news along the pike

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CENTER FOR DRUG EVALUATION AND RESEARCH

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PIKE'S CORNERS . . .

Dr. Woodcock provides highlights of her detail

Implementing quality systems, collaboration with NIH top list

BY JANET WOODCOCK, M.D.

Over the past few months, I've been on detail to the Office of the Commissioner, working on special projects. My plan was to get these well underway and return to CDER in late April. I've been enjoying working with many of you to get these initiatives started.

As you know, I have been asked to extend my detail in order to serve as the acting deputy commissioner for operations. I will continue to work on the various initiatives, and I will also be charged with managing a number of day-to-day program operations. The length of this detail is open-ended, but I will try to keep you well informed of any plans for the future as they develop.

A number of the initiatives I have been working on, such as quality systems and better collaboration with the National Institutes of Health, will have a long-lasting and far-reaching impact on the way we do our work.

Quality systems

We are starting down a long road to quality systems to bring order and clarity to the Agency's work. We already have many quality systems and subsystems in place, so we will build on those.

The basic concepts underlying quality systems are quite simple: say what you do, do what you say, prove it and improve it. We have been working on developing common nomenclature and a jargon-free framework to help you

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Office of Testing & Research first to move to White Oak

BY PATRICK E. CLARKE

The Office of Testing and Research is the first CDER group to make the long-awaited FDA consolidation move to the White Oak facilities. While there were some glitches, overall the move has been very positive for the office, according to **John M. Strong, Ph.D.,** deputy director of the Laboratory of Clinical Pharmacology.

"The CDER laboratory component has been trying to consolidate since I started with the Center in 1990," Dr. Strong said. "We've had laboratories located in Gaithersburg, D.C. and Laurel. Now, we are consolidated for the first time since I've been here."

He regards the consolidation of divisions as the biggest asset of the move (click here to view photographs). "Now, we have direct communication between all of our investigators, which provides the opportunity for more collaboration and can be more intellectually stimulating," Dr. Strong said.

In addition to the Laboratory of Clinical Pharmacology, the 48-member office includes the Divisions Applied Pharmacology Research,

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FDA issues draft guidances on direct-to-consumer advertising

FDA issued three draft guidance documents designed to improve communications to consumers and health care practitioners about health conditions and medical products on Feb. 4. The guidances are the result of FDA research and policy development, and were influenced by public participation at an open meeting on consumer-directed advertising held by FDA in September (November *Pike).*

The draft guidances provide advice on:

- Alternatives to the lengthy, detailed and technically written "brief summary" of risk information for consumer-directed print advertisements for prescription drugs, with the goal of increasing consumer understanding of the key risks of the product.
- The use of disease awareness communications, which are designed to educate patients or health care practitioners about particular diseases or health conditions and do not promote a particular medical product, with the goal of getting more patients to

(Continued on page 8)

JOE'S NOTEBOOK

Black History Month: Our scientists' stories

For Black History Month, I usually tell the story of an African-American pioneer in a particular field. This year, however, given chemistry's long-standing problem in attracting blacks into the field, I thought you might like to hear from some of CDER's own black chemists.

National statistics outline the depth and structure of the problem. There are about 1,200 to 1,300 doctorate degrees in chemistry awarded each year in the United States. As late as 1987, less than 1 percent in any year were earned by African-Americans. The percentage has increased to about 3 percent currently, but never more than 50 a year. In 1997, blacks made up 11.4 percent of the U.S. population, 10.3 percent of the workforce but only 3.4 percent of the scientific, engineering and technical workforce.

The disproportionately low numbers of African-American students enrolled in and graduating from chemistry graduate programs stems from influences in family, school, neighborhood and American culture. Some of these influences cause or result in race and gender bias in education at all levels. Some limit the vision of young African-American students.

