CDER Secure Electronic Mail Pilot

The CDER secure electronic mail pilot began Feb. 8. The secure e-mail team used the secure server to exchange encryption and signature keys with two pharmaceutical companies and negotiated the appropriate path through various firewalls.

A kick-off meeting was held with the first participating CDER review division and one of the companies. Other CDER secure electronic mail users were given instructions and a description of the system.

The exchange of secure e-mail started immediately and continues at a steady rate. Since the beginning of the pilot, eight additional pharmaceutical companies have asked about being added to the pilot. The Center for Biologics Evaluation and Research is also planning a secure e-mail system that will use the same standard but uses different encryption software. We have successfully exchanged test messages with the CBER test system and will continue to work with CBER as both systems move toward production.

The next steps for CDER are to conduct a formal evaluation of the pilot and begin the design of a full production secure e-mail system. Additional companies will be added to the pilot over the next few months so we can continue to gain experience exchanging secure messages between CDER and a variety of external systems.

The results of the pilot evaluation and plans for production will be reported in *News Along the Pike* and will be available on the OIT intranet site under OIT Activities. The OIT point of contact is **Greg Brolund** (BROLUND).

CDER Menu to Debut

OIT has developed a new utility, the CDER Menu, to provide a single menu from which CDER employees can access the following corporate information systems:

- Decision Support System.
- MIS Comments.
- Establishment Evaluation System.
- Geriatric Labeling System.
- Industry Meeting Tracking System.
- Pediatric Labeling System.
- Special Products Online Tracking System.
- Pediatric Exclusivity.

New systems will be added as they are implemented. Those systems to which you have access will appear in bright white on the menu, while systems to which you do not have access will appear in shaded blue.

Online help is available for all systems, even those to which you have not been granted access. The CDER Menu also provides a central location for you to change your password for all of these systems.

The menu will be installed automatically upon boot on all desktops in the beginning of May, and will appear as a tree icon, labeled CDER Menu. This is an additional desktop icon. The system icons you are familiar with will not be removed at this time.

To use the CDER Menu, double click on the CDER Menu tree icon. You will be prompted to log on with your user name and password. The menu can then be used to access any system listed without reentering your user name and password. To request access for specific systems, complete the new account request form and send it to your supervisor. Your supervisor will forward it with his or her approval to the Help Desk. Access will be provided within two to three days. Documentation for this new utility can be found on the OIT intranet site under the Documentation button. The OIT point of contact is **Sally Newman** (NEWMANS).

QA Development Project Update

The QA Development Project team and OIT managers finalized a project management model that will be implemented on a one-year trial basis. The model introduces a new position: the project management coordinator. The PM coordinator's job is to regularly review the progress of OIT projects and report summary status information to the OIT director. The PM coordinator is expected to be a key enabler of sustained process improvement.

This individual will actively oversee project planning and management, as well as encourage the use of other standard improvement practices. Finalization of the project management model was a prerequisite to finalizing the project plan for the OIT Improvement Project.

Now that the model has been finalized, the Improvement Project Plan will be peer reviewed by OIT senior managers on April 13. The plan will be implemented following OIT senior manager approval.

Information on the QA Development Project is available on OIT's intranet site under the Activities button. The OIT Improvement Project Plan will be posted on the Intranet once it has gained OIT senior manager sign-off. The OIT point of contact is **Vali Tschirgi** (TSCHIRGIV).

Stakeholder Concerns: Science, Risk-Benefit Communications

(Continued from page 1)

couras, said that the amphitheater environment of the schools Kiva Auditorium provided a good physical forum for getting people with different points of view together. Profit-seeking companies and consumer protection organizations view their public health roles from different perspectives. He said his "heart goes out" to Federal regulators who must seek the correct path and not simply mediate or conciliate.

