news along the pike

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CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

CDER event honors 81 individuals, 46 groups

Spirit, service, commitment cited in 'challenging year'

BY JACKIE BARBER WASHINGTON

At CDER's Fall Honor Awards Ceremony, top management presented 81 individual and 46 group awards.

"The Center experienced another challenging year but thanks to your innovative spirit, dedication to public service and commitment to our important public health mission, we met the challenges head-on," Acting Center Director **Steven Galson, M.D.,** told the awardees.

"Whether it's scientific, technical, administrative or managerial, the expertise you bring, and so willingly share, enabled us to meet our everyday deadlines and embark on exciting new initiatives."

Kevin Barber sang the national anthem, and the PHS Wind Ensemble played the "PHS March." The awards were announced by **John Emilio,** who heads the Division of Management Services in the Office of Management. Dr. Galson and members of the Center's senior management presented the awards.

FDA Outstanding Service Award

Gelind H. Grable

Andre J. Jackson, Ph.D.

Karen M. Kapust

(Continued on page 4)

Tentative approval provides quality HIV products to 3rd World

BY JUSTINA MOLZON, MSPHARM, J.D., JEFFREY MURRAY, M.D., MPH, RAO V. KAMBHAMPATI, PH.D., AND BARBARA DAVIT, PH.D.

The Office of New Drugs has provided tentative approval to the first low-cost, complete product to become eligible for purchase under the president's emergency $15 billion plan for AIDS relief around the world.

Also, the Office of Generic Drugs approved a U.S. firm's generic version of didanosine delayed-release capsules in December. This was the first approval of a generic antiretroviral drug under the emergency plan and was accomplished in less than seven months.

The OND tentatively approved product is a complete treatment for HIV-1 infection in adults. The three-drug regimen consists of lamivudine/zidovudine fixed-dose combination tablets co-packaged in a single blister card with nevirapine tablets. These tablets are generic versions of already approved products from innovator drug firms. This approval, the first for an HIV drug regimen manufactured by a non-U.S.-based generic pharmaceutical company, came on Jan. 25—within two weeks of our receiving a complete marketing application.

The product, made in South Africa, meets

(Continued on page 10)

Guidance, new review group to spur 'personalized medicine'

BY FELIX FRUEH, PH.D., AND LARRY LESKO, M.D.

The final guidance on pharmacogenomics, the newly formed Agencywide group to review voluntary submissions of genomic data and a new Web site are part of a broad effort underway at FDA to foster pharmacogenomics during drug development. When we announced the Critical Path last year (July 2004 *Pike),* we recognized the importance of pharmacogenomics and encouraged its use in drug development.

Pharmacogenomics allows health care providers to identify sources of an individual's drug response profile and predict the best possible treatment option.

"FDA's efforts will bring us one step closer to 'personalizing' medical treatment," said **Janet Woodcock, M.D.,** acting deputy commissioner for operations. "This new technology will allow medicines to be uniquely crafted to maximize their therapeutic benefits and minimize their potential risks for each patient."

Instead of a hit-or-miss approach to treating patients where it can take multiple attempts to find the right drug and the right dose, pharmacogenomics holds the promise that doctors will

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JOE'S NOTEBOOK

Risk minimization, CT guidances

Three final guidances that we issued on March 24 will help develop new ways and improve methods to assess and monitor the risks associated with drugs and biological products in clinical development and general use. The documents are part of our ongoing and comprehensive efforts to minimize risks while preserving the benefits of medical products.

"As one of the five initiatives announced in November 2004 to further strengthen our drug safety program, these guidances are further evidence of FDA's commitment to transparency in risk management decision-making," said Acting Center Director **Steven Galson, M.D.** "Continuing to improve the way safety is assessed and monitored will lead to the earlier identification of safety problems and enable a more proactive approach to minimizing these risks."

The final guidances are:

- *Premarketing Risk Assessment,* which describes additional safety testing, monitoring and interventions that may be helpful in selected circumstances and addresses pre-market risk assessment (http://www.fda.gov/cder/guidance/6357fnl.htm).
- *Development and Use of Risk Minimization Action Plans,* which discusses the development, implementation and evaluation of risk minimization action plans, (called RiskMAPs (http://www.fda.gov/cder/guidance/6358fnl.htm).
- *Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment,* which covers the assessment of reported adverse events (http://www.fda.gov/cder/guidance/6359OCC.htm).

The final guidances fulfill FDA's commitment to risk management performance goals as part of the reauthorization of the Prescription Drug User Fee Act in June 2002. They are based on three concept papers released on March 7, 2003, and on comments we received following a subsequent public workshop and publication of the draft guidances in May 2004.

We published a draft guidance on Feb. 14 that provides advice on what studies sponsors need to perform to evaluate drugs called "decorporation agents."

These are drugs that reduce health risks by increasing the rate of elimination or excretion of radioactive contaminants that have been absorbed, inhaled or ingested.

The draft document provides guidance to industry on the development of those decorporation agents when we need evidence to demonstrate effectiveness but when human efficacy studies are unethical or infeasible.

We convened a multidisciplinary group of scientists to discuss how provisions under the 2002 Animal Efficacy Rule could be used to facilitate development of new decorporation agents. This rule applies when adequate and well-controlled clinical studies in humans cannot be ethically conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers.

The rule is a major part of our effort to help make medical countermeasures available and thereby help improve the nation's ability to respond to emergencies, including terrorist events.

Other examples of approved decorporation agents are Prussian Blue, potassium iodide (KI), Ca-DTPA and Zn-DTPA. These drugs, when manufactured under conditions specified in an approved NDA, have been found safe and effective for the treatment of internal contamination with radioactive cesium (Prussian Blue), iodine (KI) and plutonium, americium or curium(Ca-DTPA and Zn-DTPA).

news along the pike

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

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

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

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

NEWS ALONG THE PIKE
CDER Office of Training
and Communications (HFD-210)
Parklawn Building, Room 12B-31

Editor: Norman "Joe" Oliver (OLIVERN)
Associate Editors: Patrick Clarke,
Sherunda Lister
Phone: (301) 827-1695
Fax: (301) 827-3055

CDER nurse anesthetist develops master's program for university

By Patrick E. Clarke

Capt. E. Jane McCarthy, CRNA, Ph.D., discovered a disconcerting fact in the spring of 2003.

"There had been no nurse anesthetist master's program in the state of Maryland for the last 20 years," said McCarthy, the science education team leader in the Division of Training and Development in the Office of Training and Communications. She is also an adjunct professor at the University of Maryland's School of Nursing.

