news along the pike

JANUARY 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

PIKE'S CORNERS

FDA Centralizes Agency's International Activities

New Office Promises Improved Support for Center's Programs

BY JUSTINA MOLZON, M.S.PHARM., J.D.

With the growth of world trade in FDA-regulated commodities, the increase in international standard setting and continued limited resources, the Agency needed a coordinated approach to international affairs, said **Sharon Smith Holston,** deputy commissioner for international and constituent relations. The Agency hopes to leverage the efforts of its regulatory counterparts around the world. "That will more and more be a part of the way we do business," she said.

The newly formed Office of International Programs, for which Holston is acting director, consolidates international activities that were formerly spread among half a dozen offices at Agency headquarters. The new organizational structure will serve to facilitate the Center's foreign relationships, provide overall policy guidance to the Center, ensure that the Agency is working on international issues in a coordinated fashion internally and represent the Agency's point of view within the federal government, Holston said. The office will set priorities, allocate resources and provide a tracking

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Mutual Recognition Agreement Explained Publicly

BY ERIK HENRIKSON

At a Dec. 8 public meeting, FDA and CDER officials outlined the Agency's progress in implementing provisions of the Mutual Recognition Agreement concerning "equivalency" of inspections of pharmaceutical manufacturers in the 15 member states of the European Union and the United States.

In addition to updating stakeholders on implementation progress and issues, the meeting provided a brief overview of the agreement between the United States and the European Union. Once the agreement becomes operational in December 2001, FDA would accept inspections performed by E.U. member states found to have equivalent systems.

The approximately 90 attendees included a cross section of representatives from industry, trade associations, foreign embassies and consumer organizations. Several members of the press were present, along with a number of former and current agency employees. While industry representatives were generally supportive of the agreement, they and representatives from the press and consumer groups expressed concerns about the agreement's potential for adversely affecting the public transparency of FDA's operations.

International programs are playing an in-

(Continued on page 11)

CDER Pharmacist Helps Malaysia Explore Drug Quality

BY VAIYAPURI SUBRAMANIAM, R.PH., M.S.

KUALA LUMPUR, Malaysia—It is not just the United States and other industrialized countries that are taking an interest in drug product quality and patient safety issues.

The Malaysian Ministry of Health invited me to represent the FDA at its pharmaceutical and cosmetic regulatory seminar held in October in their capital city. The seminar focused on post-market drug surveillance, good manufacturing practices, pharmacovigilance, patient communications and regulatory affairs.

The Agency presentation covered present activities and initiatives in FDA's post-market programs that help it meet its mission to assure the quality of drug products. In addition, I discussed efforts by the Center's Office of Compliance Post-Market Surveillance Working Group to enhance the effectiveness of the surveillance programs as well as developing cost-effective approaches in drug sample collection and analysis.

The seminar was attended by representatives from regulatory agencies, pharmaceutical manufacturers and professional pharmacy and

(Continued on page 10)

JOE'S NOTEBOOK

Black Chemist Percy Julian's Legacy

Like many African Americans we acknowledge during the upcoming Black History Month, chemist Percy Julian is little known by name but lives on through his contributions. His work revolutionized the treatment of glaucoma and arthritis. By synthesizing physostigmine in 1935 and finding a better way to synthesize hydrocortisone in 1948, he made drugs that once cost hundreds of dollars per drop available for a few cents a gram. His method of synthesizing hydrocortisone is the one most widely used today. He also figured out ways to use soybeans for everything from food to fire extinguishers. His face graces a 29-cent postal stamp issued in 1993, and the American Chemical Society has declared his 1935 achievement with physostigmine a national historic chemical landmark.

Julian was born in 1899 in Montgomery, Ala., the son of a railway clerk and the grandson of slaves. A good student, he was barred from the college preparatory program in the local public high school. Nonetheless, Julian gained admittance in 1916 to DePauw University in Indiana, a predominantly white school that accepted African American students. As he left the family home to pursue his ambition to become a chemist, his grandfather waved goodbye with a three-fingered hand—the two missing fingers had been severed as punishment for learning to read.

Julian worked his way through DePauw by digging ditches and waiting tables at a fraternity. He graduated in 1920 with a Phi Beta Kappa key and at the top of his class as valedictorian. Eager to earn an advanced degree, his professors discouraged him, saying he would have great difficulty in pursuing his profession. After graduation, Julian joined the faculty of Nashville's historically black Fisk University.

After two years at Fisk, he won a fellowship to Harvard University and earned his master's in 1923; however, he was denied the teaching fellowship that customarily led to a doctorate at Harvard. He taught at West Virginia State College and, in 1928, headed the chemistry department at Howard University. Awarded a Rockefeller Foundation grant in 1929, he enrolled at the University of Vienna in Austria where he studied organic chemistry with Ernst Späth and received his Ph.D. in 1929.

Returning to the United States in 1931, he taught at first at Howard and then at his *alma mater*, DePauw, where he completed his landmark synthesis of the drug physostigmine, which had only been available from the natural source, the Calabar bean. The sole glaucoma treatment at the time, physostigmine drops reduce the high intraocular pressure that can lead to blindness.

Even though the physostigmine work earned Julian worldwide acclaim, DePauw declined to appoint him to its faculty. Disgusted, he left academia and joined the Glidden Company in Chicago—today best known for its paints—as head of its soy products division. Julian made a wide variety of products from soybeans, including sex hormones, other steroids and foams to extinguish oil and gas fires. His research resulted in more than 160 patents. Elected to the National Academy of Sciences in 1973, he was also widely recognized as a steadfast advocate for human rights. He retired a wealthy man and continued his research and served as a consultant to the pharmaceutical industry until his death in 1975.

The American Chemical Society, of which Julian was a member, encourages African American and other minority students to study chemistry through the ACS Scholars program. Scholarship applications for the 2000-2001 year are being accepted through March 1. For more information contact the society at 1-800-227-5558, ext. 6250, or visit the ACS Web site at http://www.acs.org/minority affairs. More information about Julian and the ACS landmark program are available at http://www.acs.org/landmarks/julian/index.html.

news along the pike

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

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

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

OMBUDSMAN'S CORNER

CDER's Pet Peeves—Part II

BY JIM MORRISON

This month's column concludes my report of an informal, Centerwide poll seeking feedback on what behaviors by the regulated industry bug our staff the most. Remember, industry folks suggested this topic, so I hope it proves useful in improving our interactions.

