news along the pike

Center for Drug Evaluation and Research

July 1998

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Inside . . .

Pike's Corners . . .

PDUFA II 5-Year Plan

Center to Gain 240 New Reviewers, Staff

CDER will be able to hire an extra 240 reviewers and support staff by fiscal year 2002 with increased funds from user fees, according to FDA's internal planning document titled *PDUFA II Five-Year Plan.* The plan, released to the public July 10, can be downloaded (right mouse button) from the Internet at: http://www.fda.gov/oc/pdufa2/5yrplan.html.

Of the additional positions, the Office of Review Management will receive 147 full-time equivalent positions, and the Office of Pharmaceutical Science 60. Other Center components will be increased by a total of 33 positions.

Last year's FDA Modernization Act and the reauthorization of the Prescription Drug User Fee Act, called PDUFA II, commit the Agency to substantially faster review times for some applications, new goals for meetings and dispute resolution and the transition to electronic receipt and review of applications by the year 2002 (December and January *Pikes).*

To support the Agency's PDUFA II Five-

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First Party Audit Program

CDER Eyes Inspecting Firm's Own Audits

By C. Russ Rutledge

The FDA announced it is developing a program for drug companies to report to the Agency on their compliance with Current Good Manufacturing Practices and, in return, receive streamlined and less time-consuming inspections. At an industry exchange meeting held June 23, about 250 industry officials representing about 150 firms met with top Agency management to discuss the proposal, called the First Party Audit Program. The comments and questions received during the industry exchange meeting as well as continuing input from the regulated industry and American public are to be used to develop the concept further and produce a pilot program.

Making presentations at the meeting were Acting Commissioner **Michael Friedman, M.D.,** Center Director **Janet Woodcock, M.D.,** and Associate Commissioner for Regulatory

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FERS Open Season

Employees Get Option to Switch to Newer System

July 1 marked the beginning of a six-month "FERS Open Season." Last year, Congress enacted legislation providing an opportunity for most employees who are currently covered by the Civil Service Retirement System to switch to the newer Federal Employees Retirement System. In addition, some employees who are covered by Social Security only may elect FERS. The law does not permit employees currently in FERS to switch to CSRS. The open season ends Dec. 31.

Dave Leffler of FDA's Benefits Branch said that all CDER employees under CSRS should have received a personal copy of the "FERS Transfer Handbook." The branch has already held 24 training sessions for Agency and CDER employees. The next session will be held on Aug. 19 at 10 a.m. in Conference Room E of the Parklawn building. Additional sessions will be announced. Employees should not automatically assume that one system is better than the other.

Leffler said that any Center employees with questions should contact the Benefits Branch directly at 7-4140. The Benefits Branch can

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Joe's Notebook

PHS History Lesson 101

This July 16 passed by unremarkably for me, hanging out at the beach, hiding out from the heat and escaping from work. On July 16, 1798, President John Adams wasn't so lucky. Presumably toughing out the Washington summer, he picked that day to sign the law that provided for the care and relief of sick and injured merchant seamen—the day the Public Health Service marks as its birthday.

Marine hospitals to care for seamen became reality first in Boston and on the East Coast and later along inland waterways, the Great Lakes and the Gulf and Pacific coasts. An 1870 reorganization converted the loose network of locally controlled hospitals into a centrally controlled Marine Hospital Service with headquarters in Washington. John Maynard Woodworth was was named supervising surgeon, a position that became surgeon general. Woodworth adopted the military model for his medical staff, instituting examinations for applicants and put the service's doctors in uniform—an action formalized by an 1889 law setting up the Commissioned Corps.

Mission creep was as common in 19th century bureaucracies as it is today. The scope of the Marine Hospital Service expanded. The National Quarantine Act of 1878 gave it quarantine authority. In 1891, the Federal Government took over processing of immigrants from the states, and the service became responsible for the medical inspection of arriving immigrants at sites such as Ellis Island. Its public health responsibilities grew in the 20th century. The service took the name Public Health and Marine Hospital Service in 1902 and, 10 years later, shortened that to its current name.