McCarthy organized a group of certified registered nurse anesthetists to develop a proposal for the nursing school's dean. The proposal included:

- A needs assessment for certified registered nurse anesthetists in Baltimore and Washington area hospitals.
- Evidence of clinical site commitment for student experiences.
- Identification of possible funding sources.
- Information about the American Association of Nurse Anesthetists.

They presented the proposal to the dean and several other nursing school faculty members. "About a week later the assistant dean called me and asked me to be the one to start the program," McCarthy said.

She made arrangements with her supervisors to work on the project at the University of Maryland for four days a week for six months and one day a week for an additional six months.

"During this time I wrote a curriculum for a nurse anesthetist master's program, identified hospitals for clinical education, wrote the self-study for accreditation and set-up and implemented the on-site accreditation visit needed for the program to be accredited," McCarthy said. She also co-authored a funding grant application for the program to the Health Resources and Services Administration.

"During my second six-months, I assisted in hiring faculty and admitting students," McCarthy said. As an adjunct professor at the university, she teaches pulmonary physiology and basic principles of anesthesiology. "I'm still used as a consultant for the program and I may do a curriculum analysis for them at the end of the year," she said.

The first class of 18 students began the program in August 2004.

McCarthy notes that her work in developing the program ties right in with the mission of the Public Health Service. "This program meets a tremendous public health need. Operating rooms have had to be closed because they didn't have enough nurse anesthetists to perform surgery," McCarthy said. Currently, McCarthy noted, nurse anesthetists in Maryland are getting older and are overworked.

McCarthy had previous experience setting up a nurse anesthetist master's program for the Uniformed Services University of the Health Sciences in Bethesda, where she earned her doctorate in physiology. To do that, she took a six-year detail from FDA to the USUHS from 1993 to 1999.

"We educated nurses from all the services in this program. It was the first time ever that all the services were educated under the same nurse anesthetist program," McCarthy said. The program McCarthy set up was so well regarded that the Air Force closed down its nurse anesthetist program and started sending all its students to the Bethesda program.

Because it was a military program, McCarthy had to ensure there was a combat readiness component. "That weighed heavily on my mind," she said. "Students within six months of graduation could be in war zone with limited equipment and a hostile environment."

McCarthy's prior experience proved valuable in structuring the combat readiness component. During 1970 and 1971 she was with the U.S. Army Evacuation Hospital, DaNang, in the former Republic of South Vietnam, where she provided triage and emergency room nursing care for war casualties.

Now, at CDER, McCarthy focuses on an entirely different curriculum. "I'm the science education team leader—responsible for the science education curriculum that my division provides for the reviewers here," McCarthy said.

New CDERLearn educational tutorial focuses on generic drug review

By Ayse N. Hisim

CDER is offering "The FDA Process for Approving Generic Drugs," a free online educational tutorial that offers one hour of continuing education credit for physicians and pharmacists.

The course, available at http://www.connectlive.com/events/genericdrugs/, provides an overview of the generic drug review process, including how FDA's approval assures that generic drugs are safe, effective and high quality drug products.

The learning objectives include being able to:

- Cite the legislation that enables the approval of generic drug products.
- Describe the differences between the generic drug approval process and the innovator drug approval process.
- Identify information contained in the *Orange Book.*
- Describe the methodology for determination of bioequivalence of drug products.
- Describe the complexities of the patent certification process and the impact on the approval of generic drug products.

This CDERLearn course is one of a series of educational tutorials offered by the Center as part of its strategic initiative to inform and educate people about the safe use of medicine, the drug regulatory process and the vital role health care professionals play to assist us in fulfilling our duties.

Our other current courses are:

- "Drug Review and Related Activities in the United States," at http://www.connectlive.com/events/drugdev/.
- "Field Investigators: Adverse Drug Effects (ADE) Investigators (2000)," at http://www.fda.gov/cder/learn/ADE/ADE_Pagex.htm.

Ayşe Hısım is a public affairs specialist and the Office of Training and Communications' project officer for the generic drug education program.

CDER awards ceremony honors 81 individuals, 46 groups

(Continued from page 1)

Joy D. Mele

Leonard V. Sacks, M.D.

Cortrosyn Drug Shortage Avoidance Team: **Virgilio F. Pacio** and **Michael J. Verdi.** PHS officers nominated for companion award: **LCDR Elizabeth Girard,** and **CAPT James P. Stumpff**.

FDA Library Management Team: **Lee S. Bernstein, Lois G. Chester, Susan Laney-Sheehan, Kathrin L. McConnell** and **Colleen A. Pritchard.**

Final Physician Labeling Rule completion: **Rachel E. Behrman, M.D.,** and **Janet M. Norden.**

Office of Biotechnology Products Reviewer Training Program Team: **Leon A. Epps, Ph.D.,** and **Joseph Kutza, III, Ph.D.**

FDA Leveraging/Collaboration Award

Lewis K. Schrager, M.D.

Academy of Pediatrics Liaison Team: **John J. Alexander, M.D., Lowell H. Lima** and **Hari C. Sachs, M.D.**

CDER Strategic National Stockpile Team: **Susan S. Allen, M.D., Kathleen R. Anderson, Deborah M. Autor, Jane A. Axelrad, Nicholas Buhay, Robert A. Eshelman, John J. Feeney III, M.D., Richard L. Friedman, Maryla E. Guzewska, Ph.D., Robert Heller, Erik N. Henrikson, Mary Hennessey, Rita R. Hoffman, Joanne M. Holmes, Russell G. Katz, M.D., Lorene M. Kimzey, Brad G. Leissa, M.D., Joh P. Loh, Babette A. Merritt, Christine V. Moser, Samia M. Nasr, Robbin M. Nighswander, Frederic J. Richman, Rosemary Roberts, M.D., Barry Rothman, Waclaw J. Rzeszotarski, Ph.D., Norman R. Schmuff, Dana C. Schuhly, Michael J. Verdi, Valerie L. Whipp, Randy L. Woods** and **Su C. Yang.** PHS officers nominated for companion award: **CDR Mark W. Askine, LCDR Michael P. Bourg, CAPT Harvey A. Greenberg, CDR Valerie E. Jensen, CDR Mitchell V. Mathis Jr., CDR Kevin A. Prohaska, CAPT Mary E. Purucker, LCDR Jouhayna S. Saliba** and **CAPT George R. Scott.**

Non-Clinical Working Group on Topical Microbicides: **James G. Farrelly, Ph.D., Dorota M. Matecka, Ph.D., Julian J. O'Rear, Ph.D., Norman R. Schmuff, Ph.D., Sheryl L. Lard Whiteford, Ph.D.,** and **Ita S. Yuen, Ph.D.**

Pediatric Labeling of Pharmaceuticals for Neonates Team: **Shaahvree Y. Buckman, M.D., Hari C. Sachs, M.D., Phillip H. Sheridan, M.D., Susan K. McCune, M.D., Denise J. Pica-Branco,** and **William J. Rodriguez, M.D.**

FDA Quality of Work Life Award

Tedera Miliken

FDA Equal Opportunity Achievement Award

Janice M. Soreth, M.D.