I asked four black scientists in our Office of Pharmaceutical Science about some of the influences and challenges they faced in pursuing their dream of a career in chemistry. It's hardly a scientific survey, but a persistent drive on the part of all to learn about science appears to be an underlying theme. The scientists are:

- **Leon Epps, Ph.D.,** from the Office of Biotechnology Products.
- **Andre Jackson, Ph.D.,** from the Office of Clinical Pharmacology and Biopharmaceutics.
- **Sherita McLamore, Ph.D.,** from the Office of New Drug Chemistry.
- **Milton Sloan, Ph.D.,** also from the Office of New Drug Chemistry.

Family support for educational and career choices is a key, regardless of race or economic situation. For example, despite a lack of family or friends who were scientists, Dr. McLamore's father pushed her to pursue her Ph.D. Dr. Epps was the first in his family to graduate in chemistry. His grandmother completed a nursing program in the 1930s or 1940s but was unable to work as a nurse. "Both family and friends were and continue to be supportive," Dr. Epps said. "I am most proud to have mentored many friends, students and associates over years and it is a honor to continue to do so."

Dr. Sloan notes his family was delighted with his choice. "I was always curious as to how things were put together and came apart," he said. "Although, they may have been surprised to learn that I was curious even down to the molecular and atomic level."

All had an early interest in science and benefited from schools or programs that supported high school science. "I liked science and math in high school. History wasn't exact enough for me," said Dr. Jackson, who graduated in 1963 from Baltimore Polytechnic High School. He recalls a geometry teacher who told him to "stop fooling around" and set him on the straight-and-narrow scholastic path.

Drs. Epps, McLamore and Sloan earned their undergraduate degrees at one of the country's historically black colleges and universities. They report supportive teachers and mentors at college and graduate school. "I consider myself very fortunate in that my mentors and preceptors were able to look beyond things that made little difference," Dr. Sloan said. Dr. Jackson reported that he painfully figured out on his own how to pursue science despite discouragement and a lack of role models.

You can find more information and statistics on blacks in chemistry on a Web site maintained by Princeton University librarian, Mitchell C. Brown, at http://www.princeton.edu/~mcbrown/display/faces.html.

news along the pike

The Pike is published electronically approximately monthly on the World Wide Web at:

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

Photocopies are available in the FDA Library (Parklawn Room 11B-40) and its reading rooms (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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ORGANIZATION DEVELOPMENT CORNER

First phase of CDER culture survey completed, employees briefed

BY KEN WRIGHT

We are pleased that work on the first phase of the CDER Culture Survey has been completed. The contractor held briefings for the Center's Senior Management Team and 10 all-employee sessions in six different locations, including a video broadcast to employees in St. Louis.

An impressive survey response rate of 58.1 percent exceeded any previous Centerwide survey by almost 30 percent. The survey results were highly favorabile when compared to other government and corporate benchmarks. Thank you for your participation!

Many of the questions during the survey briefings centered on what CDER is planning to do with the survey information. The SMT recognizes that, although the results are positive, there are opportunities for moving the Center to higher levels of quality performance and continuous improvement. The SMT desires to open the lines of communications in achieving this goal in strengthening our corporate culture and involving all employees in the process.

The SMT is planning a second round of follow-up briefings and dialogue sessions with each major program office by the contractor Herbert Wong, Ph.D., and myself.

First, copies of Dr. Wong's briefing, including Centerwide indices and organization specific indices will be distributed to each CDER management officer. The management officers have the responsibility for distribution within each of their program offices as appropriate.

In the near future, each program office will meet with the management and employees for a session on their organization's findings to generate dialogue and ideas to address the findings.

The contractor will also be conducting further demographic analysis specific to each program office and sharing the results during these sessions.

We want to assure you that the SMT is committed to using the results of this comprehensive study and growing our corporate culture to be a responsive, flexible, and an even higher performing quality organization.

What can you do to help make this happen? By participation in the future dialogue sessions in each of your program offices.

Ken Wright heads the CDER organizational development program in the Office of Executive Programs and is project offi-

FDA Library consolidation to preserve local user services

BY KAREN KAPUST

The new, consolidated FDA Library officially began operations on Dec. 14. The consolidation, a result of a competitive outsourcing known as the "A-76 process" (Oct. 2 Pike), will preserve effective local user library services and save dollars by centralizing behind-the-scene, backbone services.