Now the largest public health program in the world, PHS, a part of the Department of Health and Human Services, consists of the Office of Public Health and Science, headed by Assistant Secretary for Health and Surgeon General David Satcher, 10 regional health administrators and eight operating divisions, one of which is the FDA. The Commissioned Corps has also grown. At first only open to physicians, it now includes dentists, sanitary engineers, pharmacists, nurses, scientists and other health professionals.

The only Hollywood film to feature a Commissioned Corps officer as its hero is Elia Kazan's 1950 film noir, *Panic in the Streets.* Richard Widmark plays Lt. Cmdr. Clinton Reed, a smart, cocky doctor with major attitude, assigned (understandably) to New Orleans in the days of 50-cent allowances and no air-conditioning. Except for a few moments of hopelessly hip '50s dialogue between Widmark and co-star Barbara Bel Geddes as Reed's model postwar wife, the film was surprisingly gripping for a 1998 audience gathered for the kick-off of NIH's fifth Science in the Cinema series.

Kazan exploits his black-and-white palette well to convey the growing sense of alarm as Widmark and Paul Douglas, as police Capt. Tom Warren, scour the New Orleans underworld and waterfront looking for the killers of an illegal alien. The victim had the highly virulent and deadly form of plague known as pneumonic plague, spread directly from person to person like the common cold through coughs and saliva. The cantankerous duo must find the killers before they become contagious and spread the disease. Without treatment, victims of pneumonic plague die in one to three days. An outbreak of pneumonic plague in Los Angeles in 1924 killed 31 of its 33 victims.

Remaining films in the NIH series, shown Thursdays at 7 p.m. in the Natcher Building are: *Drugstore Cowboy,* Jul. 30; *Children of a Lesser God,* Aug. 6; *As Good As It Gets,* Aug. 13; *The Three Faces of Eve,* Aug. 20; and *Gattaca,* Aug. 27. The screen is big and the films are free, so get there early.

Happy Bicentennial, PHS!

news along the pike

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

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

Photocopies are available in the Medical Library (Parklawn 11B-40) and its branches (Corporate Boulevard S-121, Woodmont I 200-S, and Woodmont II 3001).

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

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

News Along the Pike
CDER Office of Training
and Communications (HFD-200)
Parklawn Building, Room 12B-45
Editor: Norman "Joe" Oliver (OLIVERN)
Associate Editor: Lori Frederick
Summer Intern: Jason Walther
Phone: (301) 827-3471 Fax: (301) 827-3055

Ombudsman's Corner

The Internet: Problems vs. Opportunities

By Jim Morrison

Now that almost all of us have adapted to the emergence of electronic communication, it is a good time to reflect on its significance to our work. We are comfortable with e-mail, but working with the Internet plus localized variations like intranets and extranets takes electronic communication to another level. We are only beginning to see and experience the potential of this medium.

The Internet, originally created for scientists to communicate with each other, has long since been appropriated by the rest of the world. No one speculates anymore about when it will contain a critical mass of information and thus become useful to the average person. It reached that point some time ago. It is growing at an astounding rate—both in numbers of users and in the quality and amount of information, services, commerce and societal impact.

I can attest personally to the power of the Internet. After putting my Ombudsman page on CDER's site a year and a half ago, the volume of contacts I receive has more than doubled overnight. I get e-mails and calls from distant parts of the globe. Thankfully, I still remain undetected by most Web crawlers, so the people who contact me are generally limited to those who started in the FDA site. That keeps incoming e-mail to a manageable level and minimizes intrusions.

On the output end of things, the Internet has revolutionized the Agency's transparency. Now, instead of sending out material in response to individual Freedom of Information requests, we can make source documents and other information available to the world instantaneously.

As with all revolutionary advances in technology, the Internet has brought both promise and problems. To cite an oft-repeated litany, it seems that we are drowning in data, not all of which are accurate. In addition, it seems the total of letters, phone calls and e-mails to CDER is now larger than the volume of letters and calls we received in the past, meaning that e-mail is not just replacing conventional media but has opened communications with people who haven't contacted us before. That means a bigger workload, but it also means more opportunities to get our information out to where it will do the most good. It also means that we can save some costs in the way we operate.