In my last column, I covered complaints regarding overly aggressive communications and quality problems with submissions. This month we'll look at unrealistic expectations and what may appear to Center staff to be industry attempts at "gaming the system."

Unrealistic Expectations

Several complaints involved firms' requests for exceptions from stated policies and procedures or for special treatment, such as expedited review or moving up in the queue. Naturally, each such request is justified by appeals to the staff member's sense of fairness and equity. Appeals usually cite hardships, sometimes, but not always, created by CDER's past actions. It's just not realistic to expect Center staff to bend or break established rules of procedure or change priorities to accommodate everyone's specific circumstances.

Were CDER to honor these requests, charges of favoritism and misfeasance would soon follow. If you really feel you've suffered a grave injustice that needs to be addressed, I would recommend that you talk with the director of the appropriate division or contact me.

Another common complaint was that newcomers to the pharmaceutical industry sometimes expect CDER to function as a consulting service. Many of us in the Center have been approached by someone who claims to have discovered a great treatment for a disease and wants us to tell him or her how to get the product on the market. I always recommend that neophytes seek the services of a consultant.

The Center makes a lot of information about the drug review process available through the Internet and elsewhere, and it offers guidance to the industry in meetings. However, it is unrealistic to expect that the limited time CDER staff members have would be sufficient to guide a company through the entire drug product development process. One shouldn't expect extensive training in drug development from CDER anymore than one would expect training on how to build a space station from NASA.

Other examples of unrealistic expectations include:

- Asking for a determination when there is clearly insufficient information on which to base a decision.
- Seeking immediate answers to complex regulatory issues at meetings or on the phone.

Gaming the System

The term "gaming the system" implies an intentional effort to subvert or misuse procedures and systems. I know that not all examples of the behaviors discussed below are intentional gaming strategies; however, they are often perceived by Center staff as such.

From my experience, the vast majority of people who work in the regulated industry are honest and try to do the right thing. When their motives are questioned, they are understandably affronted. Industry representatives do try to further their company's position but do not see themselves as gaming the system.

However, CDER staff must occasionally deal with those who seek to test legal and ethical limits. When they see behavior that can be construed as devious, they may well assume the worst—that the person is gaming the system. Avoiding the following behaviors can materially increase trust and improve interactions:

- Deviating from an agreed-upon protocol design to achieve a more favorable result. Examples include changing inclusion and exclusion criteria or using different statistical methods.
- Burying protocol changes or other key information in general correspondence and not discussing them with the reviewing division.
- Exaggerating the consequences of failing to get whatever is being sought. Staff hear so frequently that the company will fold if the requested accommodation is not made, that they routinely ignore such claims.
- Aiming to come as close to the regulatory line as possible or to do the absolute minimum work needed to fulfill regulatory requirements.
- Complaining about a competitor's behavior and then asking to do the same thing if immediate regulatory action is not forthcoming.
- Being less than forthright about safety issues with investigational or marketed drugs.
- Asking CDER to delay an action to avoid adverse publicity or postpone bad news until after a shareholders' meeting or a critical financing decision.

The last two are particularly troubling to Center staff. Nothing destroys working relationships and trust so much as appearing to be willing to trade public safety or corporate reputation for financial advantage. In the long run, strategies that attempt to hide information, even for a short time, cause much more damage than they can ever avoid.

One of the messages I took away from this survey of pet peeves is the wide range of behaviors and ethics to which CDER staff are exposed. It is well for industry people to keep in mind that Center staff are exposed to enough examples of untrustworthy behavior that it may color other interactions. That thought may help those interacting with the Center to forgive staff members who have become generally suspicious.

The most difficult aspects of any type of law enforcement or regulatory work are how to recognize who is trustworthy and who is not—and to deal with each accordingly. It is a credit both to the regulated industry and to CDER staff that the vast majority of interactions between the Center and the regulated industry are positive, straightforward and mutually respectful.

Whether you are a member of the regulated industry or a Center employee, you should be able to expect high standards of professionalism, courtesy and respect in your interactions. I appreciate hearing about interactions that fail to meet those standards. You can contact me by phone or e-mail (301-594-5298, morrisonj@cder.fda.gov).

Jim Morrison is the Center's ombudsman.

SCIENTIFIC EDUCATION

CASE Looks at Biomedical Imaging's Promise for Drug Development

BY DAVID LESTER, PH.D.

During February and March, the Center's Committee for Advanced Scientific Education will offer a number of opportunities to learn more about the latest advances in biomedical imaging and their potential applications to the drug development process. While these sophisticated technologies have had unquestioned impact on the clinical sciences, this series of CASE offerings explores the rapid advances occurring in academia and industry and the exciting directions related to drug development.

Jerry Collins, **Ph.D.,** from the Office of Testing and Research kicked off these educational activities at the Jan. 19 CDER Scientific Seminar with the lecture "Functional Imaging in Drug Development." Other events include:

- *"Topics in Biomedical Imaging."* This series of seven lectures will be presented during February and March on a variety of imaging modalities (MRI, PET, MicroCT, IR) and their applications to the drug development process. Experts from academia and industry will be making the presentations. Check the CDER weekly calendar for exact times and dates. There is no registration but seating will be limited.
- *"Imaging Technology: The Emerging Revolution in Toxicology and Risk Assessment."* **David Lester, Ph.D.,** Office of Testing and Research will give this lecture at 4 p.m. Feb. 14, the first day of the two-day FDA Science Forum to be held at the Washington Convention Center.
- *CDER Scientific Seminar on surrogate markers.* **Greg Downing, M.D.,** NIH Office of Science, will speak on this topic March 1.
- *"Nuclear Imaging and its Application in Drug Development."* A live satellite broadcast course will be offered March 20 and 21 by the Society of Nuclear Imaging in Drug Development. Speakers for the four $2^{1}/_{2}$-hour sessions include national and international experts from academia and industry. Seating will be limited, and you can ask questions at the end of each lecture. The final program including topics will be listed in the weekly calendar and on the Division of Training and Development's CDERnet site at http://cdernet.cder.fda.gov/dtd/index.htm.

For more information, please contact me (LESTERD, 4-5855).

David Lester is a research biologist in the Office of Testing and Research.

PIKE'S PUZZLER

Test Your Knowledge

BY TONY CHITE

1. "The composition and richness that results from a variety of genders, races, cultures, disabilities, ages, language, sexual orientations, ethnicity and religious backgrounds" is defined as:

a. Prejudice. b. Appreciative inquiry. c. Harassment. d. Diversity.