What does this mean to you? Once we're fully implemented you should see more effective library services. Also, you will soon have an online, merged library catalog of all FDA Library holdings and an FDA Library Web portal acting as a gateway to all our electronic products, including virtual journals and databases.

All direct user services will continue to be provided at their current physical locations. The names of these locations will be changed to identify them as FDA Library branches and reading rooms. The FDA Medical Library facility in Parklawn will be known as the Main Library since most of the technical services functions will be performed there.

The CDRH, CFSAN and NCTR Libraries are now the CDRH, CFSAN and NCTR Branches. The former Corporate Boulevard, MOD 1 and Woodmont II Branches are now reading rooms.

While technological enhancements and movement to a more virtual environment provide opportunities for improved services and eventual cost savings, implementing the new FDA Library has brought its share of challenges. Quite a few former staff members have chosen not to remain with the Library and have accepted other positions. We are currently recruiting to fill a number of reference librarian and library technician vacancies.

In the meantime, we will make every effort to meet your information needs; however, we ask for your patience and understanding while we fill our vacacies.

All locations will remain open during their normal hours, but to conserve staffing, we will temporarily abbreviate Reference Desk staffing hours. Reference librarians will still be available by phone or e-mail during our normal hours. Check with the library you regularly use for changes in desk staffing.

As we move into 2004, our staff will continue to provide the very best service it can within our current resources. Our commitment is to maintain the high level of customer service you have come to expect. We look forward to working with all of you in the year ahead.

Karen Kapust is the director of the FDA Library.

Draft guidance on access to investigational treatments

FDA on Jan. 27 issued a draft guidance designed to make further information about the use of investigational drugs more readily available.

The draft guidance is part of the Best Pharmaceuticals for Children Act and is designed to augment information available in the Clinical Trials Data Bank (http://www.ClinicalTrials.gov).

The new information required by the BPCA includes a description of whether and through what procedure the sponsor of the research will respond to requests for access to the therapy outside of the clinical trial setting, particularly in children. This draft guidance explains how to provide that information in a straightforward and efficient way.

Clinical Trials.gov was developed by the National Library of Medicine following passage of the Food and Drug Administration Modernization Act of 1997.

INFORMATION MANAGEMENT CORNER

CDER to develop integrated system for regulatory documents

BY DON DUGGAN

The Center has started work on a major information management project to develop a single integrated system that will eventually accommodate all of CDER's regulatory submissions, including new drug applications, generic drug applications, biologics license applications and investigational new drug applications.

The new system will be called the Document Archiving, Reporting and Regulatory Tracking System, or DARRTS for short. It will replace CDER's current systems supporting the receipt, management and reporting of information about investigational and marketing submissions for human drugs and therapeutics.

The systems being replaced include:

- Components of the Centerwide Oracle Management Information System or COMIS.
- The Division Files System or DFS.
- CDER Standard Letters.

The DARRTS project is quite large in scope and a complete rollout of all identified functionality is likely to take a few years to complete. Therefore, the system will be rolled out in phases. We are currently analyzing the functionality that will be released with the first phase.

The Office of Information Management and the Office of Information Technology are working jointly to manage the DARRTS project. We have contracted with ProObject, a consulting firm specializing in advanced system design and development, to assist us in the requirements and development phases of the project.

Background

Several years ago, the Center had started separate projects to upgrade the functionality of these three core systems so that they would better meet CDER's business requirements. The new projects to redesign these systems had been identified as STARS, E-Document Check-In and E Document Generate, respectively.

We accomplished a great deal as a result of the combined work of the project team and CDER business community, including Office of Generic Drugs, the Office of New Drugs and the Office of Pharmaceutical Science. However, we became aware that the three applications had significant interdependencies, and we would need to revisit requirements based on an integrated vision.

We stopped work on the three projects and began DARRTS. The new project will revisit the "big picture" view of the integrated requirements for all of these legacy systems to ensure that we deliver a system that provides a comprehensive business solution to CDER's regulatory needs.

