news along the pike

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CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

PIKE'S CORNERS

Proposal aims to speed availability of generic drugs

Single 30-day stay, tighter patent listing rules for Orange Book

President Bush in a White House ceremony Oct. 21 announced a proposed FDA regulation that would speed the availability of generic drugs.

"For more than a year, the Federal Trade Commission has investigated delays and abuses in the process of bringing generic drugs to the market," the president said. "I have reviewed the FTC findings and I am taking immediate action to ensure that lower cost, effective generic drugs become available to Americans without any improper delays."

The proposed rule change would modify FDA's interpretation of the 1984 Hatch-Waxman Act designed to protect the patent rights of innovator drug companies while at the same time making generic drugs more widely available. The law created the current process for generic drug approval and granted up to five years of patent extension to the innovator to make up for some of the time lost in gaining initial FDA approval for its drug product. The law allows for an automatic 30-month delay in the approval of a generic drug when the generic manufacturer challenges a patent held by the innovator and is sued within 45 days of the innovator's being notified. This delay gives the innovator drug company a chance to protect its patent rights in court.

The new approach would eliminate the possibility of a brand-name pharmaceutical company receiving multiple 30-month delays related to newly obtained patents. In some instances generic drug approvals have been delayed for multiple 30-month periods. Under this

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Generic drug quality awareness program launched

BY AYSE HISIM AND CRYSTAL RICE

The Office of Training and Communications and the Office of Generic Drugs are developing an educational program to help consumers build confidence in the generic drugs they are taking.

For various reasons, some consumers may believe that the generic drug they are now taking may not be as effective as the name brand drug they received in the past.. Both Congress and the Center want American consumers to know that generic drugs are safe, effective and FDA-approved.

Generic drugs account for about 44 percent of all prescription drug purchases in the United States, so it is important that consumers be well informed and confident when taking generic drug products.

The currently available products in the program are three print public service ads—two for consumers and one for health care professionals—and an article reprint

All three ads contain a similar text message

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PDUFA III to be focus of *CDER Live!* broadcast on Nov. 5

BY ELAINE FROST

You can view the upcoming broadcast of the *CDER Live!* panel discussion on "PDUFA III: Building on Success" at the Center's videoconference rooms on Tuesday, Nov. 5, from 1:00 p.m. to 3:30 p.m. Eastern time.

Panelists will discuss the reauthorization of the Prescription Drug User Fee Act for another five years and how the new agreement builds on the success that FDA has achieved under PDUFA over the past decade.

A major area of discussion will be on how the new agreement is expected to provide additional resources to better balance workload with resources.

A second major focus will be on the new risk management components and how they are expected to have a positive impact on the safety of newly approved drugs.

A copy of the broadcast will be available in each of the libraries.

The webcast will be on the Internet for 60

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JOE'S NOTEBOOK

CDER sets pace in Quality of Work Life

CDER is a good place to work judging from the Secretary's Quality of Work Life Survey that 657 of you took the time to answer earlier this year. We scored well in the 14 general areas of the survey important to organizational performance; although, there's room to do better. Here's how your answers compared with those of FDA and HHS respondents:

- *Effectiveness of management practices:* 76 percent of you described CDER's management practices as satisfactory to very effective compared with 69 percent in FDA and 66 percent in HHS.
- *Positive employee feelings about the organization:* 73 percent of you had generally or very positive feelings about your group compared with 67 percent in FDA and 70 percent in HHS.
- *Effective use of employee abilities:* 64 percent of you report that your and your co-workers' energies and abilities are used effectively most or almost all of the time. FDA and HHS both report 57 percent.
- *Group effectiveness as seen by others:* 71 percent of you report others view CDER as almost always or usually highly effective. FDA reports 65 percent and HHS 66 percent.
- *Morale:* 9 percent of you report quite a lot of signs of employee discontent compared with 13 percent in FDA and 17 percent in HHS.
- *Fairness of management:* 86 percent of you report that employee treatment is generally to always fair compared with 79 percent in FDA and 77 percent in HHS.
- *Poor planning and organization:* 23 percent of you report frequent or very frequent wasted effort from poor planning. FDA reports 26 percent and HHS 28 percent.
- *Ineffective delegation of authority:* 26 percent of you report not having or almost never having the authority you need compared with 23 percent in FDA and 26 percent in HHS.
- *Co-worker cooperation:* 62 percent of you report your colleagues have extensive or very extensive sharing of expertise, knowledge and skills compared with 60 percent in FDA and 56 percent in HHS.
- *Performance feedback:* 62 percent of you report that you are usually or almost always told of ways to improve your performance compared with 58 percent in FDA and 56 percent in HHS.
- *Communication:* 48 percent of you report timely to very timely communications compared with 44 percent in FDA and 40 percent in HHS.
- *Operational efficiency:* 20 percent of you report quite a lot to many problems that reduce efficiency compared with 23 percent in FDA and 25 percent in HHS.
- *Climate for innovation:* 62 percent of you report some to strong encouragement for innovation compared with 58 percent in both FDA and HHS.
- *Need for change:* 29 percent of you report a rather high to high need for change in your work group compared with 36 percent in FDA and 38 percent in HHS.

Thanks to **Dawn Reid** for providing CDER's data. Dawn is a management analyst and CDER's quality of work life officer in the Office of Management's Division of Management Services. You can e-mail her (REIDD) for a copy of the report. FDA data is at http://intranet.fda.gov/ohrms/qwl/fd.htm.

Correction: In last issue's report on the Faculty Recognition Awards Ceremony, we failed to mention the carcinogenicity course and its volunteer faculty. They were: **Charles Anello, Sc.D., Anita Bigger, Ph.D., Joseph Contrera, Ph.D., James Farrelly, Ph.D., Charles Resnick, Ph.D., Adele Siefried** and **Frank Sisstare, Ph.D.**

news along the pike

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

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

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OMBUDSMAN'S CORNER

Risk management is our job

BY JIM MORRISON

One truth has been etched in my brain since I became an ombudsman seven years ago: You cannot please everyone.

Often the mistrust of governmental risk-benefit decision-making and risk management stems from a natural dichotomy between societal risk/benefit and individual risk/benefit.

For example, a mentally competent citizen may want to be able to make informed decisions about a full range of risks that he or she may assume. That position suggests that even risks that appear unreasonable for society at large should be available to individuals, but with sufficient information for them and health care professionals to make intelligent decisions.