We can distribute vital information worldwide, immediately and at minimal cost. If we can anticipate questions and put answers on our site quickly, we can possibly cut the number of letters, e-mails and phone calls we receive.

Each of us should take some time to think about what information we have and use daily that could benefit our constituencies, such as health care professionals, patients, the public, industry and other government agencies. Before I strike terror into **Carol Assouad,** who does an excellent job overseeing the CDER sites as part of the Medical Library, let me hasten to add that there are resource limitations on how much data can be added usefully to our servers and how quickly. Nevertheless, we should all contribute to planning what information appears on our sites.

I plan to follow this advice and post some guidance on intercenter jurisdiction for reviewers on CDER's intranet. If you have ideas for other information that you would like to see on our Web sites, I encourage you to tell the people who have access to the information, or tell me, and I will see what I can do to get it posted. Incidentally, that invitation goes for anyone reading this, whether you are in FDA or outside. Just send me an e-mail with your suggestions (morrisonj@cder.fda.gov).

Jim Morrison is the Center's Ombudsman.

Administrative Management Corner

Harrell, Shekitka Receive 1st of New Awards for CDER Administrators

By Tanya Abbott

The first Administrative Management Team Quarterly Awards were given to **Anita Harrell,** a senior management officer in the Office of Compliance and **Barbara Shekitka,** a program specialist in the Division of Pulmonary Drug Products. The presentations, which included presentations of personalized desktop plaques, were made at the team's quarterly meeting on June 18. Congratulations Anita and Barbara!

The awards were established by the Administrative Management Coordinating Committee to recognize exceptional contributions from Center administrators who embody the vision of the Administrative Management Team. The team includes all CDER program specialists, management specialists, management officers, administrative officers and the staff of the Office of Management. CDER administrators at all grade levels are eligible for the award.

Nominees must meet specific criteria in the areas of leadership, innovation, customer focus, empowerment of and respect for others, teamwork and professionalism.

If you are looking for a way to acknowledge the efforts of an outstanding CDER administrator, this might be just the ticket. The awards will be given out at quarterly meetings of the Administrative Management Team. The nomination process is described in full on the AMCC home page (cdernet/om/amcc/amcc.htm) and in the Administrative Guide (cdernet/admin/admin.htm). Award nominations for the Sept. 17 presentation are due July 30, and nominations for the Dec. 17 award are due Oct. 29.

Tanya Abbott is a management officer in the Office of the Center Director and a member of the Administrative Management Coordinating Committee.

Pediatrics Corner

New Guidance Announced, Implementation Team Created

By Khyati Roberts and Jonca Bull, M.D.

The FDA has issued a guidance to help industry interpret the six-month pediatric exclusivity provisions of the 1997 FDA Modernization Act. CDER has also created a Pediatric Implementation Team to improve understanding of the law's provisions and ensure consistent interpretation within CDER.

The Modernization Act grants companies six months of additional marketing exclusivity in exchange for performing pediatric studies. The goal is to obtain information on the use of drugs that will provide a meaningful health benefit in the pediatric population. The guidance is available on the Center's pediatric site at http://www.fda.gov/cder/pediatric.

Dianne Murphy will lead the Pediatric Implementation Team. Other members include: **Paula Botstein**, **Jonca Bull**, **Tom Hassall, Mac Lumpkin, Jerry Phillips**, **Khyati Roberts** and **Rosemary Roberts.** Ex-offico members include: **Jane Axelrad**, **Leanne Cusumano**, **Liz Dickinson** and **Ann Witt**. The team will meet at least weekly for the foreseeable future.

The implementation team is responsible for:

- Maintaining, updating and correcting the list of approved products published by FDA on May 20. This includes working with the Regulatory Policy Staff on citizens' petitions submitted to add products to the list.
- Tracking various components of requests for pediatric studies, including proposed requests, official requests written agreements and submission of studies.
- Meeting with the Office of Generic Drugs on exclusivity issues, including notifying OGD when various decisions or other issues regarding exclusivity may affect generic products.
- Training CDER on the implementation program for pediatric exclusivity.