The good news is that much of the data and work conducted during the earlier efforts will be used in the DARRTS project.

For the past couple of months, we have been conducting joint application development sessions with many of you throughout the Center. You have been extremely valuable to us in our efforts to understand fully the business needs of the Center. With your help, we have wrapped up our requirements gathering phase. We have begun working to iron out the technical details of the system.

If you want more information about this project please contact me.

Don Duggan is the OIM project manager for DARRTS.

PIKE'S PUZZLER

True or false test

BY TONY CHITE

Determine if each statement is true or false.

1. Of the 23 pairs of chromosomes normally present in human cells, one pair (called the sex chromosomes) determines the individual's sex. The normal female chromosome pattern is XY; the normal male pattern is XX.

2. Kepler's First Law states: The orbit of a planet or comet about the sun is an ellipse, with the sun's center of mass at one focus.

3. Moe's Scale is used to grade the hardness of a mineral. Talc scores the lowest with a score of 1; while diamond scores the highest with a score of 10.

4. The pH scale ranges from 0 to 14. At the 0 end, the concentration is increasingly acidic. Most biological fluids are between pH 6 and pH 8.

5. On the aluminum cap atop the Washington Monument in Washington are two words: *Laus Deo,* a Latin phrase which means "Praise be to God."

Answer Key: 1.F; 2.T; 3.T; 4.T; 5.T.

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

Drug OK'd for cancer linked to asbestos

On Feb. 5, FDA approved pemetrexed disodium (Alimta) for use in combination with cisplatin for the treatment of patients with malignant pleural mesothelioma. The drug received a priority review and is designated as an orphan drug. It is the first drug approved for this condition.

Cancer of the mesothelium, a membrane that covers and protects most of the internal organs of the body is rare—about 2,000 new cases are diagnosed in the United States each year.

This form of cancer is usually associated with a history of asbestos exposure. Asbestos fibers lodged in the lung attach to the outer lung lining and chest wall, causing tumors to grow. By the time symptoms appear, the disease is usually advanced, and patients live, on average, nine to thirteen months following diagnosis.

Up to now there has been no effective treatment for treating mesothelioma. The effectiveness of pemetrexed was established in one randomized clinical trial comparing the effects of treatment with pemetrexed given with cisplatin to treatment with cisplatin alone. Patients receiving pemetrexed and cisplatin lived three months longer after randomization than patients given cisplatin alone (12 months vs. nine months). More information is available on CDER's Web site at http://www.fda.gov/cder/drug/infopage/alimta/default.htm.

Your account to be duplicated on new system, log-on to change

BY JIM MARSHALL AND JOE NEUBAUER

At the end of May, CDER will begin using a new system to log into the FDA network and its resources. This will begin the first of three phases of change for CDER related to this new system.

Over the Memorial Day weekend (May 28 to May 31) all CDER network accounts will move to this new system. Your network accounts are what give you access to your PC, your e-mail and other resources such as file shares and printers.

Why this is taking place…

FDA has transitioned to a shared services model for certain support functions. As part of this transition, FDA is consolidating the computing resources of individual centers. This allows us to maximize our tax dollars by eliminating redundant servers, maintenance and support needs.

Consolidating computing resources gives us other opportunities to improve and enhance the services and applications that allow you to do your jobs more effectively.

For example, the new system will eventually provide new and enhanced ways for you to find network resources such as file shares and printers by building, floor or office. There may even be options for you to find a specific kind of printer, such as one that can bind, as well as print, a document.

What this mean for me…

Starting on June 1, your FDACDER account will be duplicated on this new system. The new account will be used to log into resources. The goal is to make this transition as transparent as possible, so every effort is being made to minimize change.

As June 1 approaches, we will provide more details about anything new or different you will have to do. Until then, we want to give you an example of one of the changes so you'll have some feel for what will be different: When you come to work on June 1, you'll need to replace FDACDER with the new system's name—FDA—when logging on to your PC.