Government generally sees its role as protecting the health and welfare of society as a whole. However, a substantial segment of the public expects to be protected from what they personally would consider unreasonable risks. Moreover, there is such a wide variation in the risks individuals are willing to accept that whatever decision the government makes regarding acceptable risk is doomed to attract criticism.

By eliminating risks that are unreasonable for the majority of its citizens, a government appears paternalistic to that subset of the population who want to make their own decisions and for whom the benefits may outweigh the risks in particular instances.

When the government makes decisions for its citizens, it automatically imposes value judgments that do not reflect the views of everyone. For example, when faced with evaluating a new drug that shortens life but improves the quality of life, conventional wisdom usually favors prolonged life over quality improvements. However, some terminally ill patients may not agree.

These reasons and more underscore the importance of CDER's risk management initiative. Without some clearly stated operating principles in risk-benefit decision making, CDER policy makers will be second-guessed by the press, the public and health care professionals. The worst scenario, as we have observed, is a risk-benefit decision altered *post facto* in the wake of media pressure. It is imperative that CDER clearly state the bases for its risk-benefit and risk management decisions and to make its decision-making transparent.

In theory, it is wise to allow the public to determine the amount of risk that is acceptable to them. However, which public should determine acceptable risk? Is it the public that won't tolerate the miniscule risk posed by saccharin? Or is it the public that downs a myriad of prescription drugs they buy online without consulting a physician?

Increasing the responsibility for risk-benefit decisions of individuals and their health care professionals, if the Center takes that course, requires more useful information about drugs than is currently available in labeling. It also means a willing acceptance of that responsibility by the public and health care professions. So far, there does not appear to be a public consensus to accept such increased responsibility.

Clearly, CDER's increased emphasis on risk management is most welcome. Part of our job will be educating the public and health professionals about the true risks and benefits associated with drugs. It also means that we need to come to a consensus within CDER about how we define acceptable risks for society. To that end, it is incumbent on each of us in CDER to understand the principles of risk management and to engage in learning opportunities and discussions within CDER and in other forums.

Jim Morrison is the Center's ombudsman.

Council for Excellence in Government selects 9 CDER leadership fellows

Nine CDER employees were selected by the Council for Excellence in Government to take part in their leadership fellows 2002-2003 program. Congratulations to these fellows for their selection:

- **Walter Ellenberg, Ph.D.,** a regulatory project manager in the Division of Over-the-Counter Drug Products in the Office of New Drugs.
- **Lydia Gilbert-McClain, M.D.,** a medical officer in OND's Division of Pulmonary and Allergy Drug Products.
- **Sharon Hertz, M.D.,** a medical officer in OND's Division of Anesthetic, Critical Care and Addiction Drug Products.
- **Matthew Holman, Ph.D.,** a biologist in the Division of OTC Drug Products.
- **Michelle Jackson, Ph.D.,** an interdisciplinary scientist and microbiologist in the Division of OTC Drug Products.
- **Owen McMaster, Ph.D.,** a pharmacology and toxicology reviewer in OND's Division of Special Pathogens and Immunologic Drug Products.
- **Arlene Solbeck, M.S.,** a biologist in the Division of OTC Drug Products.
- **Rajendra Uppoor, Ph.D., R.Ph.,** the acting team leader of the Process Analytical Technology Team in the Office of Pharmaceutical Science.
- **Sally Winthrop, MLS,** a technical information specialist in the Division of Library and Information Services in the Office of Training and Communications.

These fellows have demonstrated their capacity to embody the Center's vision, in addition to adding to its existing mission, vision and values.

Since 1996, 97 CDER employees have taken part in the Council for Excellence in Government's Leadership Fellows Program. The training develops leaders with the vision, skills and commitment needed to face present and future challenges.

This yearlong program includes seminars, site visits to successful corporations and other government agencies, small group sessions and executive coaching. Participation in this program is part of the Center's long-term strategic plan for leadership and management development.

For more information about CDER's leadership programs, contact **Noreen Gomez** (GOMEZN, 7-1261). in OTCOM's Division of Training and Development

Frequently asked questions about Secure Remote Access System

How long will you need my government-issued home PC?

The duration will depend on the amount of work that needs to be done to your PC in order for it to be upgraded to the secure remote access system. For example, PCs with Windows 95 will need to be upgraded to Windows 98, which can take about one day. Our goal is to return your home PC to you the same day we receive it; however, if your PC is outdated, it may take longer to get you another system.

Do I really need to complete the SRAS information form?

Yes, we need to account for all RAS users to ensure that RAS access doesn't get terminated. There are three types of RAS users, and all need to complete the form.

- *Government-issued PC user.* You work from home and have a government-issued PC.
- *Occasional RAS user.* You occasionally use your division's travel laptop. You will need a SecurID token to be able to use the division laptop while traveling. These laptops will have SRAS installed. You will not be able to dial into the network unless you have a SecurID token and SRAS account.
- *Personally owned PC user.* You use a personally owned PC or laptop to work from home. You will need a government-issued home PC, a SecurID token and a SRAS account to continue working from home.

Does SRAS support DSL or cable modem access?

At this time we are upgrading all the dial-in users only.

I have more than one government-issued home PC?

Please complete the form for each PC so each one can be scheduled and upgraded. Regardless of how many systems you use SRAS on, you will only need one SecurID token.

I am on vacation the week I am scheduled for the SRAS upgrade. What should I do?

Can you bring your PC in on the Friday before vacation? If not, please call the CDER Helpdesk (7-0911) and let the technician know when you can bring your PC into the office. If the SRAS installers are still in your building when you return from vacation, we will work you back into the schedule. If not, a ticket will be logged for the building technician to assist you.

Do I need a property pass?

Yes, you can use the same property pass that was used when you first took your government-issued home PC out of the building. If you don't have that you will need to speak with your property control officer.

What is the SecurID token?

The SecurID token is a security device that generates a random number every 60 seconds. The number is used with a PIN and a username to positively identify or authenticate the individual to whom the token is assigned. The token will expire on the date printed on the back of the token, which is about three years.

What happens when my SecurID token expires?

Please call the CDER Helpdesk (7-0911) and have a ticket logged. Provide the Call Center technician with the serial number located on the back of the token. We will need to have the token returned to OIT; it can be returned to the building lead. A new token will be issued to you and then you will need to set up a new PIN. You may use the same PIN.