Center Director's Special Citation

Michael Klein, Ph.D.

Mary Dianne Murphy, M.D.

Mark J. Goldberger, M.D., MPH

CDER Special Recognition Award

Wendy Aaronson

Kathryn J. Aikin, Ph.D.

Dakshina M. Chilukuri, Ph.D.

Martin H. Cohen, M.D.

Kim M. Colangelo

Kristin I. Davis

Lesley R. Frank, Ph.D.

Tarek Hammad, M.D., Ph.D.

Barbara A. Hill, Ph.D.

Matthew R. Holman, Ph.D.

Ekopimo Okon Ibia, M.D.

Michelle M. Jackson, Ph.D.

Seong H. Jang, Ph.D.

Glen D. Jones, Ph.D.

Ravindra K. Kasliwal, Ph.D.

Leslie A. Kenna, Ph.D.

Michael L. Koenig, Ph.D.

Carl N. Kraus, M.D.

Ann Corken Mackey, R.Ph., MPH

Chan H. Park, Ph.D.

Marilyn R. Pitts, Pharm.D

Ramesh Raman, M.D.

Jeffrey L. Summers, M.D.

Maria Lourdes Villalba, M.D.

Joyce P. Weaver, Pharm.D.

Jo Herbel Wyeth, Pharm.D.

Peiling Yang, Ph.D.

Vincent E. Zenger, Ph.D.

cGMP Site Selection Working Group: **H. Gregg Claycamp, Ph.D., Charles W. Gray Jr., Ph.D., Brian J. Hasselbalch, Kara M. Morgan, Ph.D., Vilayat A. Sayeed, Ph.D., Nga Tran, Ph.D., Marie Urban, Sawyie B. Wang** and **Vincent E. Zenger, Ph.D.**

Fluconazole Review Team: **Richard C. Adams. Ph.D., Arup K. Basak, Ph.D., Sema Basaran, Ph.D., Mahanaz Farahani, Ph.D., Zelleka Getahun, Ph.D., Andrew J. Langowski, Ph.D., Mayra L. Pineiro-Sanchez, Ph.D., Radhika Rajagopalan, Ph.D., Dominick C. Roselle, Ph.D., Vilayat A. Sayeed, Ph.D., Mujahid Shaikh, Ph.D.,** and **Glen J. Smith, Ph.D.**

Ophthalmic Review Team: **William M. Boyd, M.D., Wiley A. Chambers, M.D., Zhou Chen, Ph.D., Lori M. Gorski, Jennifer D. Harris, M.D., Hossein Khorshidi, Ph.D., Lucious Lim, M.D., Chih "Stan" Lin, Ph.D., Hong "Laura" Lu, Ph.D., Yong-De Lu, Linda Ng, Ph.D., Michael J. Puglisi, Lin Qi, Mohammad Atiar Rahman, Ph.D., Libaniel Rodriguez, Ph.D., Su C. Tso** and **Wen-Chic J. Yang, Ph.D.** PHS officer nominated for companion award: **LT Raphael R. Rodriguez.**

Research Involving Human Subjects—Investigator 101 Course Team: **Richard D. Diamond, M.D., MPH,** and **Thomas Maudru.**

Safety of Carbonic Anhydrase Inhibiting Anti-Epileptic Drugs Team: **Leonard P. Kapcala, M.D.,** and **James F. Knudsen, M.D.**

Therapeutics Facilities Review Group: **Anthony A. Charity, Michelle Y. Clark-Stuart, Ann L. Demarco, Colleen F. Hoyt, Elizabeth B. Klein, Calvin B. Koerner, Joseph Kutza, Ph.D., Jianming LI, Ph.D., Stephen C. Mahoney, Grace E. McNally, Edwin Melendez, Bai V. Nguyen, Jo'el M Plummer, Carolyn A. Renshaw, Gilbert T. Salud, Michael D. Smedley, Marlene G. Swider, Steven J. Thurber** and **Cynthia D. Whitmarsh.** PHS officer nominated for companion award: **LT Nikhil A. Thakur.**

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Center's spirit, service, commitment cited in 'challenging year'

(Continued from page 4)

CDER Administrative/Program Management Excellence Award

Susan M. Banks

Eldridge F. Coles Jr.

Julie M. Hurley

Sharon L. Miller

Angela F. Poe

Carol A. Smith

CDER Excellence in Communication Award

Jeanine A. Best

Kurt A. Brorson, Ph.D.

Ann T. Farrell, M.D.

Michelle R. Frazier-Jessen, Ph.D.

Lauren Y. Lee, Pharm.D.

Botanicals Review Team: **Shaw T. Chen, M.D., Ph.D., Jin Hui Dou, Ph.D.,** and **Leslie A. Vaccari.**

cGMP Seminar Team: **Monica E. Caphart, Albinus M. D'Sa, Ph.D., Richard L. Friedman, Brian J. Hasselbalch, Stephen C. Mahoney, Rosa J. Motta, Brenda W. Uratani, Ph.D.,** and **Donald F. Wisner.** PHS officers nominated for companion award: **CDR Karen Hirshfield** and **LT Nikhil Thakur.**

Establishing a collaborative relationship to resolve cGMP issues: **Richard L. Friedman** and **Brenda W. Uratani, Ph.D.**

NAFDAC (Nigeria's National Agency for Food and Drug Administration and Control) Team: **Abimbola Adebowale, Ph.D., David Diwa, Pharm.D., Oluchi Elekwachi, Pharm.D., MPH, Emmanuel Olutayo Fadiran, R.Ph., Ph.D., Ekopimo Ibia, M.D., MPH, Menfo Imoisili, M.D., MPH, Adebayo Laniyonu, Ph.D., Clement Meseda, Ph.D., Nina Nwaba, Pharm.D., Patrick Nwakama, Pharm.D., Nicholas Obiri, Ph.D.,** and **A. Olufemi Williams, M.D.**

Paxil Oral Suspension Team: **Peter C. Chow, Robert J. Doyle, Richard L. Friedman, Gurpreet K. Gill-Sangha, Ph.D., Lorene M. Kimzey, Grace E. McNally, Kathy P. Miracco, Thomas F. Oliver, Ph.D., Carmelo R. Rosa, Andrea G. Schaub, Ralph J. Schmid** and **James M. Timper Jr.** PHS officers nominated for companion award: **CAPT Paul A. David, CDR Valerie E. Jensen** and **LCDR Jouhayna S. Saliba.**

CDER Information Technology Excellence Award

Erika A. Jarvis

DACCADP PDUFA Information Technology Team: **Howard E. Josefberg, M.D.** and **Rigoberto A. Roca, M.D.**

CDER Leadership Excellence Award

John M. Dietrick

Lanh Green, Pharm.D., MPH

Robert D. Harris, M.D.