2. To verify status, current and former federal employees may be asked for a copy of their most recent complete SF-50. The SF-50 form is a:

a. Completed resume or SF-171. b. Notification of Personnel Action. c. Notarized letter from current supervisor. d. Copy of college transcripts.

3. The month with the potential for the most federal holidays in the Washington metropolitan area is:

a. November. b. July. c. January. d. December.

4. The Parklawn Building was built in:

a. 1965. b. 1969. c. 1959. d. 1961.

5. The Voluntary Leave Transfer Program allows federal employees to donate unused annual leave to another employee without leave who needs it because of a personal or family medical emergency. A donor may donate accrued leave in minimum increments of how many hours:

a. 1. b. 2. c. $^{1}/_{2}$. d. 8.

6. Prescription drug labeling functions as:

a. An educational tool, providing the prescriber with information needed to use the medication safely and effectively.
b. A legal document, often considered in medical malpractice suits when incorrect prescribing of medication is alleged.
c. A control for the marketing of the drug product, a reference standard for promotional and advertising purposes.
d. A and B only. e. All of the above

7. The Associate Director for International Affairs in the Center is:

a. Sharon Smith Holston. b. Joseph Famulare. c. Janet Jenkins-Showalter. d. Justina Molzon.

8. In 1820, 11 physicians met in the Capitol in Washington to establish the first compendium of standard drugs for the United States known as:

a. The DMF (Drug Master File). b. The U.S.P. (U.S. Pharmacopeia). c. The FDA. d. The Orange Book

9. The application that a drug sponsor must submit to FDA before beginning tests of a new drug in humans is:

a. An NDA (new drug application). b. An IND (investigational new drug application). c. An ANDA (abbreviated new drug application). d. A safety update report.

10. The term "drug" is defined as:

a. Articles recognized in the U.S. Pharmacopeia, Homeopathic Pharmacopeia or National Formulary.
b. Articles (other than food) intended to affect the structure or any function of the body of man or other animals.
c. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.
d. All of the above. e. A and C only.

Tony Chite, P.D., is a consumer safety officer and pharmacist with CDER's Freedom of Information Staff.

Answers: 1d; 2b; 3c (with Inauguration Day); 4b; 5a; 6e; 7d; 8b; 9b; 10d.

National Archives to Assume Custody of Historic CDER Records

Recently, CDER staff, in conjunction with the main FDA Records Office, the FDA Historian and the National Archives and Records Administration, participated in a review of 204 boxes of older records held at the Federal Records Centers in Suitland, Md. The records, dating from 1949 to 1976, covered many topics, including thalidomide and historic investigations of several fraudulent drug products.

The Office of the Commissioner's Executive Operations Staff and OIT's Division of Data Management Systems coordinated the review, with representatives from ODE II, ODE III and the Office of Compliance participating.

The National Archives and Records Administration determined that 199 boxes were worthy of permanent preservation, and they will be transferred in fiscal year 2001. The remaining five boxes will be sent to the FDA Historian for review. This marks the first transfer of CDER records to NARA's collection in many years and is also the first collaborative review of such records by CDER staff. It is hoped that, with this experience, future reviews of CDER records will be conducted.

This event illustrates the collaborative nature of records and information management. When we write a memo, send an e-mail or review an application, we are potentially creating a piece of data of value not only to CDER but also to future researchers as well.

To learn more about this review or about records and information management polices, please contact **Scott Zeiss** (ZEISSS).

Y2K Day One a Success

Congratulations to the CDER Y2K team. After months of activity to make sure CDER's information technology components were ready for the year 2000, the real test took place on Jan. 1. We are happy to report that the hard work of many CDER employees and contractors resulted in a very smooth Y2K transition.

A "Day One" team, coordinated by **Judy McIntyre,** was assembled to test each area that contributes to the operation of CDER's automated systems. Extensive and detailed test plans and scenarios were developed for networks, mission-critical applications, NT and VMS servers, desktop systems, e-mail and the Oracle databases. Some Day 1 team members began working the evening of Dec. 31, and others performed their tests as systems became available after midnight and through the morning and afternoon of Jan. 1. Testing uncovered a few problems with two CDER applications that were not discovered earlier.

The hard work and success of the Day 1 applications team ensured that all mission-critical systems and virtually all nonmission-critical systems were up, operational and free of dreaded Y2K bugs when CDER returned to work on Monday, Jan. 3.

Thanks to the many people who contributed to the renovation of our systems over the last year and to the Day 1 team who worked during the holiday to ensure that our systems would be available to support CDER's mission.

The CDER Day 1 team members were: **Sheila Andrew, Barry Arabia, Pete Baer, Brianna Broderick, John Brinsko, Greg Brolund, Wendy Bussey, Melissa Chapman, K. C. Cuthbert, Janet Gentry, Liz Gomez, Rich Johnson, Brett Larrabee, Vikki Levi, Ralph Lillie, Vaughan Mason, Judy McIntyre, Sally Newman, Terrence Sanders, Scott Shippey, Greg Warzala, Martin Waller** and **Barry Wheeler.**

QA Development Project

December meetings were held with OIT divisions to collect feedback on a proposed project plan template. The template will be included in an OIT guidance document on project planning that will be revised and peer-reviewed in January. Five completed guidance documents on configuration management are being circulated for OIT management signoff.

More information is located on the CDER Intranet (http://oitweb) under the OIT Activities button. The OIT Point of Contact is **Jerry Yokoyama** (YOKOYAMAJ).

Help Desk FAQs

Which server should I use to connect to TeamLinks?

Use the server OA when connecting to TeamLinks. If you are experiencing difficulty connecting to TeamLinks via the OA server or if you are using TeamLinks Remote, please use one of the following servers, in random order, as a backup: Daisy, Bambi, Pluto or Minnie.

Switch back to OA when conflicts are resolved as continued use of servers other than OA to connect to TeamLinks may result in server overload and connectivity problems. Contact the Help Desk (HELP, 7-0911) or more information.

February IT Training

Monday	Tuesday	Wednesday	Thursday	Friday
	1	2 **Word Intro** 9-12 **Word Formatting** 1-4	3 **Word Tables** 9-12 **PowerPoint Intro** 1-4	4 **PowerPoint Charts** 9-12
7 **CDER's Standard Letters System** 9-12	8	9 **DFS** 9-12 **NEST** 1-4	10 **Access Intro** 9-12 **Access Queries** 1-4	11 **Access Forms** 9-12 **Access Reports** 1-4
14	15	16 **TeamLinks Intro.** 9-12 **TeamLinks Attachments** 1-4	17	18
21	22	23 **CDER's Network** 9-12 **DFS** 1-4	24 **CDER's Standard Letters System** 9-12	25 **Creating PDF Documents** 9-12 **NEDAT** 1-4
28	29			

The catalog, training materials, schedule and online registration can be found at http://oitweb/.