The team has already held a training session on the law and new guidance for the Office of Review Management office directors, division directors, the pediatric subcommittee and supervisory project managers. Training sessions will take place in the near future for all review divisions in the Center.

Both of us will be handling day-to-day questions about the program from CDER reviewers and outside constituencies. Please use the e-mail address PDIT for your questions. All questions will be answered within a week, unless you need a reply more quickly.

Khyati Roberts is a science policy analyst in the Executive Operations Staff, and Jonca Bull is a medical officer in the Office of Review Management.

Food Drive Campaign in CDER Buildings Hits 5-Ton Mark

By Shelly Johnson

Due to the generous contributions of FDA employees, last month the Walk the Walk Campaign reached the 5-ton mark in food donations—equivalent to 10,000 16-ounce cans of tuna. For those of you unfamiliar with the campaign, Walk the Walk is a permanent food drive to fight hunger in Montgomery County. This drive collects non-perishable foods for the Manna Food Center in Rockville. Donations help many area families who seek emergency assistance. These families especially need high-protein foods, such as canned meats, peanut butter and beans. Also appreciated are other non-perishables, such as canned tuna, canned fruit, canned soups, spaghetti sauce, non-fat dry milk and gelatin.

In May, FDA started partnering in the campaign with the Substance Abuse and Mental Health Services Administration, the Health Resources Services Administration and the Office of Public Health and Science's Office of Minority Health. Many CDER employees have offered their services to this cause, particularly **Jamie Metz** and **Sally Lewis,** both of whom have contributed their time and effort serving as building contacts for Woodmont II and Corporate Boulevard respectively.

Collection boxes are located inside the main entrances of the following locations:

- Parklawn Building (Floors 1 and 5 entrances only).
- Metro Park North I and II.
- Corporate Boulevard.
- Woodmont II.
- Nicholson Lane Research Center.

Mod I collects food for food banks in Prince George's County.

Shelley Johnson is CDER's Quality of Work Life Coordinator and a personnel program analyst in the Office of Management's Division of Management Services.

FDA Science Forum Set For Dec. 8, 9

The 1998 FDA Science Forum, co-sponsored with the American Association of Pharmaceutical Scientists and the FDA chapter of Sigma Xi, will be held Dec. 8 and 9 at the Washington Convention Center.

The forum will feature lectures and focused discussion groups on topics such as bioengineered products, microbial pathogens, antibiotics and resistance, novel therapeutic and preventive approaches, diagnostics and detection methodologies, and safety and efficacy assessment. Regulatory issues related to standards and product quality and the impact of the FDA Modernization Act of 1997 will also be addressed.

A poster session sponsored by Sigma Xi will feature presentations encompassing all areas of FDA regulatory science. Deadline for submitting poster abstracts is Sept. 1.

For more information, registration or to submit a poster abstract, consult the 1998 FDA Science Forum page on the FDA intranet at:

http://first.fda.gov/scisem/sf98.htm.

Reviewer Affairs Corner

RAC in View of Unionization at FDA—A Current Perspective

By Melissa Maust

The mission of the Reviewer Affairs Committee is to provide a forum for all CDER primary reviewers, to improve communication among reviewers and to represent the needs and concerns of primary reviewers directly to the Office of the Center Director. Some have asked if the certification of the union will alter the mission statement of the RAC. This article summarizes the presentation at the June RAC meeting given by **Robert Young,** interim President of FDA Chapter 282 of the National Treasury Employees Union. Young was invited to give his perspective about the RAC's current status in view of unionization, so that members of the RAC might better understand the developing relationships of the RAC with the union and FDA management.

Young explained that an interim contract was signed by both parties, the union and the FDA management, when the union won the election. This interim contract included an agreement that business activities throughout FDA will continue as usual until an agreed-upon change is made. Therefore, the RAC will continue to remain the critical link between primary reviewers and the Center Director. Currently, the RAC communicates the needs and concerns of the primary reviewers in CDER, but does not negotiate with CDER management.