Some things that will remain the same are:

- Your existing user name and password.
- All your desktop settings, shared drives, Outlook profiles and printers.

As we get closer to the Memorial Day weekend transition, look for more instructions and information on the transition's status via CDER OIT All Hands e-mails, a Web page (to be announced) and future *Pike* articles.

Jim Marshall and Joe Neubauer work in

March OIT Training

Tuesday	Wednesday	Thursday	Friday
2	3 Enterprise Search 1-4 (C)	4	5
9 JMP I 9-12 (C)	10 AERS DataMart 1-4 (P) Enterprise Search 1-4 (P)	11	12 EST (Electronic Submissions Training) 9-12 (P) EDAT (Electronic Data Analysis Training) 1-4 (P)
16 DFS 9-12 (C)	17 DSS 9-12 (C)	18 Broadband 1-2:30 (P)	19
23 JMP II 9-12 (C) Enterprise Search 9-12 (P)	24	25 Enterprise Search 9-12 (C)	26

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

FDA launches consumer campaign on safe use of OTC pain products

BY MANDY EISEMANN

On Jan. 22, FDA launched a national education campaign to provide advice on the safe use of over-the-counter pain and fever reducers. The campaign focuses on OTC drug products that contain acetaminophen and nonsteroidal anti-inflammatory agents, which include products such as aspirin, ibuprofen, naproxen sodium and ketaprofen.

Many OTC medicines sold for different uses have the same active ingredient. To minimize the risks of an accidental overdose, consumers should avoid taking multiple medications that contain the same active ingredient at the same time.

The campaign will include:

- An OTC pain reliever brochure to be distributed in pharmacies and by health care providers.
- A newspaper article to be distributed to 10,000 community papers across the country.
- Two print public service ads that will be sent to approximately 100 major magazines.
- A reprint of "Use Caution With Pain Relievers", an *FDA Consumer* magazine article that will be distributed at national healthcare conferences and available for reprinting in health-related publications.

All of these materials are available on CDER's Web site at http://www.fda.gov/cder/drug/analgesics/default.htm.

The campaign will provide advice on how to avoid inadvertently taking more than the recommended doses of these medicines.

For more information or copies of the campaign products, please contact me.

Mandy Eisemann, a public affairs specialist in DPA, is the project officer for this campaign.

FDA task force issues final report on counterfeit drugs

FDA's final report on counterfeit drugs highlights specific steps the Agency is taking to keep the U.S. drug supply secure against increasingly sophisticated criminal efforts to introduce counterfeit drugs.

The report addresses growing concerns about the threat to consumers posed by counterfeit drugs. Though counterfeiting is not now widespread in the U.S. drug market, FDA is investigating more cases of such activity, often involving well-organized criminal operations working to introduce finished drug products that resemble legitimate drugs but may contain only inactive ingredients, incorrect ingredients, improper doses or be otherwise contaminated.

The comprehensive report highlights ways to assure that the nation's drug distribution system protects Americans from counterfeit drugs. These measures address six critical areas:

- Securing the actual drug product and its packaging.
- Securing the movement of the product as it travels through the U.S. drug distribution chain.
- Enhancing regulatory oversight and enforcement.
- Increasing penalties for counterfeiters.
- Heightening vigilance and awareness of counterfeit drugs.
- Increasing international collaboration.

The report was issued by an FDA task force, created in July 2003, to identify steps that FDA, other government agencies and the private sector could take to minimize the risks to the public from counterfeit medications entering the nation's drug distribution system.

The task force met with and heard from security experts, federal and state law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups and the general public. In October 2003, the task force issued an interim report that was followed by a public meeting and technology forum where 72 presentations were made.

The FDA report addresses the safety and security of the legal U.S. drug supply, which the Agency regulates. The FDA does not have the legal authority or resources to assure the safety and efficacy of drugs purchased from other countries outside this legal drug distribution system, or from unregulated Internet sites that are not run by pharmacies licensed and regulated by states.