PROJECT MANAGEMENT CORNER

Site Tours, Shadowing Training Programs Announced to Industry

BY DEBORAH KALLGREN

Two pilot training initiatives—the Regulatory Project Manager Site Tours and the Regulatory Project Manager Shadowing Program—were officially announced to industry in the Nov. 3 *Federal Register*. These programs are designed to enhance review efficiency and quality by providing project manages with a first-hand exposure to industry's drug development processes. The programs will also serve as mechanisms for mutually beneficial discussions between selected Center project managers and qualified industry representatives. FDA will pay the travel expenses for all CDER participants. Firms will provide the training experience.

Both programs are part of CDER's Regulatory and Project Management Certification curriculum and are coordinated and managed by a steering committee comprised of members from the Center's Project Management Training and Certification Subcommittee. The steering committee sets program criteria, chooses industry sites and selects CDER participants.

Site Tours

The Regulatory Project Manager Site Tours are open to project managers of all experience levels. The two-day visits will be limited to six or fewer Center project managers. The tours should provide participants with a basic orientation to drug development, the firm's facilities and insights into the practical applications of drug development. Tours should include an introductory overview of the firm's regulatory operations and visits to manufacturing and packaging facilities as well as pathology and toxicology labs.

Those interested in participating in the Site Tours Program must have supervisory concurrence, be able to spend two days at the site and have at least three months experience as CDER project managers. They will need to have completed Level 1 courses of the certification program, including CDER Orientation, New Reviewers Workshop, Medical Terminology, Basic Regulatory Affairs—INDs, Time Management and Computer Skills.

Shadowing Program

The Shadowing Program provides project managers who have at least two years of project management experience with an in-depth opportunity to follow their industry counterparts in day-to-day activities and responsibilities. During this two- to three-day visit, participants will accompany the firm's project management and regulatory affairs representatives and observe the team approach to drug development. The overall objectives are for participants to learn industry best practices relating to project management and teams, improve performance through increased understanding of industry processes and procedures that directly impact their jobs and to enhance professional and personal growth.

Persons interested in the Shadowing Program must have supervisory concurrence, be able to spend two to three days on site and have two or more years experience as a CDER project manager. They must have completed Level 2 courses of the certification program, including Regulatory Sciences, Basic Regulatory Affairs—NDAs, Project Management in the Pharmaceutical Industry and FDA, Successful Meetings and Minutes and MS Project.

Site Selection

Company sites will be chosen primarily on a first-come, first-served basis. However, preference will be given to those firms that have not participated in previous site tours or shadowing programs. Proximity of the site to the FDA may become a selection factor based upon amount of travel funds available for the programs.

Project managers actively involved with the review of a pending NDA or efficacy supplement will be precluded from visiting with that sponsor. In addition, sites may be disqualified for several reasons including a compliance action at the firm or a planned inspection that will have participants from CDER or other headquarters offices.

Companies interested in hosting either the site tours or shadowing programs should contact me (kallgrend@cder.fda.gov, 301-594-5481) for additional information. A background package describes both programs and provides suggestions for potential agenda topics. Candidate firms are encouraged to submit proposed agenda for review and consideration.

Deborah Kallgren is a regulatory health project manager with CDER's Project Management Program Staff

Latest Edition of *From Test Tube to Patient* Incorporates FDAMA Changes

BY NANCY SMITH, PH.D.

CDER has extensively revised and reprinted the popular FDA publication *From Test Tube to Patient: Improving Health Through Human Drugs.*

The book tells the story of new drug development in the United States and highlights the Center's consumer protection role. The latest edition captures the most recent changes and reforms to the U.S. drug regulatory system, including the 1997 FDA Modernization Act.

Copies of the new magazine will be given to new CDER employees and will be available at the Center's exhibit during upcoming conferences. Previous versions have been a popular introduction to the U.S. drug development system.

If you would like multiple copies for your meetings with CDER constituents, please contact **Laura Alvey,** Division of Communications Management, (7-1676, ALVEYL). Individual copies are available from the Drug Information Branch at 7-4573. It is also available online at http://www.fda.gov/cder/about/whatwedo/testtube-full.pdf.

The public can order multiple copies from the Government Printing Office using the order form in the back of either the printed or on-line versions.

Special thanks are due to the many CDER experts who contributed to the updates and to the book's editor, **Marcia Trenter,** in DCM.

Nancy Smith is OTCOM's director.

Chapter, CDER Agree on Alternative Work Schedules; Any 80 Possible

BY ROBERT YOUNG

On Dec. 22, NTEU Chapter 282 and CDER signed a memorandum of understanding that settled the framework for alternative work schedules within the Center. In the June issue of *News Along the Pike,* I discussed alternative work schedules generally.

This article explores some possibilities for the most flexible of the regular alternative work schedules—"Any 80." No employee is required to adopt an alternative work schedule, and any alternative work schedule requires supervisory approval. A form to request approval of alternative work schedules can be found in the contract on page 91. Regular fixed schedules (the default) and compressed schedules will not be discussed in this article.

The purpose of alternative work schedules is to allow employees the flexibility to meet obligations they might have outside of work and still accomplish the Agency's mission. The contract recognizes that the duties and responsibilities of some positions preclude a flexible schedule and that the Agency's mission must be given great deference.

Article 25 of the NTEU-FDA contract allows the Agency to set core hours in consultation with the union. All other aspects of alternative work schedules are determined by negotiation. In mid-December, the union and CDER consulted and negotiated an alternative work schedule agreement. The memorandum of understanding defines "core hours" and "flexible work bands."

CDER's core hours are Monday through Friday, 9:30 a.m. to 3:30 p.m. The principle purpose of these hours is to facilitate the scheduling and holding of meetings with outside parties on a time-sensitive schedule imposed by statute.

CDER's flexible work bands are all hours other than core hours on Monday through Friday and all day Saturday. During these flexible work bands, both basic work requirements may be fulfilled and credit hours earned. On Sunday, only credit time may be earned.

Only 24 hours of credit time can be carried over from one pay period to the next. Employees not on duty during core hours have to cover their absence with some form of leave such as annual leave, sick leave, comp time or credit time.