The Center's afternoon discussion was preceded by a live television broadcast of a meeting with FDA Commissioner **Jane Henney, M.D.,** and Associate Commissioner for Strategic Management, **Linda Suydam, Ph.D.,** and stakeholder representatives. That discussion took place in the Gaithersburg television studio of the Center for Devices and Radiological Health and was moderated by the CDRH communications director, **Mike Barnett.** Deputy Center Director (Review Management) **Murray Lumpkin, M.D.,** was in the studio to answer CDER-specific questions.

In addition to Philadelphia, the centers and ORA held meetings at seven other cities across the country. The FDA's Internet site, http://www.fda.gov, has an on-demand Webcast of the videoconfernce and will have transcripts and summaries of the meetings when they are available.

Dr. Henney emphasize her five priorities: the Modernization Act, the science base, food safety, blood safety and restricting youth access to tobacco.

Dr. Woodcock provided an update on the Center's activities. CDER performs at a high level, especially in its traditional tasks, such as premarket review of drugs, which the Center controls, she said. Newer tasks, such as risk-benefit communications, which CDER only partially controls, present a mixed report card.

She said the soon-to-be-released Agency report on medical product risks should open a public dialogue on the safe use of medicines. The Center makes sure the label outlines risks and benefits for the tested population, but nurses and doctors make sure the benefits outweigh risks for a particular patient.

Coordinating the Philadelphia meeting were **Marcia Trenter** and **Elaine Frost** OTCOM; **Anitra Brown-Reed** and **Marie Falcone,** ORA; and Wendy Lebling and Sylvia McNally, Temple University School of Pharmacy.

Steering Committee Reports ICH Common Technical Document on Track

(Continued from page 1)

ceiver.

- The ICH Medical Dictionary for Regulatory Activities was launched on March 1, according to a report from the MedDRA management board.
- The steering committee officially adopted the finalized Q-6B guidance, *Specifications for Biotechnological and Biological Products.*
- The expert group working on clinical trials in pediatric populations, a topic adopted in September, reported major progress. The project scope includes ethical considerations, age categories as well as types and timing of studies.
- The steering committee discussed ways to make the advantages of harmonization available globally. They proposed to set up a special subcommittee to develop an action plan and oversee globalization activities.

The two milestones for the common technical document expert working groups are:

- Completion of a table of contents and guidance for each section.
- Agreement on summaries and tabulations of data for the safety and efficacy sections; agreement on detailed content for the quality section.

The safety working group reported that, subject to coordination with the two other groups, they had achieved both milestones for their parts of the document, which will deal with animal pharmacology and toxicology.

The efficacy group had agreed on a table of contents for the portions of the document concerning human clinical trials. The quality group was close to agreement on a table of contents for the manufacturing quality sections of the document.

Roger Williams, Deputy Center Director (Pharmaceutical Science), is FDA's lead delegate to the ICH steering committee. As Deputy Center Director, he is responsible for CDER's international activities.

HHS Honors Johnson, Papio for Quality of Worklife Efforts

(Continued from page 1)

and wellness, in addition to work and family programs. Representatives from different programs were on hand to answer questions and provide health and fitness screenings, making the Center's celebration a success.

Shelley and Lynda worked with the Center for Biologics Evaluation and Research to sponsor a joint CBER/CDER QWL day for the two adjoining facilities at the Woodmont Office Complex. This collaboration between the two centers generated a tremendous amount of positive feedback on the services provided during the QWL week.

Shelley and Lynda's dedication, initiative and persistence in strengthening the quality of work life for all employees with CDER epitomize excellence. Their willingness to share their expertise with regard to policy and precedent, demonstrates their outstanding communication skills, professionalism and commitment to teamwork.

The DHHS award recognizes those whose talent and daily activities show the dedication and exemplary acts and services that have made the FDA and the Department a success. The opportunity for this award rotates through each major organization in DHHS on a 14-month cycle. February was CDER's month. Nominees for this award must have provided overall excellent services to a center or office in FDA enabling its efficient operation as well as demonstrating initiative, persistence and adaptability in performing their duties or demonstrating the ability to work as a team member.

Jackie Barber is the Center's awards officer.