The report describes specific steps that can be taken now and in the future to protect consumers from counterfeit drugs and to secure the U.S. drug distribution system. These measures include:

- Implementation of new technologies to better protect legitimate drugs against tampering or replacement with counterfeits.
- Adoption of reliable modern track-and-trace technology, which FDA has concluded is feasible by 2007, to accomplish and surpass the goals of the Prescription Drug Marketing Act.
- Adoption and enforcement of stronger anti-counterfeiting measures by the state regulators of drug wholesalers and distributors.
- Increased criminal penalties to deter counterfeiting and more adequately punish those convicted.
- Adoption of secure business practices by all participants in the drug supply chain.
- Development of a system that helps ensure timely and effective reporting of counterfeit drugs to the FDA and that strengthens the ability of the FDA, other regulatory agencies and the other participants in the drug distribution system to respond rapidly to such reports.
- Education of consumers and health professionals about the risks of counterfeit drugs and about how to respond if they encounter such products.
- Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs globally.

Implementing these steps will:

- Help prevent the introduction of counterfeit drugs into the U.S. drug distribution chain.
- Facilitate the identification of counterfeit drugs.
- Minimize the risk and exposure of consumers to counterfeit drugs.
- Avoid unnecessary additional costs in the prescription drug distribution system, and unnecessary restrictions on lower-cost sources of drugs.

The FDA Counterfeit Drug Task Force Final Report is available at http://www.fda.gov/oc/initiatives/counterfeit/.

Import 'blitzes' reveal potentially dangerous imported drug shipments

FDA and the Customs and Border Protection Agency announced in January that their second series of import blitz examinations found 1,728 unapproved drugs, including so-called "foreign versions" of FDA-approved drugs, recalled drugs, drugs requiring special storage conditions, drugs requiring close physician monitoring and drugs containing addictive controlled substances.

These findings provide additional evidence of the serious risks posed by the illegal importation of prescription drugs. Unapproved drugs lack assurances of safety, effectiveness, quality and purity. Moreover, FDA cannot assure the safety and efficacy of a drug product the Agency has not reviewed and approved and when FDA has not monitored the manufacturing and quality control processes of the facility in which the product was produced.

The blitz examinations were performed in November at the Buffalo, Dallas, Chicago and Seattle mail facilities and the Memphis and Cincinnati courier hubs In September, FDA released the results of a similar study which had also been conducted in collaboration with Customs at the Miami, New York (JFK), San Francisco and Carson, Calif., mail facilities in July and August.

The most recent blitz marked the first time that imported drugs entering the country through courier hubs were targeted in addition to those that pass through mail facilities.

Details regarding the first joint FDA and Customs import blitz, which occurred in July-August 2003, are available online at http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html.

Details on the most recent blitz are at http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html.

Office of Testing and Research is first to move to White Oak

(Continued from page 1)

Analysis. They moved into the first and second floors of what is known as the Life Sciences Building. OTR has some administrative offices on the third floor, but the third and fourth floors are mainly occupied by Center for Devices and Radiological Health. "CDER and CDRH will share the animal facility in the basement, which isn't quite completed yet," Dr. Strong said.

Dr. Strong had high praise for the people who coordinated the move. "Timothy Hinton was the contractor who oversaw the move. He met with all the scientists and researchers, was always available to us and overall did a wonderful job."

He also singled out **Patricia Long-Bradley,** who was the CDER contact for both the laboratory and office moves. "She did an amazing job juggling all the myriad details involved in making this move," Dr. Strong said.

She also has contributed greatly to setting up the animal facility and, after moving to the Center for Veterinary Medicine, is presently the program officer for the animal program at White Oak.

Dr. Strong also mentioned that **Tammy Mueller** should be recognized for her efforts after becoming the OTR contact for issues involving White Oak following the move. Among other duties, she was the one who received all the complaints from the end-users concerning modifications that were required to their laboratories or offices.

Dr. Strong was one of the scientists on the design committee for the Life Sciences building and served as a CDER technical point of contact regarding the move. His involvement with the White Oak consolidation goes back a few years. In fact, he recalls representing CDER approximately eight to nine years ago at a meeting between FDA and military officials at the White Oak facility to discuss the possible impact of ongoing armed forces' initiatives on any future CDER laboratories.