An exemption mechanism has been set up for those CDER employees whose duties and responsibilities are such that core hours may not be particularly applicable to them.

In an Any 80 alternative work schedule, a full-time employee is required to complete 80 hours of basic work requirement in a pay period and cover core hours. A pay period in which the employee works less than 80 hours requires the difference to be made up with some form of leave. Hours worked in excess of 80 hours earn credit time. Except for Sunday, all initial hours worked in a pay period are considered basic work requirement hours until 80 hours are accumulated. After that, all hours in excess of 80 hours are considered credit hours.

The employee must be on duty during core hours even if the basic 80-hour work requirement has been met. In this circumstance the hours in excess of 80 hours would all be credit hours. Employees are responsible for completing their basic hourly work requirements, covering their core hours and work assignments and tracking their credit time account.

Although the CDER core hours encompass 30 of the 40 hours in a work week, CDER's alternative work schedule is still more flexible than schedules previously available. Some illustrations of how Any 80 could work are presented below. Supervisory approval for the Any 80 alternative work schedule is all that is required for the first three examples. The examples are:

- *Core hours Monday through Friday, balance on Saturday.* The employee would work Monday to Friday from 9:30 a.m. to 3:30 p.m. With mandatory half-hour lunch breaks this covers $27^1/_2$ hours of work. The employee then supplies $12^1/_2$ hours of work requirement on Saturday.
- *Core hours Monday through Friday, balance in three evenings.* The employee would work Monday to Friday from 9:30 a.m. to 3:30 p.m. with lunch breaks and then $4^1/_2$ hours on one evening and 4 hours each on two other evenings.
- *Early completion of the basic work requirement and credit time accumulation.* For employees who complete their basic work requirement sometime before 3:30 p.m. on Friday of the second week in a pay period, all additional hours worked are credit time. If, for example, an employee completes the basic work requirement for a pay period on Tuesday of the second week, core hours on Wednesday to Friday are automatically credit time.
- *A week off in a pay period without using annual leave.* To do this, an employee would need 24 hours of credit time going into a pay period. On the first Sunday of the pay period, the employee would work $3^1/_2$ hours to accumulate enough credit time to cover the $27^1/_2$ core hours of the week the employee will be absent (30 hours less five half-hour lunch breaks). The employee would then work 11-hour days Monday to Friday of the week at work. Since these days include the half-hour lunch break, they accumulate $10^1/_2$ hours of work requirement. This will cover the 40-hour work requirement for the week at work. The extra $2^1/_2$ hours a day will cover the $12^1/_2$ hours of work requirement remaining from the week off. Supervisory approval is necessary to be absent during core hours of the week off. This schedule sounds tough, but there are employees who are probably doing something similar to it already.

It is the union's position that Any 80 is the most fair and flexible schedule for most employees.

Operating divisions all over FDA are coming up with local rules limiting the number of credit hours that their employees can earn on a given day. If any employee objects to these restrictions, the union will challenge them in a class action before the joint labor-management alternative work schedule committee.

Similar rules being applied to individuals should be taken by the adversely affected individual to the joint committee.

Robert Young is Chapter 282 president.

Officers, Representatives to Continue During Union Transition

BY C. RUSS RUTLEDGE
AND LYDIA VELAZQUEZ KIEFFER

Some might say that RAC's achievements were all in the last century, so what have we done lately? We're pleased to continue the tradition of reviewing the RAC's accomplishments for the past year.

The 1999 RAC officers were **Lydia Velazquez Kieffer,** chairperson, and **Robert Shore,** vice chair. **Tanya Abbott** continued her duties as project manager. She has provided invaluable perspective and continuity to RAC for seven years.

Traditionally the year's first article introduced the incoming and thanked the outgoing officers, chairpersons and division representatives for their time and efforts. However, since the NTEU now represents some of the FDA's non-management employees, the current activities of the RAC require representatives who are familiar with the issues that the committee faced last year in order to collaborate with the NTEU in a meaningful and expeditious manner. Therefore, the current officers and many division representatives have agreed to continue in their roles to facilitate the transition. Most of the RAC subcommittee chairs are continuing in their positions as well, including:

- **Sousan Altaire,** Team Model.
- **Lydia Velazquez Kieffer,** Networking.
- **Kate Meaker,** Guidance Process and Regulatory Changes.
- **Robert Shore,** Operational Procedures and By-Laws.
- **Milton Sloan,** Comparable Pay.
- **Jackie White,** Training and Communications.
- **C. Russ Rutledge,** New Reviewer's Handbook

The CDER Reviewers Career Path subcommittee lost its chairperson, **Jahnavi Kharidia,** who has taken a position outside the Agency.

The officers, project manager and subcommittee chair positions require many hours of extra effort in addition to their regular jobs. We would like to offer our thanks to all for their efforts, and extend our appreciation to these individuals who have committed to extend their time in these positions until the NTEU transition phase is complete.

1999 Highlights

In late January the RAC held its annual networking event, in which FDA members were invited to meet members of the RAC, learn about our activities and discover our plans for the upcoming year. FDA Commissioner **Jane Henney, M.D.,** was our keynote speaker.

The Comparable Pay Subcommittee facilitated the advancement of clinical pharmacologists and pharmacokineticists toward obtaining classification for comparable pay purposes. Other disciplines are in the process of obtaining the necessary data to present to the subcommittee in order to begin their own process in obtaining special pay in their disciplines. A protocol for establishing such pay grades was identified.

Other highlights included:

- The Team Model Subcommittee successfully collaborated with **Jean Yager** and launched their first workshop.
- The CDER Reviewers Career Path Subcommittee will be involved with the collection and analysis of all data obtained from the CRCP pilot year and will be sharing it with CDER reviewers in the coming year.
- The Guidance Process and Regulatory Changes Task Force has identified the elements of a planned survey of CDER reviewers to obtain data that will reflect what CDER reviewer's think of the recent guidances and regulatory changes that have taken place.
- The RAC officers and subcommittee chairs met with the Senior Management Team regularly to report progress on the various projects underway.

Good communication is an important element to be successful in our jobs within CDER, and the RAC accomplished numerous items to further this:

- Established a RAC account on both the e-mail system and the Russell Calendar Manager with viewing proxy for all of CDER.
- Established a RAC site (http://cder-net/rac/index.htm) on the CDER intranet.
- Lydia Velazquez Kieffer and Rob Shore gave presentations on RAC at all three 1999 New Reviewer's Workshops.
- Articles were regularly published in *News Along the Pike.*
- RAC documents on the X-drive were converted to MS Word.
- The Guidance Process and Regulatory Changes Task Force has made plans to survey CDER reviewers in the year 2000 to obtain information on the impact all of these changes within CDER.