How do I get a SecurID token?

The SecurID token will be given to you when your PC has been updated with the SRAS software. The SRAS installer will give you a tutorial on how to dial into SRAS and how to use the token.

What if my SecurID token is damaged?

First, don't dispose of the token; we must have it back. Second, please call the CDER Helpdesk (7-0911) and have a ticket logged. Finally, provide the Call Center technician with the serial number of the token, which is located on the back.

What if I lose my SecurID token?

If you lose your SecurID token, please call the CDER Helpdesk (7-0911) and have a ticket logged. OIT will have the old token deactivated and a new token assigned to you. A building technician will provide you with the new token. This could take up to three days.

If I receive a new SecurID token will the PIN be reset?

Yes, you will need to establish a new PIN. And yes, you can use the same PIN you used previously.

I was not able to bring my PC into the office on my scheduled date. What should I do?

Please let the Helpdesk know when you can bring the PC into the office. We will make every effort to work you back into the schedule. If the SRAS team has left your building then a ticket can be logged for the building technician.

Can I have the Secure RAS software for my personally owned PC?

No, with the new system and Agency security policy now in place, personally owned PCs will not be able to access the CDER network as of Jan. 1.

Can my personally owned PC have SRAS installed on it until Jan. 1?

(Continued on page 5)

November OIT Training

Tuesday	Wednesday	Thursday
5	6 Outlook E-mail (C) 9:00-12:00 Outlook Calendar (C) 1:00-4:00 JMP Session I (P) 1:00-4:00	7
11	13	14 PowerPoint Intro (P) 9:00-12:00 PowerPoint Charts (P) 1:00-4:00
19 Word Tables (C) 1:00-4:00	20 DSS (C) 9:00-12:00 DFS (C) 1:00-4:00 JMP Session II (P) 1:00-4:00	21

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

Panel urges improvements to acetaminophen, NSAID labeling

BY CRYSTAL RICE

Improvements to labeling and consumer information for acetaminophen, aspirin and non-steroidal anti-inflammatory drugs or NSAIDs such as ibuprofen were among the recommendations made by FDA's Nonprescription Drugs Advisory Committee at a September meeting.

The panel recommended including the word "acetaminophen" in bold on labels of all drug products containing the ingredient. The advisers also recommended that labels warn consumers not to take multiple products containing acetaminophen at the same time and not to exceed the recommended daily dosage and dosing for acetaminophen as this may lead to liver damage.

The panel recommended adding dosing information for infants and children under 2 years of age to liquid products containing acetaminophen. The labels for these products currently do not have recommended dosages for children in these age groups, and parents are instructed to call a health care provider.

The committee also noted the need for additional pharmacist and consumer education about unintentional overdoses of acetaminophen and the risk of serious liver damage that can result from such use.

The panel also recommended that labeling for aspirin, ibuprofen and other NSAIDs include warnings about the possibility for gastrointestinal bleeding that may be associated with chronic use of these products.

Finally, the committee recommended adding language to urge patients to ask their health care provider about NSAID use if they have kidney disease, high blood pressure, heart failure, liver disease or are taking diuretics because of the concern with potential renal toxicity.

FDA will evaluate the advice and feedback received at the advisory committee meeting and work to complete its rulemaking for these products—the final monograph for OTC internal analgesics—as soon as possible.

Crystal Rice is a public affairs specialist in OTCOM.

Token, 3-step log-in process enhance remote access security to network

(Continued from page 4)

CDER policy states that we cannot work on individually owned PCs. Due to the complexity of the installation and configuration, we are not able to provide the SRAS software to you.

How do I get a government-issued home PC?

If you have already been approved to work off site and have completed the Off-Site Computing Form, then please call the CDER Helpdesk and they will log a ticket for your request. A government-issued home PC will be delivered to you as soon as one is available.

I have a division laptop with Windows 95. Can this be upgraded to Windows 98 and Secure RAS installed?

Possibly; however, not all laptops will be able to be upgraded to Windows 98. Please check with your building technician for an evaluation of your laptop.

Do I need the training provided by the SRAS Team?

We highly recommend that you participate in the one-on-one training with the SRAS technician. But, no, the training is not mandatory. We will provide you with printed instructions on how to log into SRAS and how to create your PIN.

Will I still be able to use the old RAS?

Once you are setup for Secure RAS, you will not be able to log into the CDER network via the old RAS dial-up networking process. Please note that SRAS is a totally different RAS system, which uses a different phone number to dial into the CDER network

I am bringing my government-issued home PC into the office to be repaired. Can I have SRAS installed while the PC is in the office?

Unfortunately, we won't be able to handle special requests. Our schedule is tight and we might not be in your building at the time your PC is in the office.

What is a PIN?

A PIN is a personal identification number you create. This is a four- to eight-digit number that only you know. Please create a number that you can remember so that it doesn't have to be reset.

What if I forget my PIN?

If you forget your PIN, please call the CDER Helpdesk and have a ticket logged. You will need your SecurID token serial number found on the back of the token. OIT will have your PIN reset. This should only take one day, but it could take up to three days. Once the PIN is reset you will be prompted to create a new PIN the next time you log into SRAS.

Do I need to bring in my entire computer system, including the monitor, keyboard and mouse?

You only need to bring in your CPU and your external modem if applicable.

I need my division's travel laptop with SRAS installed for travel. What should I do?

Please call the CDER Helpdesk. A building technician can set up SRAS on a division's travel laptop that has not yet been upgraded. The CDER Helpdesk needs at least 72 hours notice to get the division laptop upgraded. All individual users of the laptop will need a SecurID token and SRAS account in order to dial into the network.

How do I know if my division's travel laptop has been setup for SRAS?

The laptop will have a label on it stating that it has been upgraded and that all individual users of the laptop will need a SecurID token and SRAS account in order to dial into the network.

Why does it take longer to log in using SRAS?

Secure RAS has three separate log-in screens. The first is for dialing into the server; the second identifies you to the server; and the third and final screen is to log into the CDER network.

If I am on travel and I don't have my SecurID Token with me will I still be able to use SRAS?

No. The SecurID token is required to use SRAS. The CDER Helpdesk won't be able to issue you a new token or provide you with an alternative means to dial into SRAS.