Brian E. Harvey, M.D., Ph.D.

David Hilfiker

Robert H. King

Sheldon B. Markofsky, Ph.D.

Guiragos K. Poochikian, Ph.D.

Daniel A. Shames, M.D.

CDER Excellence in Mentoring Award

Marina Y. Chang, R.Ph.

Sang M. Chung, Ph.D.

Gregory M. Dubitsky, M.D.

Amna Ibrahim, M.D.

Michael L. Lanthier

Dorothy W. Pease

Thomas J. Permutt, Ph.D.

John H. Powers, M.D.

CDER Project Management Excellence Award

Rosemary Addy

Dale C. Slavin Chiorini, Ph.D.

Susan F. Daugherty

Maureen A. Hess

Cathryn C. Lee

Connie J. O'Leary

Sharon K. Sickafuse

Division of Dermatologic and Dental Drug Products Project Management Staff: **Kalyani Bhatt, Suzanne M. Childs, Melinda J. Harris, Margo L. Owens, Jacquelyn E. Smith** and **Millie Wright.** PHS officers nominated for companion award: **CDR Frank H. Cross Jr., CAPT Mary J. Kozma-Fornaro** and **CDR Virginia A. Giroux.**

CDER Regulatory Science Excellence Award

Robbe C. Lyon, Ph.D.

Virginia E. Maher, M.D.

Ingrid Markovic, Ph.D.

Arlene H. Solbeck

Erythropoietin Safety Review Team: **Clare A. Gnecco, Ph.D., Monica L. Hughes, Karen D. Jones, Harvey S. Luksenburg, M.D., Amy S. Rosenberg, Ph.D., Mark D. Rothmann, Ph.D., Kaushikkumar A. Shastri, M.D., Ruth E. Wager, Ph.D., Andrea B. Weir, Ph.D.** PHS officer nominated for companion award: **CAPT Martin D. Green.**

Special Circumstance QT Review Effort Team: **Mark S. Hirsch, M.D., Suresh Kaul, M.D., MPH, Leslie A. Kenna, Ph.D.,** and **Ameeta Parekh, Ph.D.**

CDER Support Staff Excellence Award

Patricia M. O'Connor

Donna M. Stewart

Division of New Drug Chemistry III Administrative Support Team: **Amanda J. Mickley** and **LaVaughn M. Wilbur.**

CDER Team Excellence Award

ADE Team: **Carol L. Krueger** and **Denis Mackey.**

Adolescent Safety and Effectiveness Team: **Julie G. Beitz, M.D., Jin Chen, M.D., Ph.D., Daniel Davis, M.D., Tia M. Frazier, Donna J. Griebel, M.D., Karen M. Kirchberg, Andrea Leonard-Segal, M.D., Scott E. Monroe, M.D.,** and **Curtis J. Rosebraugh, M.D., MPH.**

Avastin BLA Review Team: **Michelle R. Frazier-Jessen, Ph.D., Joseph E. Gootenberg, M.D., Karen D. Jones, Steven Kozlowski, M.D., Joseph Kutza, III, Ph.D., Virginia E. Maher, M.D., Iftekhar Mahmood, Anita M. O'Connor, Carolyn A. Renshaw, Mark D. Rothmann, Ph.D., Sharon K. Sickafuse, Michael D. Smedley, Patrick G. Swann, Ph.D., Jose Tavarez-Pagan, Barbara J. Wilcox, Ph.D.,** and **Boguang A. Zhen, Ph.D.** PHS officer nominated for companion award: **CAPT David M. Green.**

CDER Emergency Response Coordination Team: **Thomas J. Christl, Larry W.**

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CDER awards ceremony honors 81 individuals, 46 groups

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Cress, Joan S. Flaherty, Joanne M. Holmes, Rene Kimzey, Brad G. Leissa, M.D., Ralph B. Lillie, Francis R. Pelsor, Pharm.D., Rosemary Roberts, M.D., Lewis K. Schrager, Alla Shapiro, Cheryl A. Turner and **Su C. Yang.** PHS officers nominated for companion award: **LCDR Michael P. Bourg, CAPT Mark A. Gonitzke, CAPT Harvey Greenberg, CDR Valerie Jensen, LCDR Tracy C. MacGill, CDR Lisa L. Mathis, CDR Mitchell V. Mathis Jr., LCDR Narayan Nair, CAPT Mary E. Purucker** and **LCDR Jouhayna Saliba.**

Ciprofloxacin Review Team: **Bing Cai, Ph.D., Hoainhon N. Caramenico, Barbara M. Davit, Ph.D., Kuldeep R. Dhariwal, Ph.D., James M. Fan, John F. Grace, Liang Lii Huang, Ph.D., Yih Chain Huang, Gil Jong Kang, Ph.D., Carol Y. Kim, Pharm.D., Jenny Lee, Shing Hou Liu, Ph.D., Moheb H. Makary, Ph.D., Nashed E. Nashed, Ph.D., Shriniwas G. Nerurkar, Ph.D., Patrick E. Nwakama, Pharm.D., Kathy Woodland-Outlaw, Suhas J. Patankar, Susan M. Pittinger, Sikta Pradhan, Ph.D., Surendra P. Shrivastava, Zakaria Z. Wahba** and **Robert L. West.** PHS officers nominated for companion award: **CDR Beth F. Fritsch, LT Craig P. Kiester, CDR Steven D. Mazzella, LT Wanda Pamphile, LCDR Aaron W. Sigler, LCDR Thuyanh Vu** and **LCDR Beverly Weitzman.**

Compliance Accomplishments Tracking System Working Group: **Nicholas Buhay, Ladan Jafari, Crystal A. King, P.D., Kathy P. Miracco** and **Frederick J. Richman.** PHS officers nominated for companion award: **CDR James L. Cobbs** and **CAPT Joan C. Ginetis.**

Continuous Marketing Application Pilot 1 Implementation Team: **Gary M. Gensinger, Michael L. Lanthier, Nancy G. Maizel, Sally A. Newman, Heather W. Pierce** and **Linda G. Stone.** PHS officers nominated for companion award: **CAPT Anna M. Myers** and **CAPT Cathie L. Schumaker.**