The RAC hosted several guest speakers at their monthly meetings, including:

- Jean Yager presented a proposal to finalize the team model proposal. The Team Model Subcommittee worked with the CDER Team Model Design Team, assisted in developing the next phase of this ongoing project and conducted a pilot "best practices" workshop. Jean Yager gave updates to this project at two additional RAC monthly meetings.
- **John Senior, M.D.,** provided an overview of the Reviewers Evaluation and Education Project. This is a tool to improve the quality of medical reviews by developing guidelines and standardized practices as part of the Good Review Practices initiative.
- **Robert Young** presented an overview of the draft Union-FDA contract.

Overall, it has been a productive and rewarding year for the RAC. We have been proactive in anticipating the needs of CDER reviewers with the implementation of many programs and surveys that are underway.

The fate of the RAC has been uncertain due to the NTEU. However, all RAC representatives were committed to do their jobs in representing their colleagues within CDER and persevered regardless of uncertainty.

C. Russ Rutledge is a compliance officer in the Division of Manufacturing and Product Quality. Lydia Velazquez Kieffer is a clinical pharmacology and biopharmaceutics reviewer in the Division of Pharmaceutical Evaluation I.

EEO CORNER

Organization Meetings; Asian American, Pacific Islander Initiative

BY GLORIA MARQUEZ SUNDARESAN

The following organizations are planning conferences at the locations and dates indicated:

- National Image Inc., Puerto Rico, June 4-11, 303-534-6534.
- Federal Asian Pacific American Council, Arlington, VA, May 9-12, 202-782-7335.
- Asian Pacific American Institute for Congressional Studies, Washington, May 25-27, 202-547-9100.
- League of United Latin American Citizens, Washington, June 25-July 1, 202-408-0060.
- Federally Employed Women, New Orleans, July 17-21, 202-898-0994.
- National Council of La Raza, San Diego, Calif., July 2-5, 202-785-1670.
- Blacks in Government, Washington, Aug. 21-25, 202-667-3280.
- Society for the Advancement of Chicanos and Native Americans, Atlanta, Oct.12-15, 831-459-0170.

For more information, contact the organization at the number listed or the EEO Staff at 4-6645.

White House Initiative

Executive Order 13125 signed by President Clinton on June 7 is the second in U.S. history that affects Asian Pacific Americans. The first, during World War II, mandated the internment the Japanese people residing in this country regardless of whether they were citizens of this country or not. Although passed by the same government, what a world of difference separates these two initiatives. The first caused so much grief in the lives of Americans of Japanese ancestry. The second aims at uplifting their lives as well as those of other Asian Americans and Pacific Islanders in this country.

The White House Asian American and Pacific Islander Initiative is intended to improve the quality of life for Asian and Pacific Americans in the areas of health, education, housing, transportation and business by letting them participate in Federal programs particularly where they are underserved. The initiative will conduct research and provide data where necessary. To implement this initiative, two groups will be organized:

- A 15-member presidential advisory commission, drawn from those experienced and active in the APA community and appointed by the president.
- A federal interagency working group composed of employees from the different departments and independent Agencies to advise the HHS Secretary on the implementation of this initiative.

Departments and agencies will be required to submit their implementing plan with measurable objectives to HHS, which will develop an integrated federal plan to submit to the White House. The advisory commission may be extended beyond its two-year mandate, depending on the outcome of the federal plan.

Gloria Marquez Sundaresan is an equal employment specialist in CDER's EEO Staff.

DRUGS IN THE NEWS

Cisapride, Flu Treatments Spark FDA Public Health Advice

FDA advised health care professionals and patients on Jan. 24 of important new information, including recommendations for performing diagnostic tests, that should be considered prior to any use of the drug cisapride (Propulsid).

Cisapride is a treatment for severe nighttime heartburn in patients with gastroesophageal reflux disease who do not adequately respond to other therapies. The new measures are being recommended to help physicians avoid giving cisapride to patients at known risk of rare, but serious, cardiac events associated with the drug.

As part of an ongoing risk management effort, FDA is also announcing a public advisory committee meeting to be held on April 12, where the safety of the drug and additional methods to reduce the occurrence of adverse events will be discussed.

On Jan. 12 FDA published a public health advisory at http://www.fda.gov/cder/drug/advisory/influenza.htm for health care practitioners to remind prescribers of important and therapeutic considerations when treating patients with influenza-like symptoms.

Recent promotions of two of the four drugs approved for flu, have focused attention on antiviral therapies for treating influenza. However, prescribers should consider that vaccination remains the primary method of preventing and controlling influenza and that some patients may have significant bacterial infections instead of or in combination with influenza and these should be treated with appropriate antibacterial therapy.

A new indication for celecoxib (Celebrex) received FDA approval on Dec. 23. It is the first drug treatment aimed at reducing the number of intestinal polyps in patients with a rare genetic disorder called familial adenomatous polyposis. Patients with FAP develop large numbers of intestinal polyps and, as a consequence, have a greatly increased risk of developing colon and rectal cancer at an early age. Celecoxib, a COX-2 selective non-steroidal anti-inflammatory drug, was approved in l998 for the relief of signs and symptoms of rheumatoid and osteoarthritis.

FDA on Dec. 23 approved docetaxel (Taxotere) for treating non-small cell lung cancer that does not respond to cisplatin-based chemotherapy. Taxotere was approved for treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior cisplatin-based chemotherapy. Taxotere was initially approved in l996 for treating patients with advanced breast cancer.

CORRECTION: In last month's Drugs in the News, Penlac Nail Lacquer (ciclopirox) was misspelled.

LEADERSHIP DEVELOPMENT CORNER

25 Take Part in CDER-Designed 7-Month Training Program

On Jan. 10, the inaugural class of 25 employees began seven months of training in CDER's Leadership Development Program.

The program replaces the Leadership Fellows Program operated by the Council on Excellence in Government. The CDER-designed program combines the best features of other leadership programs while being attentive to the Center's own unique leadership issues.

The program's faculty includes experienced CDER leaders and facilitators, consultant facilitators and guest speakers from government, industry and academia. Features include off-site workshops, individual and peer coaching, a comprehensive reading list and individual skills assessment and development.