INTERNATIONAL CONFERENCE ON HARMONIZATION

Electronic Common Technical Document specifications approved

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

The steering committee for the International Conference on Harmonization and its expert working groups met in Washington to discuss implementation of the Common Technical Document (August 2000 *Pike)* and to adopt the final version of the electronic Common Technical Document.

The CTD allows data in the same format to be submitted to drug review authorities in all three ICH regions—the European Union, Japan and the United States. In July, use of the CTD will become "highly recommended" in the United States and mandatory in Japan, the European Union as well as the non-ICH countries Canada and Switzerland.

National regulatory authorities will implement the eCTD according to their own procedures. The eCTD contains the specifications and the document type definition standard.

The steering committee also noted the significant progress on the three new pharmacovigilance topics:

- The addendum to *Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs* (E-2C) was released for initial public comment.
- The expert working group draft of *Good Case Management Practices* (a follow-up to the existing E-2A guidance) is maturing and is expected to be approved for initial public comment in Tokyo in February.
- A final concept paper was endorsed for the development of a guidance to be titled *Prospective Planning of Pharmacovigilance.*

A one-day scientific symposium was held to discuss the comparability of biotechnological and biological products. The steering committee agreed to establish an official expert working group to develop harmonized guidances.

A discussion on implementing the guidance *Ethnic Factors in the Acceptability of Foreign Clinical Data* (E-5) that had begun in February was pursued with detailed information on a series of case studies. The steering committee agreed to establish an implementation working group to develop recommendations and clarifications that will be published in the form of questions and answers.

The steering committee reached final agreement on a minor maintenance to the guidance *Residual Solvents* (Q-3C(M)) revising the permissible daily exposures for tetrahydrofuran and N-methyl pyrrolidone.

The management board for the Medical Dictionary for Regulatory Affairs reported that version 5.1 was released in September. Spanish and Portuguese translations are now available. The next release of MedDRA, version 6.0, is scheduled for early March.

About 150 participants attended ICH's first open workshop on gene therapy. A report is on the ICH Web site at http://www.ich.org/ich7.html#Gene%20Therapy. The steering committee agreed to formalize the gene therapy discussion group under the official ICH work process.

The steering committee was updated on a meeting in which the Global Cooperation Group agreed to develop further cooperation with non-ICH countries and to organize a special symposium during the ICH 6 conference in Osaka, Japan, in November 2003. The steering committee agreed on a detailed proposal for the ICH 6 program.

Justina Molzon heads the Center's International Program.

PROCESS ANALYTICAL TECHNOLOGIES CORNER

Panel works on plan to encourage progress on modern manufacturing

BY MARY JANE MATHEWS

Representatives from industry, academia and FDA met in June to hammer out a plan to encourage progress on the Center's initiative to modernize drug manufacturing. The experts met in June for the second meeting of Process Analytical Technologies Subcommittee of the Advisory Committee for Pharmaceutical Science.

The meeting brought together leading experts with interest in the development of PAT, an initiative that has the potential to promote efficiency and reliability in drug manufacturing while reducing expenses (July *Pike).*

"We should think of PAT as paradigm shift from a regulatory perspective," **Ajaz Hussain, Ph.D.,** the deputy director in the Office of Pharmaceutical Science, told the panel in opening remarks. "The agency has adopted a win/win approach to application of PAT. We wish to create a win for public health and a win for industry."

James Whetstone, a division chief in the Chemical Science and Technical Laboratory, National Institutes of Standards and Technology, shared his agency's experience with similar initiatives in the industries they serve.

After presentations by invited speakers, the subcommittee discussed a series of questions prepared in advance and distributed with conference materials. A beneficial exchange of information and opinions resulted from using these questions to discuss solutions to important issues.

In the afternoon, working groups met to consider questions from the subcommittee. Of the four groups initially formed, two remain operative:

- *Product and process development,* chair, Judy P. Boehlert, Ph.D., Boehlert Associates.
- *Process and analytical validation,* chair, Arthur H. Kibbe, Ph.D., Wilkes University.

A third working group met informally to discuss education and training. Kenneth R. Morris, Ph.D., Purdue University, chaired this group.

The next meeting of the PAT Subcommittee was planned for Oct. 23 and focused on three areas:

- Rapid microbial testing.
- Computer validation issues.
- Case studies.

Mary Jane Mathews is a writer and editor in the Office of Pharmaceutical Science.

PHARMACOLOGY/TOXICOLOGY CORNER I

Mini-course presented state of art in reviewing carcinogenicity

BY LAWRENCE F. SANCILIO, PH.D.

The Education Subcommittee of the Pharmacology/Toxicology Coordinating Committee, under the leadership of **Robin Huff, Ph.D.,** organized a six-session mini-course this spring titled Evaluation, Interpretation and Integration of Pharmaceutical Carcinogenicity Studies. Dr. Huff is from the Division of Pulmonary and Allergy Drug Products.

The goal was to present the state of the art for the carcinogenicity bioassays to new and experienced reviewers. The topics discussed included:

- The mechanisms of carcinogenicity.
- The need for and design of studies.
- Selection of doses.
- The statistical analyses and interpretation of the results from the two-year carcinogenicity bioassay.

In addition, there were presentations on the alternative carcinogenicity animal assays, integration of genotoxicity data, computational toxicology from CDER's in-house database for predicting potential carcinogenicity, risk assessment and the role of the Carcinogenicity Assessment Committee.

In the assessment for carcinogenicity, pharmaceutical compounds are generally tested in a two-year bioassay in the rat and mouse. However, the 1997 ICH guidance, *Testing for Carcinogenicity of Pharmaceuticals* (S-1B), proposed alternative animal assays as a replacement for the long-term mouse carcinogenicity assay.

Currently, there are seven of these short-term, alternative transgenic mouse models being used or under development. Each of the models was described along with its current use and its experience with known test compounds.

This course was well received as 84 registered, and about 60 attended each session.

The speakers from CDER were:

- **James G. Farrelly, Ph.D.,** and **C. Anita Bigger, Ph.D.,** Division of Anti-Viral Drug Products.
- **Charles A. Resnick, Ph.D.,** Division of Cardio-Renal Drug Products.
- **Charles Anello, Ph.D.,** Office of Biostatistics.
- **Frank D. Sistare, Ph.D.,** director of the Division of Applied Pharmacology and Research.
- **Abigail C. Jacobs, Ph.D.,** Division of Dermatologic and Dental Drug Products.
- **Joseph F. Contrera, Ph.D.**, Office of Pharmaceutical Science.
- **Adele S. Seifried, M.S.,** Office of New Drugs.