Division of Information Disclosure Policy Staff: **Abiola O. Adesioye, Stephanie M. Boucher, Heidi N. Brubaker, Marsha T. Casey, Roy V. Castle Jr., Krisitn D. Cook, Easter Carol Doyle, Cynthia A. Durant, Denise Figueroa, Jennifer J. German, Claudia V. Grillo, Robert R. Herrell, Sandra L. James, Shirley D. Johnson, Lee D. Korb, Stephanie A. Mason, Larry L. McDaniel, Howard R. Philips, JoAnna M. Riggs, Sudarshini Satchi, Harold Stepper, Debra A. Taub** and **Diane F. Walker.** PHS officer nominated for companion award: **LCDR Jeanne Skanchy.**

Domperidone Team: **Susan S. Allen, M.D., Kathleen R. Anderson, R.Ph., Deborah Autor, Peter Beckerman, Mehul Desai, M.D., Donna J. Griebel, M.D., Rita R. Hoffman, Ada Irizarry, Ann Mackey, R.Ph., MPH, William A. McConagha, Samia N. Nasr, R.Ph., Margaret M. O'Rourke, Bruce Patsner, M.D., Frederic J. Richman, Steven D. Silverman** and **Douglas C. Throckmorton, M.D.** PHS officers nominated for companion award: **CAPT Dianne L. Kennedy, CAPT George R. Scott** and **CDR Kathleen Uhl.**

Erbitux BLA Review Team: **Chana Fuchs, Ph.D., Clare A. Gnecco, Ph.D., Karen D. Jones, Steven Kozlowski, M.D., Lee Hong Pai Scherf, M.D., Mark D. Rothmann, Ph.D., Genevieve A. Schechter, M.D., Sharon K. Sickafuse, Michael D. Smedley, Patrick G. Swann, Ph.D., Marlene G. Swider, Jose J. Tavarez Pagan, Mark O. Thornton, M.D., Deborah M. Trout, Wendy C. Weinberg, Ph.D., Hong Zhao, Ph.D.** PHS officer nominated for companion award: **CAPT Martin D. Green.**

Foreign Drugs Team: **Deborah M. Autor, Frances G. Bormel, Lucinda F. Buhse, Ph.D., Constance E. Bulawka, Roma J. Egli, Andrew S. Fussner, Richard E. Kolinski, Terry W. Moore, Steven D. Silverman, Linda E. Silvers, DVM, MPH, Anjanette P. Smith, John A. Spencer, Ph.D., Melvin F. Szymanski, Duckhee Y. Toler, Benjamin J. Westenberger** and **Anna M. Wokovich.** PHS officers nominated for companion award: **LCDR Sean J. Belouin** and **LT Daniel K. Nguyen.**

Ketek Review Team: **John J. Alexander, M.D., Wiley A. Chambers, M.D., Philip M. Colangelo, Ph.D., Charles Cooper, M.D., Edward M. Cox, M.D., Alma C. Davidson, M.D., Anitra P. Denson, M.D., Brenda R. Friend, Mark J. Goldberger, M.D., MPH, Venkateswa R. Jarugula, Ph.D., Ni A. Khin, M.D., Joyce A. Korvick, M.D., MPH, Frances V. Lesane, Tsae Yun D. Lin, Ph.D., Frederic J. Marsik, Ph.D., Judit R. Milstein, Nasim R. Moledina, M.D., Robert E. Osterberg, Ph.D., Terry S. Peters, Ph.D., Janice K. Pohlman, M.d., Joanne L. Rhoads, M.D., George Rochester, Ph.D., David L. Roeder, David B. Ross, M.D., Harold V. Silver, Thomas D. Smith, M.D., Janice M. Soreth, M.D., Mathew T. Thomas, Thamban I. Valappil, Ph.D., James D. Vidra, Ronald T. Wassel, Pharm.D., Andrew B. Yu** and **Jenny J. Zheng.** PHS officers nominated for companion award: **CAPT Lillian Gavrilovich** and **CAPT Sandra L. Kweder.**

Neutrospec Review Team: **Kassa Ayalew, M.D., Leon A. Epps, Ph.D., Chana Fuchs, Ph.D., Lydia O. Martynec, M.D., Satish C. Misra, Ph.D., Carolyn A. Renshaw** and **Marlene G. Swider.** PHS officers nominated for companion award: **LT Felicia Duffy, CDR David M. Frucht, CAPT Martin D. Green** and **CDR Joseph L. Johnson.**

New Drugs and Labeling Team: **John P. Loh, Sakineh H. Walther** and **Valerie L. Whipp.** PHS officers nominated for companion award: **CDR Mark W. Askine** and **CDR William A. Russell.**

Office of Drug Safety Case Definition Working Group: **Renan A. Bonnel, Pharm.D., MPH, Min Chu Chen, M.S.,R.Ph., Lopa R. Gohel, Pharm.D., Cindy M. Kortepeter, Pharm.D., Lauren Y. Lee, Pharm.D., Susan Lu, R.Ph., Ann C. Mackey, R.Ph., MPH, Melissa M. Truffa, R.Ph.,** and **Joyce P. Weaver, Pharm.D.** PHS officer nominated for companion award: **CDR Robert G. Pratt.**

Oncology Drug Products Chemistry Review Teams: **Xiao H. Chen, Ph.D., Nallaperum Chidambaram, Ph.D., Li-Shan Hsieh, Ph.D., Yung Ao Hsieh, Ph.D., Josephine M. Jee, Ph.D., Cheng Yi Li-**

(Continued on page 7)

Parklawn Spanish Club helps you learn language, culture

BY JOE TONNING

Learning Spanish can help you get promoted within the federal government, and the Parklawn Spanish Club can help you learn the language.

For many federal jobs, knowledge of another language is highly desirable. Currently, Hispanics comprise about 13 percent of the U.S. population, so it's easy to understand why knowing Spanish is becoming more important each day.

According to the Census Bureau, there were almost 40 million Hispanics living in the United States in 2002. This number is expected to increase over the next few decades. It's very likely that you encounter people every day who speak Spanish as their primary language. Spanish, used by 300 million people, is the dominant language spoken in 21 countries on five continents and is the fourth most widely spoken language in the world.

In addition to opening more career doors, learning Spanish can help you gain an appreciation of other cultures. Reading Latin American newspapers and watching Spanish language television can help you understand how other people think and feel in ways that may be different from your own. Knowing Spanish can improve your critical and creative thinking skills, enhance travel opportunities and open up a whole new world of history, art and music. Spanish also allow you to enjoy great literary and cinematic masterpieces in their original language.