Young indicated the RAC performs a valuable function for the Center by providing feedback to CDER management and primary reviewers. However, he explained that when the union won the election, it became the exclusive representative of all FDA employees in the bargaining unit. Because of the concept of "exclusive representation," Young said that in the future there may be a change in the status of the RAC. This change may alter the current working relation between the RAC and FDA management because the union has certain rights and powers from the law. These are currently under discussion between the FDA management and the union. The resolution will result in a permanent contract between the FDA management and the union. At the time this contract is negotiated, the RAC will have a better understanding of any change in its activities. Young could only speculate what the change in status may be for the RAC's mission. Young clearly stated that the RAC should continue to function according to its current by-laws until otherwise notified.

The RAC will continue to conduct quarterly meetings with the Senior Management Team and will continue to be actively involved with issues about the Team Model Proposal, the RAC website, the Reviewer's Handbook and the Quality of Work Life.

The RAC will continue to support enthusiastically its current mission statement of providing a forum for all CDER primary reviewers, improving communication among reviewers, and representing the needs and concerns of primary reviewers directly to the Office of the Center Director.

For details of the June RAC meeting see:

X:\coorcomm\rac\minutes\min0698.

Melissa Maust is a chemist in the Office of Generic Drugs.

Thalidomide Approved With Significant Restrictions

On July 16, FDA approved the use of thalidomide for the treatment of the debilitating and disfiguring lesions associated with erythema nodosum leprosum, a complication of Hansen's Disease, commonly known as leprosy. Because of thalidomide's potential for causing birth defects, FDA invoked unprecedented regulatory authority to control tightly the marketing of thalidomide in the United States. An oversight program, called System for Thalidomide Education and Prescribing Safety or STEPS, will include limiting authorized prescribers and pharmacies, extensive patient education about the risks associated with thalidomide and a 100 percent patient registry. The oversight program is designed to help insure a zero tolerance policy for thalidomide exposure during pregnancy.

Celgene Corp. of Warren, N.J., will market thalidomide as Thalomid.

Extensive information, including consumer and patient education materials, transcripts of the thalidomide advisory committee and workshop meetings, the approved labeling text and the medical review is on CDER's Web site at:

http://www.fda.gov/cder/news/thalinfo/default.htm.

FDA to Mandate Use of MS Word for Reviews, Official Documents

FDA recently established a common information systems architecture that sets Agency standards for the network operating system, electronic messaging, desktop operating system and office automation. The standard office automation suite is Microsoft Office Pro 97, which includes MS Word. Beginning Dec. 1, everyone in CDER will be expected to use Word for all reviews, correspondence with industry and other official documents created with a word processor.

"Many of you already use Word, and it is also widely used by the pharmaceutical industry," said Center Director **Janet Woodcock, M.D.,** in making the announcement. "However, for some of you, this move won't be painless, because you have become proficient with other word processors, such as WordPerfect. Therefore, there is a relatively long transition period to give you time to learn and begin using Word. To help, the Office of Information Technology will provide MS Office Pro software centrally and add focused training for current WordPerfect users."

Pike Interview

Schumaker Cites Teamwork Lessons from AIDS Ride

By Jason Walther

On June 21, Cathie Schumaker of the Division of Pulmonary Drug Products pedaled into Washington on the final leg of the four-day 350-mile AIDS Ride. The riders traveled a combined total of 487,500 miles, or roughly 19.5 times the earth's circumference. The riders also drank 15,000 gallons of water and ate 25,000 eggs. The Pike has been reporting on her training progress over the past months.

Why did you decide to do this ride?

I did this for my own personal challenge. I had known people who rode in the Ride before and how much support there was—how much team camaraderie there was. That's what attracted me. There are a lot of bicycle rides around and lots of groups that do this to raise money, but none that push you as hard as this ride. The whole idea is that if you think as an individual you can do this much, you can do more with a team because you will have people there who are giving you support, who are encouraging you to go on. You set your own personal goals and then use the energy of the group to achieve the goal.

Click here to view photographs.

What did your family think about your decision to participate in the ride?