Guest speakers were:

- **John E. French, Ph.D.,** and **John R. Bucher, Ph.D.,** National Institute of Environmental Health Sciences.
- Joseph J. DeGeorge, Ph.D., Novartis Pharmaceuticals Corp.
- R. Michael McClain, Ph.D., a consultant.

Dr. Huff, Dr. Sistare and **Barrie N. Rosloff, Ph.D.,** from the Division of Neuropharmacological Drug Products, were instrumental in the selection of the topics and speakers.

James Minter, Ed.D., from the Division of Training and Development in OTCOM, and I coordinated the course.

- The goals of the Education Subcommittee are to:
- Provide programs to increase the knowledge of reviewers.
- Facilitate the review process.
- Train new reviewers in the fundamentals of the regulatory process and assessment of the adequacy of toxicity and related studies.

Reproductive toxicology next

In October, the subcommittee sponsored a five-session program on reproductive toxicology.

Lawrence Sancilio is a pharmacologist in the Division of Pulmonary and Allergy Drug Products.

EEO CORNER

National Hispanic Heritage Month ran from Sept. 15 to Oct. 15

BY GLORIA SUNDARESAN

The president proclaims the annual observance of National Hispanic Heritage Month to run from Sept. 15 to Oct. 15. The period is observed with programs, ceremonies and activities to honor Hispanics who contributed to all aspects of American life and culture.

Hispanics in this country come from Spain, Mexico, Central America, South America and the Caribbean. Many have come to this country in search of economic progress and to fulfill their life's dreams for their family. They have shared their music, food and strong commitment to religion, work ethics, family and the community. Hispanics have enriched American culture in the past and will do more so in the future because they are one of our the fastest growing ethnic groups. In 1990, they represented 9 percent of the population. They are now 12.5 percent according to the 2000 census.

> Hispanics are underrepresented in CDER, FDA, HHS and other federal agencies.

Hispanics came to this country in pursuit of freedom; enjoyed this freedom; and as soldiers, lost their lives to keep this freedom, an integral part of the American way of life. About 38 Congressional Medals of Honor have been presented to those who served this country with highest distinction during the Civil War, WW I, WW II, Korean War and the Vietnam War.

Besides the military, Hispanics are also in science, medicine, business, politics, universities and sports. Hispanic men and women serve in the national, state and local governments. The most recent Hispanic heroes were men and women who lost their lives to save others at the Twin Towers in New York City last Sept. 11.

Hispanics are underrepresented in CDER, FDA, HHS and other federal agencies. The Center has about 50 dedicated Hispanic employees who contribute to the safety and efficacy of the drug products in the market. An educational display was set up in the Parklawn Building's 5th Floor lobby.

Gloria Sundaresan is an equal employment specialist on the Center's EEO/ Recruitment Staff.

OFFICE OF DRUG SAFETY

Information sharing, good data use support of risk management

BY PATRICK E. CLARKE

The Division of Surveillance, Research and Communication Support, one of the three divisions in the Office of Drug Safety, will lead the development of the risk management guidance for industry required by reauthorization of the Prescription Drug User Fee Act.

"DSRCS didn't exist until January," said **Anne Trontell, M.D., MPH,** the division's director, "so we're still in the process of establishing positions, processes and policies. We will chair the FDA working group that is developing a risk management guidance for industry as spelled out in PDUFA III."

The division will work in conjunction with the CDER Office of New Drugs and the Center for Biologics Evaluation and Development on the guidance.

Dr. Trontell's mantra is: "We're always looking for more data."

Not that her division doesn't already have extensive databases. "We actually have four in-house databases to draw from as to how drugs are used," Dr. Trontell said.

One of the databases is available through a contract with IMS Health. This company audits the number of prescriptions filled as well as how physicians mention or prescribe outpatient drugs. "We can break down the statistics demographically and get a rough idea of who is prescribing and using particular drugs," Dr. Trontell said.

However, IMS data do not indicate how drugs are used over time or within hospitals.

That problem was resolved last year when CDER awarded three contracts that give the Agency access to additional commercial databases. These describe inpatient prescription drug use in adults and children and longitudinal outpatient use (November 2001 *Pike)*.

ODS series

The article on the Division of Surveillance, Research and Communication Support is the last in a series profiling the Office of Drug Safety.

The other articles are available at:

- Overview: http://www.fda.gov/cder/pike/janfeb2002.htm#ODS.
- Division of Medication Errors and Technical Support: http://www.fda.gov/cder/pike/july2002.htm#DMETS.
- Division of Drug Risk Evaluation: http://www.fda.gov/cder/pike/august2002.htm#DDRE.

"These help us set the context in which drugs are used," Dr. Trontell said. They can approximate the degree of human exposure underlying reports of adverse events to FDA.

"Longitudinal data can give us a sense of how long people are being exposed to a drug," Dr. Trontell said. There may be a different risk profile if a person uses a drug for one month as opposed to one year.

The division also administers the Cooperative Agreements Program with three major health systems (United Health, Harvard Pilgrim and the Tennessee and California Medicaid populations) to look at population-based data regarding drug safety. The division is piloting and exploring data sharing with the Departments of Defense and Veteran's Affairs and Kaiser Permanente among others. "We share a common public health mission, and medical encounters are increasingly computerized, "Dr. Trontell said.

Her division also shares responsibility for the Adverse Events Reporting System, which had more than 280,000 reports last for drugs.

"We also provide quality control for and help triage MedWatch reports which come in for all FDA-regulated products," Dr. Trontell said. The division along with the Office of Information Technology facilitates companies' changing their adverse event reporting systems to allow direct electronic submissions to FDA.

The MedWatch program moved to the division in January 2002 and promotes reporting of medical product safety problems for all FDA-regulated medical products. MedWatch also broadcasts FDA safety alerts, notices of Dear Health Care Practitioner letters, Class I recalls and labeling revisions.

"MedWatch is largely electronically

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PIKE'S PUZZLER

Medicine in the cinema

BY TONY CHITE

Identify the movie from the brief description below.