The Spanish Club meets every Wednesday from noon to 1 p.m. in Conference Room 17B-43 in the Parklawn Building. There are no dues. People of all knowledge levels are welcome, from beginners to native speakers.

In addition to practicing Spanish, we also learn about history, food, travel and different Latin American cultures.

Even native Spanish speakers from Latin America are amazed at how much they learn about other Latin American cultures. If you would like more information about the Parklawn Spanish Club please contact me at (301) 827-7720.

Joe Tonning is a senior program manage in the Office of Pharmacoepidemiology and Statistical Science

CDER honor awards

(Continued from page 6)

ang, Ph.D., Hasmukh B. Patel, Ph.D., Haripada Sarker, Ph.D. and **William C. Timmer, Ph.D.**

ONDC Recruitment Team: **Chi-Wan Chen, Ph.D., David T. Lin, Ph.D., Amanda J. Mickley, Patricia M. O'Connor, Angela F. Poe, Guiragos K. Poochikian, Ph.D.,** and **John E. Simmons, Ph.D.**

Ophthalmic Drug Products Chemistry Review Team: **Hossein S. Khorshidi, Ph.D., Yong De Lu, Ph.D., Linda L. Ng, Ph.D., Lin Qi, Ph.D., Libaniel Rodriguez, Ph.D.,** and **Su C. Tso, Ph.D.**

Pancreatic Exocrine Product Guidance Team: **Suliman I. Al Fayoumi, Ph.D., Jane A. Axelrad, Lawrence L. Bachorik, Jason D. Brodsky, Mary E. Catchings, Jasti B. Choudary, B.V.Sc., Ph.D., Jennifer J. Cooke, Susan M. Cruzan, Elizabeth H. Dickinson, Suresh Doddapaneni, Ph.D., Eric P. Duffy, Ph.D., Hugo E. Gallo Torres, M.D., Ph.D., Herbert Gerstenzang, Ed Haas, Martin Habar, Maureen A. Hess, Monika Houston, Robert L. Justice, M.D., Joyce A. Korvick, M.D., MPH, Marie Kowblansky, Diane V. Moore, Thomas J. Permutt, Ph.D., Olivia A. Pritzlaff, Ramesh Raghavachari, David T. Read, Mary L. Reuther, Kathy M. Robie Suh, M.D., Ph.D., Bradford W. Stone, Lilia Talarico, M.D., Maria R. Walsh, Sakineh H. Walther, Sally Winthrope, Maria E. Ysern** and **Liang Zhou, Ph.D.**

Pediatric Emergency Consultation Team: **Sara Goldkind, M.D., Susan K. McCune, M.D.,** and **Philip H. Sheridan, M.D.**

Postmarketing Safety Reporting Requirement Waiver Procedures Team: **Chris Champagne, Bronwyn E. Collier, Michael M. Folkendt, Gary M. Gensinger, Paul S. Henig, Nancy G. Maizel, Sally Newman, Dotti W. Pease, Heather Pierce, Mia Y. Prather, Lena Staunton, Linda Stone, Ivan Tagoe** and **Samuel Y. Wu.** PHS officers nominated for companion award: **LT Jeen S. Min** and **CDR Ellen Molinaro.**

Quality Assurance Staff: **Rubynell Jordan.** PHS officers nominated for companion award: **CAPT Judith E. Arndt** and **LCDR Dianne C. Hanner.**

Risperdal Warning Letter Review Team: **Carol H. Barstow, Gerard A. Boehm, M.D., Michael Brony, Pharm.D., Kristin I. Davis, Russell G. Katz, M.D., Thomas P. Laughren, M.D., Norman S. Marks, M.D., Judith A. Racoosin, M.D.,** and **Lisa L. Stockbridge, Ph.D.** PHS officers nominated for companion award: **CDR Mark W. Askine** and **LT Rebecca Williams.**

Statistical Team Supporting the Division of Anti-Viral Drug Products: **Rafia N. Bhore, Ph.D., Suktae Choi, Ph.D., Thomas S. Hammerstrom, Ph.D., Fraser B. Smith, Ph.D., Guoxing Soon, Ph.D.,** and **Susan Y. Zhou, Ph.D.**

Tazarotene Working Group: **Mohamed A. Alosh, Ph.D., Kalyani Bhatt, Paul C. Brown, Ph.D., Barbara D. Buch, M.D., Denise Cook, M.D., Tapash K. Ghosh, Ph.D., Claudia B. Karwoski, Pharm.D., Stanka Kukich, M.D., Shiowjen Lee, Ph.D., Jill A. Lindstrom, M.D., Andrew D. Mosholder, M.D., Francis R. Pelsor, Ph.D., Marilyn R. Pitts, Pharm.D., Arzu Selen, Ph.D.,** and **Jiaqin Yao, Ph.D.** PHS officers nominated for companion award: **CAPT Dianne L. Kennedy** and **CDR Kathleen Uhl.**

Topical Drug Nomenclature Team: **Lucinda F. Buhse, Ph.D., Chi Wan Chen, Ph.D., Mamta Gautam-Basak, Ph.D., Gil Jong Kang, Ph.D., Richard E. Kolinski, John A. Spencer, Ph.D., Saleh Turujman, Ph.D., Benjamin J. Westenberger,** and **Anna M. Wokovich.**

Unintended Consequences of Risk Management Plans Working Group: **Gerald J. Dalpan, M.D., Florence Houn, M.D., MPH, Joyce A. Korvick, M.D., MPH, Carol L. Krueger, Ann Mackey, R.Ph., MPH, Ann M. Trentacosti, M.D., Maria R. Walsh.** PHS officer nominated for companion award: **CAPT Anne E. Trontell.**

Jackie Barber Washington is the Center's incentive awards officer.

Pharmacist Professional Advisory Committee seeks volunteers

CDR PATRICIA N. GARVEY

The Pharmacist Professional Advisory Committee is seeking pharmacists who are interested in serving on the committee. While there are currently no anticipated openings for a CDER representative, all nominations will be kept on file for future consideration. Members serve a three-year term.

The committee provides advice and consultation to the surgeon general and to the pharmacist chief professional officer on issues related to both the professional practice of pharmacy and the personnel activities of Commissioned Corps and Civil Service pharmacists.

The committee meets at least monthly in the Rockville area, and teleconferencing is available.

The committee is composed of pharmacists representing the various HHS agencies and operating divisions as well as non-HHS programs that employ Commissioned Corps and Civil Service pharmacists.