The competitive program is open to the Center's civilian staff in pay grade GS-12 and Public Health Service Commissioned Corps officers in pay grade O-4 and above.

The CDER offices represented and students in the first class are:

- Office of Compliance: **Jan Davis** and **Sakineh Walther.**
- Office of the Center Director: **Gloria Sundaresan.**
- Office of Management: **Don Kim.**
- Office of Medical Policy: **Mark Askine.**
- Office of Pharmaceutical Science: **Richard Adams, Barbara Myers Davit, Angelica Dorantes, Andrea High, Ameeta Parekh, Atiqur Rahman, Kathleen Uhl, Richard Vengazo** and **Mona Zarifa.**
- Office of Review Management: **Regina Alivisatos, Aloka Chakravarty, Marina Chang, David Graham, Stella Machado, Norman Stuart Marks, Mary Mease, Susan Molchan, Kathleen Reedy** and **Evelyn Rodriguez.**
- Office of Training and Communication: **Kathrin McConnell.**

TRAINING AND DEVELOPMENT CORNER

Two DTD Medical Writer-Editors Available to Help with Manuscripts

BY JANICE NEWCOMB

OTCOM's Division of Training and Development has two new medical writer-editors, **Sakti P. Mukherjee, M.Sc., M.D., D.Sc.,** and **Jack E. Morin, MHSA.**

With these two highly skilled and experienced professionals on board, DTD has enhanced capability to:

- Review manuscript styles, formats, consistency, clarity and congruity.
- Develop instructional and self-learning modules for science and policy education.
- Review biochemical, metabolic, pharmacological, nutritional and toxicologic parameters in scientific reports and articles.
- Develop risk communication documents.
- Edit draft guidance documents.
- Edit book chapters or journal articles.

Dr. Mukherjee works closely with DTD's Science Education Team and the Committee on Advanced Scientific Education to develop alternative medical science training programs and prepare CASE's scientific documents. He is preparing self-learning modules in several clinical pharmacology topics and other scientific documents based on CDER seminars.

Mr. Morin works with DTD's Policy Education Team to develop effective policy-related education programs for CDER's review staff. He is writing self-learning courses for the Pediatric Final Rule and Human Pregnancy Outcome Data.

Dr. Mukherjee and Mr. Morin also work with the *Virtual Journal* Committee to develop articles for CDER's *Virtual Journal.*

If you need assistance in medical writing, editing or documentation projects, please contact me (NEWCOMBJ, 7-1262).

Janice Newcomb is director of DTD.

Malaysian Drug Regulators Show Strong Interest in Product Quality Issues

(Continued from page 1)

medical societies from Malaysia, India, Japan and Australia as well as other Asian and European countries.

As a result of my last visit for a similar conference in 1996, officials from Malaysia's National Pharmaceutical Control Bureau expressed a increased interest in FDA's drug surveillance programs and initiatives to assure drug quality.

They invited me to discuss these issues at an additional two-hour informal session following the conclusion of the seminar. They were looking to discuss processes that will be useful in developing programs for the surveillance of their country's products.

We covered strategies for examining drug quality such as selective testing of samples and targeting high-risk drugs and difficult to manufacture products. We looked at ways that regulators can help companies use their own internal data to help them comply with drug quality standards.

We examined how the U.S. programs for post-market drug surveillance provide useful information about a product's safety and effectiveness as an extension of the drug approval process.

FDA's drug surveillance programs for gathering this vital information about product quality from the marketplace could serve as a model for other countries' efforts to improve drug quality.

We also discussed methods for determining best practices and benchmarking in partnership with stakeholders.

Vaiyapuri "Puri" Subramaniam is a compliance officer in the Division of Prescription Drug Compliance and Surveillance and was recently appointed to a three-year term by the surgeon general to the HHS-PHS Pharmacy Professional Advisory Committee.

U.S., European Union Evaluating Each Other's GMP Inspections

(Continued from page 1)

creasingly important and dominant role in everything FDA does to protect the public health, said **Sharon Smith Holston,** deputy commissioner for international and constituent relations, in her introductory remarks. She outlined the developments that led to the agreement, including provisions of the FDA Modernization Act of 1997 that require the Agency to move ahead on the MRA with the European Union and the widening gap between FDA's inspection workload and the resources to carry it out.

FDA will continue to have the final responsibility for making certain that imported regulated products comply with U.S. standards, she said. This large-scale reliance on foreign regulatory information—critical for assuring the quality of imported products—"is really unprecedented in our history as far as meeting our public health protection mandate," she said.

She noted that imports of FDA-regulated products have grown 360 percent in the 1990s, from about 1.5 million line entries per year to 5.5 million line entries in 1999. The number of FDA employees who survey these imports has remained just about constant at about 770.

"In the same decade," Holston said, "our inspectional responsibilities have gone up about 32 percent, from about 87,000 business establishments to about 115,000 business establishments. Most of these are facilities that are using methods and equipment that are a lot more sophisticated, a lot more complex and, therefore, more difficult to inspect than was the case a decade ago."

The number of FDA inspectors has increased by less than 10 percent, from about 1,000 to just under 1,100. The number of employees who handle all of the FDA programs except for drug reviews has actually declined since 1992, she noted.

Joseph Famulare, director of the Division of Manufacturing and Product Quality in the Center's Office of Compliance, leads the six-member U.S.-FDA implementation team. A similar team from the European Union coordinates their implementation efforts. Famulare and members of the team then described the framework for achieving mutual recognition of GMP inspections.

Mutual recognition means accepting the other party's conformity assessment procedures, Famulare said. The concept of equivalence is established by the World Trade Organization and is not a harmonization process.

The agreement emphasizes finding equivalence individually with each of the 15 member states. The ultimate goal is the exchange and endorsement of each party's inspection reports.

"Once we go through this equivalency assessment process, we will be able to receive an inspection report from our European counterparts that we have found equivalent," he said "and use it as if it were our own report. . . . The actual compliance decision will be up to the FDA."

The agreement provides three years for each side to examine the other side's systems. At the end of this three-year transition, a joint U.S.-E.U. committee will publish a list of authorities and processes found to be equivalent. Each regulatory system that is determined to be equivalent should be able provide the same level of public health protection as the U.S. system of GMPs and regulatory enforcement. The products covered are human and animal drugs, vaccines, therapeutic biologics and active pharmaceutical ingredients.

"As each side looks at each other," Famulare said, "the equivalence assessment process may actually result in improvements—as we put ourselves under the microscope—as the U.S. is going to be evaluated by our colleagues in the E.U. and as we evaluate our European colleagues."