They probably didn't understand how much time training for it would take. The organization says you have to do 65 miles on back-to-back days to be in good enough shape do the ride. You usually average about 10 to 12 miles per hour, so if you are talking 65 miles, it's about six and a half hours. I would do my long rides during the weekend and my short 20-mile rides during the week. But that's still two hours I would spend going out and riding, instead of cooking dinner or doing what I usually would do. I started in February, and by the end of the training, my 10-year-old son said to me: "When you're done with this ride, you're not going to ride a bike anymore." My family was incredibly supportive of the hours of training. I couldn't have done it without them.

How many riders were there?

Around 1,300, but there were also about 400 to 500 crew members who provided all of the support for taking care of the gear and the food, bringing showers and handling the medical treatments. We were basically a moving city of close to 2,000 people. The crew members were just as important a part of the group as the riders.

Was there a point in the ride that you wanted to give up?

The third day was a long day, 102 miles. It was very hot and very hilly. Right outside of Fredricksburg, there was a hill that must have been a half mile long. I thought: "I'm not going to make it. I cannot make it up this hill." A man who is a very strong rider came up next to me and pedaled right alongside the whole way. He said: "You will make it, just keep pedaling, you know you can do this." Pretty soon I wasn't thinking about making it up the hill, I was listening to him.

There was a woman who went up and down that hill 5 times, bringing people up the hill just like that. And that's the inspiring thing—if you know somebody else there is giving you support, urging you along, you can do it.

I remember thinking two things during the ride. One, if people were always this nice to each other, what a wonderful place the world would be. Number two was about the team—about how we talk about building teams in CDER, but do we ever really and truly rely on somebody else?

Do you think CDER should do more with teamwork?

Yes, I do. Because we're based in science, we have scientists who are used to making decisions and who aren't used to relying on other people, forming teams and working together. We have this tendency for individuals to want to lead the way and carry the banner. We are moving in the direction of more teamwork, but it's a tough thing. It's a real cultural change.

Do you have plans to do another AIDS Ride?

I want to do it again next year, and I want to take an FDA team with me. To my knowledge, there weren't very many FDAers on this ride. It would be a great experience for anyone looking to challenge himself or herself. Personally, I still feel that it's one of the best things that I have ever done, and I want to thank everybody in the Division of Pulmonary Drug Products for their support.

Jason Walther is a summer intern in the Office of Training and Communications.

Bowen Named ODE V Deputy Director

The Office of Review Management has selected **Debra Bowen, M.D.,** to be the Deputy Director for the Office of Drug Evaluation V. Dr. Bowen joined the Agency in 1990 as a reviewing medical officer in the Division of Anti-Infective Drug Products. In 1993, she became director of the medical review staff in the former Office of OTC Drug Evaluation. Since 1995, she has served as Director of the Division of OTC Drug Products.

Dr. Bowen has made many substantial contributions in the review and regulation of both prescription and over-the counter drugs. In the past several years, she has effectively reorganized the Division of OTC Drug Products into an ORM review division, improved the science of labeling and actual use for OTC drug products, implemented consumer friendly labeling changes, coordinated the publication of several precedent-setting OTC drug rulemakings and supervised several major switches that have allowed over-the-counter marketing of drugs for smoking cessation, heartburn and hereditary baldness.

Dr. Bowen received her M.D. from Harvard and completed residency in internal medicine at Dartmouth. She then held a clinical and research fellowship at the National Institute of Allergy and Infectious Diseases. She is board certified in internal medicine and allergy and immunology. Dr. Bowen will serve as acting Director of DOTCDP until a successor is named.

First Party Audit Program Eyes Inspecting Firm's Own Audits

(Continued from page 1)

Affairs **Ron Chessmore** as well as members of the Office of Compliance's Division of Manufacturing and Product Quality and the Agency's Office of Regulatory Affairs Field Drug Committee who worked on developing the concept. Other presenters included: **Douglas I. Ellsworth**, **Joseph C. Famulare**, **Stephanie R. Gray**, **Diana Kolaitis**, **Paul J. Motise**, **Brian Nadel** and **C. Russ Rutledge.**