If you are interested in the committee, please submit your *curriculum vitae*, a cover letter describing your interest and the date of your first licensure as a registered pharmacist. Also, please provide a memo or letter of endorsement from your immediate supervisor. The committee is strongly considering membership requirements to include meeting basic readiness standards.

I need all materials by May 30. Please contact me (GARVEYP) for the mailing address if you are sending paper copies.

If you would like to participate in the committee's activities as a non-member, please volunteer to serve one of the following sections and activities:

- *Administration:* awards, membership, charter, data analysis, history, legislation, and external pharmacy affairs.
- *Career development:* emergency response, professional guidance and retention, and public health issues.
- *Communications:* Web site, listservs, events/meetings, and community interaction.
- *Recruitment:* associate recruiter program, student programs, point of contact initiative, and placement.

Working with a section or activity is a great way to contribute while learning about the PharmPAC and its activities.

Patricia Garvey is a senior regulatory manager in the Office of New Drugs.

FDA Science Forum to feature free public session, achievement awards

On April 26 at 1:00 p.m. at the Washington Convention Center—the afternoon before the 11th annual Science Forum—FDA will present a free symposium for the general public entitled "Personalizing your Healthcare: The Best Consumer is an Educated Consumer."

This session, which requires a separate registration, gives the general public an opportunity to hear about the science behind personalized medicine (page 1), an issue of critical importance to both consumers and FDA. **Janet Woodcock, M.D.,** acting deputy commissioner for operations, will moderate the presentations from an expert panel, and there will be time for questions.

A link to the public session registration form is available on the Science Forum Web site at http://www.fda.gov/scienceforum or directly at http://www.cfsan.fda.gov/~frf/forum05/pubsci.-html.

The Science Forum, from April 27 to 28, showcases the broad range of FDA science and its relationship to our public health mission. The registration for employees is $25.

FDA's Office of Science and Health Coordination notes that the winners of the 2005 Center-ORA Scientific Achievement Awards—to be picked from center and ORA nominees—will be announced April 28 at 1:30 p.m. during the Science Forum.

The awards, the CDER-level nominees and the nominated teams with CDER members and their CDER members, are:

Excellence in Analytical Science

Mary E. Willy, Ph.D.

Excellence in Laboratory Science

Raymond P. Donnelly, Ph.D.

Excellence in Review Science

Leslie A. Kenna, Ph.D.

Outstanding Junior Investigator

Joan Buenconsejo, Ph.D.

Outstanding New Reviewer

Chenxiong Le, Ph.D.

Outstanding Intercenter Scientific Collaboration

Sculptra Injectable Gel PMA Review Team: **Kimberly Struble, Pharm.D.**

Process Analytical Technology Team: **Joseph Famulare, Keith Webber, Ph.D., Frank Holcomb, Jr., Ph.D., Moheb Nasr, Ph.D., Ajaz Hussain, Ph.D., Christopher Watts, Ph.D., Ali Afnan, Ph.D., Huiquan Wu, Ph.D., John Simmons, Karen Bernard, Ph.D., See-Yan Lam, Pharm.D., Ph.D., Albinus D'Sa, Ph.D,, Mike Gavini, Ph.D., Brenda Uratani, Ph.D., Norman Schmuff, Ph.D., Lorenzo Rocca, Ph.D., Vibhakar Shah, Ph.D., Rosario D'Costa, Ph.D., Bryan Riley, Ph.D.**

Pike's Puzzler: *Number, Please*

BY TONY CHITE

Match the phrase to the correct value:

1.	Approximate number of drops in 1 milliliter of ophthalmic solution	**a.**	3
2.	Number of teaspoons in a 4-ounce bottle of cough syrup	**b.**	5
3.	Number of milligrams in 1 grain	**c.**	20
4.	Number of micrograms in 1 milligram	**d.**	24
5.	Number of ounces in 1 quart	**e.**	30
6.	Number of milliliters in 1 teaspoon	**f.**	32
7.	Number of milliliters in one ounce	**g.**	60
8.	Number of teaspoons in one tablespoon	**h.**	1,000

Key: 1c; 2d; 3g; 4h; 5f; 6b; 7e; 8a

Tony Chite, a former Center employee, is a pharmacist practicing in Olney, Md.

Final pharmacogenomics guidance to spur 'personalized medicine'

(Continued from page 1)

be able to analyze a patient's genetic profile and prescribe the best available drug therapy and dose from the start.

The field has experienced significant growth over the last few years. The sequencing of the human genome and the advent of new tools and technologies have already opened new possibilities in drug discovery and development.

For example, genomic tests are helping to identify cancers that have a good chance of responding to a particular medication or regimen. This has enabled the development of targeted therapies like trastuzumab for metastatic breast cancer, imatinib mesylate for chronic myeloid leukemia and cetuxmab for metastatic colorectal cancer.

Also, the Center for Devices and Radiological Health in December last year approved the first laboratory test—based on a DNA microarray (December 2002 *Pike)*—which will enable physicians to use genetic information to select the right doses of certain medications for cardiac, psychiatric diseases and cancer. The new test analyzes two genes from a family of genes called cytochrome P450s, which are active in the liver to break down certain drugs and other compounds. Variations in one or more of these genes can cause a patient to metabolize certain drugs more quickly or more slowly than average or, in some cases, not at all.

"We hope ultimately to bring personalized, or targeted, medicine, to every healthcare professional's prescription pad for the benefit of their patients and U.S. consumers," Dr. Woodcock said.

Guidance

The final guidance, *Pharmacogenomic Data Submissions,* clarifies:

- What pharmacogenomic data to submit during drug development and when.
- What format to use for the submissions.
- How the data will be used in regulatory decision-making.

The guidance also explains a new mechanism for industry to submit research data voluntarily to further the scientific exchange of information as we move into more advanced areas of pharmacogenomic research. The voluntary data will be reviewed by an internal, Agencywide group and will not be used for regulatory decision-making. However, the data will help FDA and industry gain valuable experience as the field continues to evolve.

A voluntary data submission should benefit both sponsors and FDA because:

- It creates an opportunity for early informal meetings with FDA pharmacogenomics experts.
- It offers flexibility in review and meeting process.
- Sponsors receive informal peer-review feedback on pharmacogenomic issues and questions.
- Sponsors gain insight into current FDA thinking about pharmacogenomics that may assist in reaching important strategic decisions.
- It offers time- and cost-savings by familiarizing both parties early with novel pharmacogenomic approaches and avoiding future delays in review.
- It provides an opportunity for sponsors to influence FDA's thinking and help build consensus around future pharmacogenomic standards, policies and guidances

We have already received several pharmacogenomic data submissions, both required and voluntary. A variety of large and small companies have made voluntary submissions, most of them in second half of last year. The submissions covered a wide range of topics from whole genome scans and the use of gene expression biomarkers in peripheral blood to study designs. In addition, we have held several meetings with sponsors of voluntary data to discuss their data and conclusions.