Nine years later, he's still working out details for OTR. "Tammy and I went through all the labs and offices and discussed with the laboratory personnel any deficiencies requiring attentions. This information was used to develop a punch list, or list of building deficiencies, which was given to the facilities people to work on," Dr. Strong said.

"I was impressed. My guess is that they got 90 percent of the building right, but there's always that 10 percent," Dr. Strong said. Those for the most part are minor things, according to Dr. Strong, such as power outlets that aren't the correct type or haven't been placed in the correct area and shelving that needs to be added to the laboratories. "These things are to be expected, but it can take up to a year to get everything corrected," Dr. Strong said.

One area that was a rather large glitch was the movement of chemicals to the White Oak facility. "The movement of the lab equipment, glassware and so on, wasn't well-coordinated with the movement of chemicals," Dr. Strong said. "We had all of our equipment moved during the first and second weeks of December, but we didn't get all of our chemicals delivered until around January 16."

He also pointed out that while they do have a nice kitchen and canteens in the building, they lack a cafeteria. Some of the support staff who depend on public transportation are having some problems with the move.

"But, something that everyone appreciates is that we all have our own offices," Dr. Strong said. "Before, except for senior investigators, most of the scientists just had desks located in their labs. Plus, because the offices have been placed next to the outside building wall, we even have windows. There's a very open, light feel to the whole work area."

Dr. Strong does have one bit of advice for other offices planning their move to White Oak: "Don't ever plan to move in the month of December with the holiday season coming on—it can be next to impossible to contact people. There were some immediate things we needed done and we just couldn't reach people."

Dr. Strong acknowledged that people in OTR had apprehensions about the move. "After all, we were the first, the pioneers, so to speak. But now, I think by far the majority of us are happy to be in such a spacious, intellectually stimulating environment."

FDA approves monoclonal antibody cetuzimab to treat colorectal cancer

FDA on Feb. 12 approved cetuximab (Erbitux) to treat patients with advanced colorectal cancer that has spread to other parts of the body. Cetuximab is the first monoclonal antibody approved to treat this type of cancer and is indicated as a combination treatment to be given intravenously with irinotecan, another drug approved to fight colorectal cancer, or alone if patients cannot tolerate irinotecan.

Cetuximab was approved under FDA's accelerated approval program, which allows FDA to approve products for cancer and other serious or life-threatening diseases based on early evidence of a product's effectiveness. Although treatment with cetuximab has not been shown to extend patients' lives, it was shown to shrink tumors in some patients and delay tumor growth, especially when used as a combination treatment.

Cetuximab is a genetically engineered version of a mouse antibody that contains both human and mouse components. It can be produced in large quantities in the laboratory. This new monoclonal antibody is believed to work by targeting a natural protein called "epidermal growth factor receptor" or EGFR on the surface of cancer cells, interfering with their growth.

For patients with tumors that express EGFR and who no longer responded to treatment with irinotecan alone or in combination with other chemotherapy drugs, the combination treatment of cetuximab and irinotecan shrank tumors in 22.9 percent of patients and delayed tumor growth by approximately 4.1 months.

For patients who received cetuximab alone, the tumor response rate was 10.8 percent and tumor growth was delayed by 1.5 months.

Colorectal cancer—cancer of the colon or rectum—is the third most common cancer affecting men and women in the United States and is the second leading cause of cancer-related death.

Dr. Woodcock's top projects: quality systems, NIH collaboration

(Continued from page 1)

implement quality systems in your work.

The Senior Management Team and I will be having a strategic planning retreat in preparation for the quality systems program that will have projects starting in the summer

Collaboration with NCI

We are exploring ways to facilitate interactions between FDA and NCI in the development and review of drugs and biologics to treat cancer.