The proposal is part of the Agency's effort to find alternative and more efficient ways to assure that quality drugs are available for the American public. One area previously identified for improvement is the gathering of information about a firm's Current Good Manufacturing Practices. This sometimes time-consuming process is performed by FDA's field inspection force. Meanwhile, pharmaceutical manufacturers are already required under CGMP regulations to have quality control programs in place to monitor their manufacturing processes on a continuous basis. Moreover, many of these firms already conduct internal audits of these operations

Although FDA has found some firms with ineffective quality-assurance programs, other have effective programs that prevent CGMP problems from occurring. When CGMP deviations are detected, these firms act rapidly to implement corrections, assess the effect on product quality and evaluate the health risk to the public. These firms have responsibly informed the FDA and worked with the Agency to resolve problems, such as recalling shipped product or taking other voluntary corrective measures. The two building blocks of the proposal are based on recognition of this corporate commitment to maintain and improve high quality standards of manufacturing and FDA's confidence in self-evaluation.

The FPAP proposal would allow firms with quality assurance programs that meet FDA standards to send their own CGMP information to the FDA. In return, these manufacturers would undergo abbreviated and more focused FDA inspections.

The proposal is being developed in two phases:

- A two-year pilot phase to evaluate the concept in 25 firms. FDA anticipates this will begin early next year.
- A follow-up phase, modified from experiences gained in the pilot, that will enroll additional firms.

Preliminary qualifications for participating in the program were outlined at the meeting. In selecting candidates, the FDA would evaluate a firm's history of compliance and factors such as the firm's responses to consumer complaints, implementation of manufacturing improvements, employee training programs and related qualities. Other criteria would include a history of substantial CGMP compliance, an effective quality-assurance system, a recent comprehensive CGMP inspection and an on-site quality control laboratory.

Participation would be voluntary, and a firm would be able to withdraw from the pilot program or follow-up phase at any time. FDA would continue to conduct for-cause inspections and would reserve the right to cancel a firm's participation at any time. CDER will invite firms to take part based on the recommendations from each district. Selection will be on a first-response basis.

Firms that agree to take part in the development of this program would file reports about their quality assurance activities every six months with the districts along with a statement certifying that the reports accurately portrayed the firm's CGMP status. Reports would include results of the firm's continuing QA program, problems found and solutions instituted, a summary of consumer complaints and their resolution, and improvements to the manufacturing process.

The FDA would use these reports to assess the firm's CGMP status. The districts would evaluate these reports for relevant issues and compare them with information obtained from other sources, such as reports from other agencies and consumer complaints. With this information, districts would conduct a modified CGMP inspection. The inspection might consist of an audit limited to what is contained in the report. The inspection could be broadened when necessary to cover any specific problems found.

During the pilot period, the Agency will evaluate the program and individual firms to determine if the goal of ensuring CGMP compliance through the self-audit process is being met. Evaluation will be an ongoing theme during the pilot, and a report will be made at the end of the two-year pilot. Modifications to the program will be based on experience gained from the pilot program. If the pilot program meets its intended goals, additional firms will likely be added to the program during the second phase.

C. Russ Rutledge is a consumer safety officer in the Division of Manufacturing and Product Quality.

GAO Conducts Audit of Accountable Property, Including PCs at Home

The Government Accounting Office, in conjunction with the HHS offices of the inspector general and the assistant secretary for management and budget, is currently conducting an audit of FDA's accountable property. This will include a search for a statistically valid sample of CDER's accountable property, as well as a review of the methods used to manage the property.

FDA inventory of accountable property has been under congressional oversight for the past two years. All CDER employees are asked to cooperate with their property custodial officers in identifying accountable property charged to their work place or private residence and for having proper paperwork describing the location of off-site property. PCOs must confirm that the list of accountable property assigned to their location code is accurate and that each piece is locatable.

"I know that each of you will take a moment to seriously consider the impact if we are unable to locate our accountable property, especially highly sensitive property like PCs or printers," said Center Director **Janet Woodcock, M.D**.

Plan Calls for Standardizing Review Practices, Enhancing IT

(Continued from page 1)

Year Plan, CDER developed a detailed overall plan based on individual plans and estimates from CDER components. Of the $415 million in total projected user fees allocated to the Center over five years, about $271 million will maintain the existing user fee program. The rest—$164 million—will bolster three areas critical to achieving PDUFA II goals by:

- Increasing personnel and support.
- Enhancing the application review process.
- Improving information technology.