1. Jack is a gifted but arrogant surgeon who suddenly is a patient instead of a doctor. He then learns firsthand the callous attitude of the professional medical community.

a. *Regarding Henry*
b. *Awakenings*
c. *Patch Adams*
d. *The Doctor*

2. Concerned parents take matters into their own hands to start their own investigation of their son's debilitating fatal disease (adrenoleukodystrophy). Nominated for Best Actress and Best Original Screenplay.

a. *Death Be Not Proud*
b. *Lorenzo's Oil*
c. *Mask*
d. *From Here to Eternity*

3. Courageous true story in which Lou discovers that he has a fatal neurological disease called amyotrophic lateral sclerosis, now known as Lou Gehrig's disease. Nominated for 10 Academy Awards including Best Actor, Best Actress and Best Picture. Winner for Best Editing.

a. *The Rookie*
b. *Fear Strikes Out*
c. *The Pride of the Yankees*
d. *Bang the Drum Slowly*

Key: 1d; 2b; 3c

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

Two presidential management interns assigned to work in Center

BY PATRICK E. CLARKE

Two presidential management interns will perform their internships with CDER's Office of Compliance. Both were chosen from among recent master's and doctorate graduates for outstanding leadership, scholarship and commitment to public service. The presidential management interns are:

- **John R. Finley,** who is a graduate of the Oklahoma University College of Public Health and its College of Law.
- **Stephen Papagiotas,** who just completed his master's degree in Public Health at the Rollins School of Public Health at Emory University in Atlanta.

The nomination and final selection processes are grueling, according to Finley. Both interns had to pass through three rounds of the selection process.

Finley will have the opportunity to serve as regulatory counsel and Papagiotas as a consumer safety officer in OC. In addition, both may also have opportunities to experience work at the White House, on Capitol Hill or with various other departments of the executive branch of the federal government.

Finley indicated that the salary disparity between government service and the private sector discourages some recent graduates from considering a career with the federal government.

However, he said that he looked beyond pay in pursuing this program. "I am not really concerned about the pay. I am more excited about the work," Finley said. "I was looking for something different than typical lawyer, first-year associate work. I will have a chance to learn and lead.

"Yes, the starting pay is low, but you have to think about quality of life and the long-term rewards. I definitely will not be stuck in some cubicle proofing some partner's 800-page contract for typos. I want to be caught-up in the dynamic environment of the Hill and in the rooms where decisions are made. I want to be in the mix, doing great work and making it happen."

He predicts that the presidential management intern program and CDER will provide him the opportunities he seeks.

Papagiotas expressed similar reasons for wanting to be a presidential intern working at CDER.

"Personally, I wanted a position that would enable me to put my epidemiology knowledge to good use," Papagiotas said. "Working in OC gives me that chance, plus the overall emphasis on public health matches up well with my background."

Papagiotas intends to make a career with the federal government.

For the past 24 years, the Presidential Management Intern Program has been attracting outstanding master's and doctoral-level students to federal service.

It provides interns with an opportunity to apply their knowledge acquired from graduate study. Intern assignments may involve domestic or international issues, technology, science, law, health, financial management and many other fields in support of public service programs.

Since the inception of the program in 1977, more than 6,000 interns have been hired by all cabinet departments and over 50 federal agencies.

More information about the PMI Program can be found at: http://www.pmi.opm.gov/.

New division's support of risk management keys on data use, sharing

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based. MedWatch has an electronic mailing list of 25,000 health professionals and 170 professional organizations representing various health care associations and societies. Electronic notifications can even be picked up by doctors on their personal digital assistants through a program called ePocrates," Dr. Trontell said.

The division is composed of primarily of pharmacists, epidemiologists as well as nurses and social scientists who formerly worked in the Division of Drug Marketing, Advertising and Communications. The latter two groups are responsible for reviewing the content of patient package inserts and medication guides.

"We examine whether the format is consistent and that the language can be well understood by those with lower literacy rates," Dr. Trontell said. One of her frustrations is that not all patient package inserts are brought to the division's attention. The division does have expertise to contribute in this area. "Having social scientists representing the cognitive sciences allows us to gather and apply data about the success of our risk communication efforts," Dr. Trontell said. "It's a small pocket of experts we'd like to grow."

These experts also review information regarding over-the-counter products. "We look at label comprehension studies for over-the-counter products. Such studies help to ensure people understand how to self-diagnose and treat safely and effectively without a physician's help. One question we were asked recently is whether people can understand the distinction between an OTC medication to prevent heartburn as opposed to one to treat heartburn?"

The division also oversees evaluations of the quantity and quality of medication information provided by pharmacists when they dispense prescriptions. "Congress set a performance goal that by 2006, 95 percent of people should get useful written information regarding their medications," Dr. Trontell said. A recent FDA-commissioned study showed that about 90 percent of consumers did receive some form of written information, although the average "usefulness" rating was only about 50 percent (July *Pike).*

Internationally, the division works with the European Medicine Evaluation Agency, the World Health Organization and the drug regulatory bodies in Canada, Australia and New Zealand. "We share emerging drug safety signals," Dr. Trontell said.

For Dr. Trontell, the heart of her division's mission is to provide evidence-based drug safety information to both health care professionals and the general public. "We want to use data to help guide the development and evaluation of risk management activities," Dr. Trontell concluded.

Patrick Clarke is a public affairs specialist in OTCOM.

Fall retreat hears Dr. Jenkins, neurotox issues

BY ELIZABETH HAUSNER, DVM

The Center's semi-annual retreat for pharmacology/toxicology reviewers included regulatory updates from standing committees of the Pharm/Tox Coordinating Committee, a discussion with OND Director **John Jenkins, M.D.,** and an afternoon session devoted to neurotoxicology issues.

The September 18 retreat was organized and arranged by **Fred Alavi, Ph.D., Hanan Ghantous, Ph.D., Pat Harlow, Ph.D., Wafa Harrouk, Ph.D., Tushar Kokate, Ph.D., Tom Papoian, Ph.D., Luqi Pei, Ph.D., Tim Robison, Ph.D., Jui Shah, Ph.D., Adele Seifried, M.S., William Taylor, Ph.D., Josie Yang, Ph.D.,** and myself.

Following opening remarks by Dr. Ghantous, who is from the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, **Robert Osterberg, Ph.D.,** the Center's acting deputy associate director for pharmacology/toxicology, gave an update of the status of the Common Technical Document, the Q-3BR4 document (impurities and drug products) and the tentative agenda for the November PhRMA/Agency meeting. New reviewers were introduced.