Review group

The Interdisciplinary Pharmacogenomic Review Group, organized formally in January, is responsible for reviewing all voluntary genomic data submissions. Data from these submissions will go directly to the review group and reside on a dedicated server that only members of the group can access.

Members of the review group are drawn from the Office of the Commissioner, the Agency's medical product centers and the National Center for Toxicological Research.

Although interdisciplinary and Agencywide, the group will be located in CDER in the Office of Clinical Pharmacology and Biopharmaceutics.

In addition to reviewing voluntary data, the group has several responsibilities related to implementing genomic review practice within the Agency. Among its duties, the group will:

- Meet with sponsors upon request before or after a voluntary submission.
- Consult upon request with review staff on required submissions containing genomic data.
- Integrate pharmacogenomics into the regulatory review process and help develop future guidances and review standards.
- Harmonize review practices and quality review systems for applications with genomic data.
- Coordinate public discussions and set agendas for a special genomic subcommittee of the Drug Safety and Risk Management Advisory Committee.

Web site

Our new pharmacogenomics Web site is available at http://www.fda.gov/cder/genomics/default.htm. Titled "Genomics at FDA," the site includes links to:

- Detailed information on submitting genomic data, including a decision tree to simplify data submissions and frequently asked questions.
- Relevant regulatory information and guidance documents.
- FDA contact information and members of the special review group.
- Published papers and presentations by FDA scientists.
- Workshops and public meetings.

Along with the Drug Information Association, we are sponsoring a scientific workshop April 11 to 13 that will focus on integrating pharmacogenomics in clinical trials for new drugs, biologics and associated devices. We will also address ways to translate pharmacogenomics into medical product development and clinical practice.

Larry Lesko is the office director and Felix Frueh is the associate director for genomics in OCPB.

Fixed-dose combination, co-packaged HIV drugs eyed for 3rd World use

(Continued from page 1)

FDA's quality, safety and efficacy standards and thus qualifies for purchase under policies implementing the President's Emergency Plan for AIDS Relief.

Tentative approval, whether for a new drug application or a generic drug application, will be the regulatory mechanism by which low-cost versions of innovator drugs sold in the developed world become eligible for purchase under the emergency plan. Our tentative approval means that existing patents or exclusivity prevent the product from being sold in the United States.

Through our commitment to expedited review, we hope to make safe, effective and affordable quality drugs available quickly for patients with HIV or AIDS in the undeveloped world.

The president's plan was announced in the 2003 State of the Union address and has a special focus on 15 countries hardest hit by the HIV epidemic. It targets three specific areas related to HIV/AIDS:

- Prevention of HIV transmission.
- Treatment of AIDS and associated conditions.
- Care, including palliative care, for HIV infected-individuals and care for orphans and vulnerable children.

In May 2004, HHS announced that we would implement a new, expedited review process to ensure that the United States could provide safe, effective drugs to developing countries. That same month, we published a draft guidance encouraging manufacturers to submit applications of fixed-dose combination and co-packaged versions of previously approved antiretroviral therapies. In June, we traveled to South Africa and India to discuss the new guidance with generic drug manufacturers.

The guidance outlines four scenarios for review of different fixed-dose combination and co-packaged products. Some of the scenarios could permit approval in as little as two to six weeks after submission of a high-quality application.

For companies making products where another firm owns the U.S. patent rights, we are able to issue a tentative approval when we find the product meets our normal safety and efficacy standards.

In addition to the approval scenarios, the guidance (http://www.fda.gov/oc/initiatives/hiv/hivguidance.html) outlines the bioequivalence studies needed for approval and the acceptable three-drug regimens.

We are encouraging fixed-dose combination or co-packaged regimens for ease of use in Third Word countries. Three-drug regimens are needed to avoid treatment failure and prevent the emergence of drug resistant strains of HIV.

A fixed-dose combination package has two or three drugs in a single pill. A co-packaged product contains two or three pills in a single package, and one of the pills can be a fixed-dose combination of two drugs.

Tentative approval, whether for a new drug application or a generic drug application, will be the regulatory mechanism by which low-cost versions of innovator drugs sold in the developed world become eligible for purchase under the emergency plan.

When the generic versions of the regimens have a brand-name equivalent, the route to tentative approval will be a generic drug application. When the fixed-dose combination or co-packaged product has no brand-name equivalent, the first such regimen will be tentatively approved as a new drug. That will then become the reference product for future generic applications. Many three-drug regimens in the developed world consist of drugs from different innovator firms, so a fixed-dose combination or co-packaged reference product is unavailable.

Some generic manufactures are copying European versions of drugs. In those cases we have been successful in negotiating with the innovator firms to obtain a limited right of reference to their data. The right of reference only applies to tentative approvals and avoids the potential sale of the products in countries where they are protected by patent or exclusivity.

We are committed to ensuring that only quality drug products reach the affected nations as quickly as possible. Because many firms will have little or no experience with FDA, we lack information about most clinical laboratories and manufacturing sites associated with the new and generic drug products seeking approval under the emergency plan. Therefore, our involvement also includes:

- *Outreach activities.* We are developing programs that include train-the-trainer sessions, training for general application and approval process information, current good manufacturing practices, active pharmaceutical ingredients and post-market reporting.
- *Expedited application review and manufacturer assistance.* We will conduct our traditional drug product review activities for both new and generic products to ensure safety and effectiveness. Our review time will be significantly less than the traditional review time. We will work closely with sponsors to explain our scientific and regulatory policies. We also will help identify potential products in order to foster their development.
- *Inspections.* FDA will conduct pre-approval inspections of laboratories and cGMP inspections to ensure drug product quality during manufacturing.
- *Post-marketing activities.* After approval, we will monitor the drug products by reviewing drug adverse event reports to ensure continued drug safety after the drug enters the market. In addition, we will review any changes made to approved products to ensure that they are still safe and effective.

Justina Molzon is the Center's associate director for international programs, Jeffrey Murray is deputy director of the Division of Anti-Viral Drug Products, Rao Kambhampati is a senior regulatory review scientist in the Office of New Drug Chemistry, and Barbara Davit is deputy director of the Division of Bioequivalence. This article is based on their presentations at the Jan. 26 CDER Scientific Rounds. The presentation slides are available—to FDA employees only—at http://cdernet.cder.fda.gov/dtd/Rounds/rounds.htm.