Raymond Mars, from the Office of Regulatory Affairs, presented highlights from the first meeting of the joint U.S.-E.U committee held in May. The meeting focused on establishing communications and discussing U.S. laws that require FDA to release information about recalls and inspection results to the public. "Frequently the Europeans do not have that kind of oversight," Mars said. FDA explained U.S. regulations that protect commercial confidential information, trade secret information and the government's internal deliberative documents.

Brian Hasselbalch, a compliance officer in the Division of Manufacturing and Product Quality, gave a presentation on equivalence assessment, providing an overview of the process for evaluating the pharmaceutical GMP regulatory systems among the European Union's member states. Hasselbalch said that there are seven major areas of assessment: the legal and regulatory authority and structures; standards of conduct; avoidance of conflicts of interest; administration of the regulatory authority; execution of enforcement activities; effective use of surveillance systems; and conduct of inspections.

Sylvia Henry, a CBER compliance officer, reviewed the development of procedures to ensure the rapid exchange of information about product quality problems by means of the "Two-Way Rapid Alert System." The purpose of the alert system is to share information in a timely and effective manner in order to alert the public. "Under the alert system, we will be notified of defective products which are potentially life-threatening or could cause an injury to health" she said. Elements of the alert system include documentation, the definitions of crises and emergencies, standing operating procedures, classifications, language and the transmission of information.

Merton Smith, with the FDA's Office of International Programs, gave the final presentation on public transparency of MRA processes, discussing information disclosure requirements regarding non-public documents. He also emphasized the need for industry cooperation in sharing trade secret information. He stressed FDA's belief that it is critically important for information that will be the basis for the equivalence determinations to be made available to the public.

The sixth member of the FDA project management team is **Judy Gushee** from the Center for Veterinary Medicine.

The summary and transcript of the meeting along with other MRA material are on FDA's Web site at http://www.fda.gov/oia/homepage.htm.

Erik Henrikson is a compliance officer in the Division of Manufacturing and Product Quality.

Office of International Programs to Leverage Limited Resources

(Continued from page 1)

system for official correspondence.

Several members of the OIP staff outlined the functions of the new office at a January meeting of the Center's International Affairs Coordinating Committee.

OIP is composed of four major groups and several advisors:

- International Scientific Activities and Standards Staff.
- International Relations Staff.
- International Agreements Staff.
- International Planning and Resource Management Staff.

The International Scientific Activities and Standards Staff, directed by **Janet Jenkins-Showalter,** is responsible for a number of international standardization efforts including the International Conference on Harmonization. She said that the ICH harmonization model, which is now a decade old, warrants reevaluation to ensure that it is the most effective mechanism for bringing the "right people together to discuss technical issues."

ICH implementation and maintenance issues are becoming increasingly important now that the majority of the ICH guidelines have reached the draft or final consensus stage. ICH maintenance and implementation could be instructive in dealing with some of the other international harmonization programs. These include the Global Harmonization Task Force for medical devices and the VICH for veterinary drugs.

Jenkins-Showalter said that an important goal for her group is to provide a mechanism for discussing harmonization and standards initiatives that involve several components of the Agency .

The International Relations Staff, directed by **Walter Batts,** provides FDA clearance for international travel. Batts emphasized following advance notice guidelines for official travel since it requires time-consuming coordination with the State Department and embassies.

His staff coordinates about 1,500 visits to the Agency each year from foreign government officials and scientists. His group maintains liaisons with international health and trade organizations and is the focal point for international information sharing, risk communications and explaining the U.S. position on issues.

OIP's International Agreements Staff serves as the focal point for various agreements, trade issues and regulatory standards. **Linda Horton,** the director, said her staff has expertise in developing and clearing *Federal Register* documents involving international activities; sharing confidential information with foreign regulators; and policy issues involving imports and exports.

She said her staff can help people in CDER avoid the many pitfalls that await those familiar with domestic regulation when they move to the international arena. "For example," she said, "the word 'will' is considered mandatory in international agreements, where we think that 'shall' is mandatory."

Beverly Corey, who directs the International Planning and Resource Management Staff, said her group is in the process of consulting with the centers with the aim of finding better ways to leverage limited resources for international programs.

Maritza Colon-Pullana, the associate OIP director, said she is continuing her work with the University of Puerto Rico to develop training in the areas of standards and good manufacturing practices for the Americas.

Frequently, FDA staff have been sent to conduct training in different countries, only to be faced with similar requests a few years later. Institutionalizing the expertise in a Spanish language academic setting will help lessen the resource demands on the Agency, she explained.

Stuart Nightingale, M.D., the associate commissioner for health affairs and senior health advisor, continues as the FDA's representative to the World Health Organization and advises OIP.

Eric Flamm is the liaison between OIP and the Office of Policy, Planning and Legislation.

Justina Molzon is the Center's Associate Director for International Affairs.

International Affairs Coordinating Committee Sets Priorities for Center

The Center's International Affairs Coordinating Committee provides a coordinating function within the Center similar to the one that the Office of International Programs provides at the Agency level. CDER's international activities include:

- Standard setting.
- Regulatory and compliance surveillance.
- Scientific collaboration.
- Technical assistance, training and education.
- Hosting of foreign visitors.
- Monitoring of trade and export issues related to health and safety.
- Cooperating with foreign governments and international organizations.
- Communicating with other federal agencies.
- Supporting FDA's international programs.

The IACC is about to issue two MAPPs. One will detail the the committee's responsibilities and relationships. The other will outline how the Center will prioritize requests for training and visits from foreign regulatory agencies and international regulatory organizations.

The committee is developing both CDERnet and Internet sites about the Center's international activities and will be conducting a survey of CDER staff to determine those fluent in foreign languages. IACC consists of these members representing the organizations indicated:

- **Carol Drew,** Regulatory Policy Staff.
- **Stephanie Gray,** Office of Compliance.
- **David Lepay, M.D., Ph.D.,** Office of Medical Policy.
- **Ralph Lillie,** Office of Information Technology.
- **Justina Molzon, M.S.Pharm., J.D.,** chair and executive secretary.
- **Dianne Murphy, M.D.,** Office of Review Management.
- **Eric Sheinin, Ph.D.,** Office of Pharmaceutical Science.
- **Nancy Smith, Ph.D.,** Office of Training and Communications.
- **Janet Woodcock, M.D.,** center director, *ex officio* member.

—Justina Molzon