"Pros and Cons of the SHE cell Assay" was presented by **Jui Shah, Ph.D.,** from the Division of Pulmonary and Allergy Drug Products, and **Anita Bigger, Ph.D.,** the co-chair of the Genetic Toxicology Subcommittee and a member of the Division of Anti-Viral Drug Products. This was a case example of a sponsor's reaction to our request to perform a SHE cell assay or a p-53 mouse bioassay due to a genotoxicity signal requiring elucidation. The validation of the assay, sensitivity, specificity, level of discrimination, mechanism and the use in decision-making were discussed.

Regulatory updates

Organized by **Pat Harlow, Ph.D.,** from the Division of Cardio-Renal Drug Products, recent activities of some standing pharm/tox committees were summarized by the following presenters:

- *Clinical Pathology Committee,* **Jim Farrelly, Ph.D.,** (Division of Anti-Viral Drug Products).
- *Pharmacokinetics/Toxicokinetics,* **Jeri El-Hage, Ph.D.,** (Division of Metabolic and Endocrine Drug Products).
- *Non-clinical Pharmacogenomics,* **John Leighton, Ph.D.,** (Division of Oncologic Drug Products).
- *Immunotoxicity,* **Dan Mellon, Ph.D.,** (Division of Anesthetics and Critical Care).
- *Reproductive Toxicity,* **David Morse, Ph.D.,** (Division of Oncologic Drug Products)

Wafa Harrouk, Ph.D., from the Division of Metabolic and Endocrine Drug Products, provided a review and discussion of the Carcinogenicity Study Protocol Submission Guidance for Industry.

OND overview

Dr. Jenkins addressed the reviewers about such issues as the consolidation of pharmaceutical product review, PDUFA III, restoring a balance between resources and workload, ongoing pilot programs and the interview process for the associate director for pharm/tox position. A question-and-answer session followed, including questions about the reorganization, the reviewer career path and the review formats.

Neurotoxicology workshop

After the working lunch with its question and answer session for Dr. Osterberg, the neurotoxicity workshop began. This was presented by representatives of Center for Food Safety and Applied Nutrition, the pharmaceutical industry, CDER and the Office of Testing and Research in the Office of Pharmaceutical Science from the viewpoints of protecting people from neurotoxicity associated with food or pharmaceuticals.

CFSAN's **Tom Sobotka, Ph.D.,** talked about minimizing the risk of human neurotoxicity by assessing the neurotoxic potential of food ingredients. He described CFSAN's tier approach to this type of evaluation, describing the testing strategies and emphasizing the need for routinely making systematic observations.

Mary Jeanne Kallman, Ph.D., from Eli Lilly and Co. presented testing approaches from the industry point of view. As well as describing various neurological tests, Dr. Kallman discussed other points of consideration such as the appropriate species, gender, time points and dose selection. The context of the observation relative to other effects was stressed as important.

Joe Hanig, Ph.D., acting director of OTR's Division of Applied Pharmacology Research, gave an example of a multicenter approach to investigating a signal of neurotoxicity in a marketed drug. Ketamine, an injectable anesthetic acting through NMDA receptors, is used off-label for general anesthesia in children. In 1999, a group of scientists demonstrated severe, widespread cell death in the brains of 7-day-old rats that had received ketamine (*Science*, 283, 70-74).

Rapid follow-up to these findings came about through a collaborative effort between CDER's PTCC Research Subcommittee, the OPS Rapid Response Team (July *Pike),* the Neurotoxicology Division of FDA's National Center for Toxicological Research as well as the Defense Department's Uniformed Services University of Health Sciences.

Studies by OTR conducted at USUHS in conjunction with NCTR reproduced the ketamine-induced neurodegeneration in the dorsolateral thalamic nuclei and other brain areas of 7-day-old rats. Limited behavioral studies one to three months later did not indicate significant differences between treated and untreated animals. The data resulted in CDER's successful nomination of ketamine to the National Toxicology Program and the endorsement and funding of further investigative efforts (http://ntp-server.niehs.nih.gov/htdocs/Chem_Background/ExSumPdf/Ketamine.pdf).

(HHS's NTP is an interagency program consisting of toxicology activities of the National Institutes of Health's National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health and FDA's National Center for Toxicological Research. NTP's mission is to evaluate agents of public health concern by developing and applying tools of modern toxicology and molecular biology.)

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FDA to consolidate reviews of new pharmaceuticals in CDER

On Sept. 6, FDA announced that responsibility for reviewing new biological drugs, other than gene therapy, will be transferred to CDER.

This will consolidate the review functions for therapeutic drug and biologic products, now performed both by CDER and the Center for Biologics Evaluation and Research. The move will enhance the efficiency and consistency of the Agency's regulatory processes.

"FDA's drug and biological product reviews have long been the gold standard for the world," said **Lester M. Crawford, DVM, Ph.D.,** FDA's deputy commissioner. "By carefully combining part of our present biologics review operation responsibilities with our drug review operation, FDA will be optimally positioned to uphold that gold standard by continuing to review novel pharmaceutical products promptly and rigorously in an accountable and consistent manner."

In an e-mail to CDER employees, Center Director **Janet Woodcock, M.D.,** said: "The goal is to effect the transition as smoothly and painlessly as possible for all involved."

The CBER-CDER Product Consolidation Working Group will address the timing of the transfer and other logistical issues. Co-chairs of the working group are:

- **Murray Lumpkin, M.D.,** the associate commissioner for international affairs and strategic initiatives.
- **Theresa Mullin, Ph.D.,** the associate commissioner for planning.

The group expects to have an action plan and timeline by January and is working on these premises:

- Review of biologic products other than vaccines, blood cells, tissues, gene therapy and related products will be transferred to CDER.
- Scientific staff and support functions, including laboratories associated with review of these products, will be consolidated within CDER.
- The transfer plan will be accomplished with the greatest attention given to minimizing disruption to staff and current product reviews.
- There will be no reductions-in-force associated with these transfers.

On Oct. 28, Drs. Lumpkin and Mullin announced that the product categories currently regulated by CBER and to be transferred to CDER are:

- Monoclonal antibodies.
- Cytokines, growth factors, enzymes and interferons (including recombinant versions).
- Proteins intended for therapeutic use that are extracted from animals or microorganisms.
- Therapeutic immunotherapies, with some specifics yet to be worked out.

Dr. Crawford said that he made his decision after a lengthy process of fact finding and deliberation. Consultants hired in the fall of 2001 conducted an assessment of the drug review process to identify best practices and make recommendations for improving those processes.