As part of the FDA-NCI collaboration we will pull together all that's known about the use of imaging agents in oncology drug development and make that available to developers and reviewers. We have a large steering committee that will invite speakers and likely organize a workshop on imaging techniques. We are setting up three subcommittees to draft papers for publication in peer-reviewed journals on:

- Development of volumetric anatomical imaging for oncology—revision of RECIST (Response Evaluation Criteria in Solid Tumors).
- Validation of FDG-PET for oncologic drug development and as a surrogate endpoint for drug approvals.
- Pathway for accelerating molecular imaging including first-in-man studies in diagnosed cancer patients.

We are also working on clarifying various regulatory procedures.

NIH Roadmap

We are setting up other collaborations with the NIH on their Roadmap initiative. Achieving some of their objectives, especially in the clinical research area, will require partnership with FDA. The NIH Roadmap sets forth an ambitions vision for a more efficient and productive system of medical research. It focuses on the most compelling opportunities in three areas: new pathways to discovery, research teams of the future and re-engineering the clinical research enterprise. (More information is available at http://nihroadmap.nih.gov/.)

Good Manufacturing Practices

I will continue to chair the GMP initiative. In addition to moving this broad initiative forward, we also are working on a multicenter draft guidance that will help laboratory- and small-scale drug developers comply with our cGMP regulations. This will help researchers, who only make a batch or two of a drug for investigational use in humans, understand what is required to reproducibly make a good quality investigational product. The cGMP regulations were writen primarily with large-scale production and postmarketing manufacturing operations in mind.

Follow-on biologics

We are writing a scientific guidance that describes the principles of determining the similarity of protein molecules. CDER regulates proteins of many kinds under the Food Drug and Cosmetic Act and also the Public Health Service Act.

Cross-Agency guidances

We want to expedite publication of guidances on pharmacogenomics and drug-eluting coronary artery stents. The comment period on the pharmacogenomics guidance closed on Feb. 2, and we are evaluating the comments. We have set up a working group to begin drafting the drug-eluting stent guidance.

Center Director Janet Woodcock is currently on detail as the deputy FDA commissioner for operations.

FDA draft guidances encourage more consumer-friendly DTC advertising

(Continued from page 1)

discuss under-treated conditions with their doctor.

- Compliance with federal risk disclosure rules for consumer-directed broadcast advertising for certain medical devices.

Brief summary

Typically, manufacturers fulfill the brief summary requirement by including the complete risk-related sections of the FDA-approved professional labeling in the ad in small type. Risk information presented in this manner is designed to satisfy applicable regulations but is not user friendly.

While this risk information is technically in compliance in that it contains important information on benefits and risks, it does not convey key information effectively to many consumers. This draft guidance is designed to encourage manufacturers to deliver more user-friendly information to the public so that they can be better-informed partners in their own health care.

Help-seeking, disease awareness ads

This draft guidance clarifies the criteria that FDA will use to distinguish manufacturer communications that provide information about the importance of recognizing that certain signs and symptoms may be evidence of a treatable disease from manufacturer promotional messages for particular treatments for a disease. The latter, but not the former, are subject to FDA regulation as advertising or promotional labeling.

FDA hopes that, by providing clarity, it will encourage manufacturers to provide more educational messages to the public. This draft guidance includes clarifications on "bookend" advertisements in print or broadcast formats. These advertisements or labeling pieces consist of two parts:

- First is either a "reminder" piece, which includes the name of a drug or device but makes no safety or effectiveness claims or a full product promotional piece.
- Second is a disease awareness message, which encourages consumers to seek health care practitioner assistance or practitioners to provide such assistance in identifying and treating a particular health condition but does not mention any product by name.

Disease awareness and reminder communications alone would not be subject to FDA rules for requiring risk disclosure. But, when reminder and disease awareness or full product and disease awareness pieces that use similar themes, story lines or other presentation elements are taken together, FDA is concerned that they can be understood as product claim pieces and the Agency will regulate them as such.

The draft guidance provides advice to manufacturers on the criteria FDA uses in determining whether such disease awareness messages are subject to regulation as advertisement or labeling. The criteria, in brief, are whether the two components are perceptually distinct and whether they are separated in space or time.