Personnel and Support: CDER plans to spend $91.4 million—56 percent of the increase—to hire and support additional staff for the drug evaluation process. Of the 240 additional positions planned, the largest increment—138 positions—will take place in the upcoming fiscal year with most allocated to ORM and OPS. About 23 new hires will be authorized through the remainder of this fiscal year, and the remaining 70 will be hired in approximately equal increments over the final three years of the plan.

The 240 new positions called for in the plan will represent an addition to the 418 positions currently supported by user fees and the 749 positions supported by appropriated funds for PDUFA to activities. This will bring the total PDUFA effort to 1,407 full-time equivalent positions by fiscal year 2002.

This component of the plan also includes funds to acquire more space for the additional staff—$3.8 million over the five years. This amount will probably be used to pay increased rental costs to Government Services Administration and will be held in reserve until arrangements are made for acquisition of this additional space.

Review Process: The second component allocates $11.9 million—7 percent of the total plan—for a number of enhancements to the application review process, including:

- Standardizing and improving review practices.
- Expediting the validation of methods in new drug applications.
- Training reviewers.
- Increasing clinical trial inspections.
- Improving PDUFA time-reporting systems.

Also included in this component are estimated travel funds for International Conference on Harmonization meetings that will promote accelerated drug development through agreements on shared standards for use by U.S., Japanese and European pharmaceutical authorities. The actual distribution of these funds will be decided each year by FDA's Office of External Affairs, which coordinates ICH activities.

Information Technology: The final component allocates $60.7 million—37 percent—for information technology enhancements to the drug review process that will:

- Establish the capability to receive and store standardized electronic regulatory submissions.
- Expand CDER's electronic document management system and enhance its corporate management information system.
- Provide the technical infrastructure for reviewers to access and review electronic submissions from their desktops, including replacement of one-third of their personal computers every three years.

The FDA will make annual adjustments to the plan to reflect changing circumstances, including adjustments for workload and user fee revenue.

General points of contact regarding CDER's portion of the PDUFA II Five-Year Plan are **Bob Linkous,** Director, Division of Planning, Evaluation and Resource Management in the Office of Management (phone 7-0502, e-mail LINKOUS), and **Rixie Scott,** Chief, Planning and Resource Management Branch, DPERM, (phone 7-0528, e-mail SCOTTRI).

The CDER contact for the IT portion of the plan is **Pat Sporn,** Special Assistant to the Director, Office of Information Technology, (phone 7-6231, e-mail SPORNP).

Friedman Lauds Implementation Efforts

In a July 19 message, Acting Commissioner **Michael Friedman, M.D.,** praised Agency employees for their efforts to implement the provisions of the Modernization Act. Since November, FDA (CDER actions in parentheses) has issued:

- 10 final rules (CDER, 5).
- Two proposed rules (CDER, two).
- 25 final guidance documents (CDER, nine).
- Three draft guidance documents.
- 10 notices (CDER, four).
- One report (CDER, one).

"This record is a demonstration of the skill and professionalism of FDA employees, and an example of the Agency's dedication to serving the public health needs of our citizens," Friedman said. In total, the new law explicitly requires FDA to complete 17 regulations, 11 guidance documents, six notices, nine reports, and 18 other tasks. More information can be found by going to http://www.fda.gov/opacom/7modact.html and then clicking on the CDER link under Modernization Act Actions.

Retirement System Training Sessions Still Available, More on Way

(Continued from page 1)

prepare an individualized CSRS and FERS comparison for employees who request it.

"Both FERS and CSRS are excellent retirement programs," said HHS Secretary **Donna E. Shalala** in announcing the open season. "However, they are very different, and each provides a different array of retirement benefits. These benefits vary according to the circumstances of each individual, so some will find FERS more attractive while others will prefer to remain in CSRS. The decision whether or not to switch is highly personal, and should be made only after careful consideration of the comparative benefits of each in light of your personal situation."