"After carefully reviewing the data and the options that were presented to me, I noted the wide variety of functions performed by CBER, many of which have a broad public health focus such as the regulation of vaccines and ensuring the safety of the nation's blood supply," Dr. Crawford said.

"The therapeutic biologics review function was quite distinguishable from these activities. I decided that the therapeutic biologic review could be handled with less duplication of effort and greater consistency if it was integrated into similar drug review functions that reside in CDER."

Pharm/Tox fall retreat

(Continued from page 10)

The final sessions were two case presentations. **David Hawver, Ph.D.,** from the division of Neuropharmacologic Drug Products, presented an example of AMPA receptor potentiator. The preclinical findings of the drug included a comparison of therapeutic blood levels in humans and blood levels in animals associated with neurotoxicity.

Wendy Schmidt, Ph.D., from the Division of Anti-Infective Drug Products, presented an example of a new antibiotic with neurotoxicological potential. There was a detailed comparison of plasma levels in several species, including humans and the correlation with the points at which different levels of neurotoxicology were manifested.

The focus issue for both Drs. Hawver's and Schmidt's presentations was the characterization necessary to permit clinical trials to proceed.

Elizabeth Hausner is a pharmacologist in the Division of Cardio-Renal Drug Products.

CDER experts to discuss PDUFA III

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days afterward at http://www.lmpdg.com/index.cfm?pgname=4.04.

The live broadcast can be viewed at these locations:

- Parklawn, Room 13B-39.
- Corporate II, Room S-400.
- Metro Park North I, Room 259.
- Metro Park North II, Room B.
- Woodmont II, Room G.
- Park Building, Room 314.
- Laurel, Room 2004.

Deborah Henderson, the director of the Office of Executive Programs, will moderate the discussion, and the scheduled panelists are:

- **Steven Galson, M.D., MPH,** the Center's deputy director.
- **John Jenkins, M.D.,** the director of the Office of New Drugs.
- **Victor Raczkowski, M.D.,** the director of the Office of Drug Safety.
- Timothy Franson, M.D., the vice president of clinical research and regulatory affairs-U.S. at Lilly Research Laboratories.
- Alan Goldhammer, Ph.D., the associate vice president for regulatory affairs at the Pharmaceutical Research and Manufacturers of America.

The Center cosponsors the videoconference with the non-profit Drug Information Association. DIA is handling registrations for both the live videoconference and the webcast.

Registration information for those outside CDER is available at http://www.diahome.org/Content/Events/02055.pdf.

Elaine Frost is a public affairs specialist in OTCOM and producer of the CDER Live! series.

Single 30-day stay, tighter patent listing for Orange Book proposed

(Continued from page 1)

proposal brand name pharmaceutical companies would still be able to protect their patent rights through traditional patent infringement lawsuits.

The proposed rule would also clarify the requirements for listing drug patents in the "Orange Book," which is the official compendium of drug products that FDA has approved.

The proposal would limit the types of patents that have the potential to block generic drug approvals. It would clarify the types of patents that can be submitted to FDA as protection for the brand-name drug product and listed in the Orange Book.

In particular, the regulation would make clear that drug manufacturers could not submit to FDA patents on such product aspects as packaging, metabolites and intermediates that are unlikely to represent significant innovations.

Manufacturers of new drugs would have to provide FDA additional information when they file their patents. This is aimed at discouraging them from submitting patents that are not permitted to be listed under the statute and regulations. This detailed patent declaration will be subject to criminal penalties for misrepresentation.

"This proposal provides a common sense balance between providing patent protection for brand name pharmaceutical manufacturers and our desire to speed generic drug approval," said FDA Deputy Commissioner **Lester Crawford, DVM, Ph.D.**

The proposals are consistent with recent recommendations made by the Federal Trade Commission. In its July 2002 study, *Generic Drug Entry Prior to Patent Expiration,* FTC recommended that there be only one 30-month approval delay per generic drug application. FTC's study found an increase in the listing of patents, which had been issued by the Patent and Trademark Office after the brand name drug product had been approved and also after a generic application had been filed. For eight drugs, the additional 30-month stays held up approvals of generic drugs for an additional period of from four to 40 months.

FDA's proposed rule change would eliminate a significant impediment to prompt approval of generic drugs while preserving the legitimate incentives necessary for innovative drug development.

FDA will accept public comments on its proposal until Dec. 23 and then will move to issue a final rule. The proposed rule is at: http://www.fda.gov/OHRMS/DOCKETS/98fr/102402b.htm and http://www.fda.gov/OHRMS/DOCKETS/98fr/102402b.pdf.

The FTC report is at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

Educational effort aims to build confidence in quality of generics

(Continued from page 1)

explaining that FDA ensures generic drugs safe and effective.

"All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA's high standards," the ads say. They point out that FDA makes it tough to become a generic drug in America so consumers can rest assured and health care providers can feel confident.

The versions for consumers have two different headlines:

- "You know that question that goes through your mind when you take your generic drug? Here's the answer."
- "If you're experiencing anxiety about taking your generic drug, read this ad and repeat as needed."

The headline in the ad for health care providers reads: "Think it's easy becoming a generic drug in America? Think again." Below the headline, a graphic of a pill is surrounded by captions reading: "Consistent labeling. Rigorous manufacturing standards. Performance evaluation. Same drug. Purity check. Assured quality."

The ads come in three sizes:

- 7 inches by 10 inches.
- 3.375 inches by 10 inches.
- 4.5 inches by 4.687 inches.

Send an e-mail to hisima@cder.fda.gov for a CD with the images and request either PDF or Mac QuarkXPress format. A PDF of each large-sized ad is posted on CDER's Consumer Education page at http://www.fda.gov/cder/consumerinfo/generic_info/default.htm.

Use the same e-mail address to request reprints of an updated article on generic drugs from the 1999 *From Test Tube to Patient.*

In addition to consumers, this program will educate health care professionals, associations, industry and others about FDA's generic drug review process.

The multimedia educational program will eventually include:

- Brochures for pharmacies in English and Spanish.
- Print and radio public service announcements in English and Spanish.
- Continuing education for health professionals.
- Newspaper articles.
- Ads on trains and buses.
- Information on the Internet.

The Center will also work with other organizations to disseminate the generic drug message.

Crystal Rice and Ayse Hisim are public affairs specialists in OTCOM.