news along the pike

AUGUST 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

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INSIDE . . .

PIKE'S CORNERS . . .

Center event honors 56 individuals, 73 teams

Agency recognizes 12 individuals, 5 teams in 2 ceremonies

BY JACKIE BARBER WASHINGTON

At the Center's Spring Honor Awards Ceremony, 56 individuals and 73 teams were recognized. Ten individuals and four teams from CDER were recognized at the Agency-level ceremony. FDA's 2004 scientific achievement awards were presented to two individuals and one team with CDER scientists at the annual Science Forum.

"In the three years that I have been at CDER, I have had the opportunity to work with many of our employees, and I continue to be impressed by their abilities," said Acting Center Director **Steven Galson, M.D.** "I am extremely proud to be associated with an organization of such dedicated and highly competent professionals."

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

The awards were:

FDA Outstanding Service Award

Min Chu Chen

Suresh Doddapaneni, Ph.D.

John Z. Duan, Ph.D.

Bobbi M. Jones

Jang Ik Lee, Ph.D.

(Continued on page 4)

CDER's consumer information spreads across U.S.

BY PATRICK E. CLARKE

CDER is involved in 41 partnerships to develop and disseminate messages about the safe and wise use of medicines. Fifteen of the agreements are with state pharmacists' professional associations to spread our message about the risks of buying medicines outside FDA's regulatory scope.

Some of the partnerships involve the co-development of messages with other HHS agencies and independent, non-profit health and consumer organizations. Other partnerships involve "co-branding" of our messages with retail pharmacy chains, health care organizations, insurers and health information providers. In co-branding, another organization republishes our materials with their logo alongside FDA's logo.

"Tens of millions of Americans have been exposed to our public health messages," said **Ellen Shapiro,** director of the Division of Public Affairs in the Office of Training and Communications. "More importantly, our partnerships help ensure the messages in our public health campaigns reach the right audience at

(Continued on page 10)

FDA approves drugs to treat exposure to radioactive isotopes

FDA on Aug. 11 announced the approval of two intravenous chelators for treating exposure to certain kinds of radiation contamination.

The approvals of pentetate calcium trisodium injection (Ca-DTPA) and pentetate zinc trisodium injection (Zn-DTPA) are part of our ongoing effort to provide the American public the best available protection against nuclear accidents and terrorist threats.

The FDA had previously determined that Ca-DTPA and Zn-DTPA would be safe and effective for treating internal contamination with plutonium, americium or curium when produced under conditions specified in approved marketing applications. The drugs increase the rate of elimination of these radioactive isotopes from the body.

"The approval of these two drugs is another

(Continued on page 9)

JOE'S NOTEBOOK

Toastmasters; Botanical Web site

Stephan Ortiz, R.Ph., Ph.D., has an invitation for you. He's the new publicity chair for the Parklawn Toastmasters Club that meets every Tuesday from noon to 1 p.m. in Room 10-40.

"If you're interested in improving your public speaking skills, both prepared and extemporaneous, or just wish to learn more about Toastmasters, come on by," Stephan says.

Toastmasters International, founded in 1924, promotes itself as the leading movement devoted to making effective oral communication a worldwide reality. With over 8,000 self-help clubs, Toastmasters International helps men and women learn the arts of speaking, listening and thinking—vital skills that promote self-actualization, enhance leadership potential, foster human understanding and contribute to the betterment of mankind, Stephan notes.

"A Toastmasters charter club has existed in the Parklawn Building since 1970," Stephan says. "The mission of the Parklawn Toastmasters Club is to provide a supportive and positive learning environment in which every member has the opportunity to develop communication and leadership skills, which in turn foster self-confidence and personal growth."

By the way, whatever skill I have in public speaking I owe to Toastmasters, which a mentor early in my Army career recommended to me. If, like me, you're a product of the 20th century educational system, you may be surprised to learn most colleges and universities up until the late 19th century and early part of the last century deemed competence in rhetoric and public speaking a requirement for graduation. A pale remnant of that old system remains, at many institutions, in oral exams for advanced degrees.

Toastmasters International's success and growth is largely due to the continued development of its educational programs that fill a need unmet by the specialization of modern higher education. The organization has come a long way since its first speech manual, *Basic Training,* was developed more than 50 years ago. The current manual, now called *Communication and Leadership Program,* was most recently updated in 2003. After club members complete all 10 speech projects in the manual, they may apply for a Competent Toastmaster award and then choose from any combination of 15 advanced manuals.

Stephan, a reviewer in the Office of Clinical Pharmacology and Biopharmaceutics, says he'll be happy to answer any questions you have about the program if you send him an e-mail. Better yet, stop by Room 10-40 any Tuesday at noon. The club is having a pizza party on Sept. 14 and a Speech-a-Thon in October.

Associate Editor **Patrick Clarke** notes that the Botanical Review Team, which he reported on in last year's spring issue of the *Pike,* now has an external Web site.

The team developed the site as another tool to help accomplish their mission of facilitating botanical drug development and the review of new drug investigations under INDs and later as NDAs. The Web site includes:

- Descriptions of who the team members are and what the team does.
- A section with answers to the most frequently asked botanical questions.
- A link to the guidance for industry on botanical drug products.
- Other information useful to industry, consumers and FDA staff.

The automatic email contact provided will ensure that all botanical questions are answered promptly. According to Pat, the Botanicals Team unanimously stated: "We are all very excited that we are able to provide this additional service to our internal and external constituents."

The site can be found at: http://www.fda.gov/cder/Offices/ODE_V_BRT/default.htm.

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).

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

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

NEWS ALONG THE PIKE
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Panel examines moving CDER's thinking forward to 'desired state'

By Robert King

The exciting new *Critical Path Initiative* and the ongoing *cGMPs for the 21st Century Initiative,* which will reach its second anniversary in September, were the major focus of presentations and discussions at the July 20-21 meeting of the newly formed Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science.

"In some ways I look at all these initiatives as a desire to define a desired state, which is more efficient and which is more effective in meeting the needs of the customer, that is, a patient," **Ajaz Hussain, Ph.D.,** deputy director of the Office of Pharmaceutical Science, told the subcommittee in his opening remarks.

Topic areas for the meeting were:

- Quality by design. Updates on International Conference on Harmonization topics Q-8 on pharmaceutical development, Q-9 on risk management for good manufacturing practices and a proposed Q-10 on life cycle management for process and system control.
- ASTM E-55 Committee: Pharmaceutical Applications of process analytical technologies (PAT). The non-profit ASTM provides a global forum for the development and publication of voluntary consensus standards for materials, products, systems, and services.
- Introduction to Bayesian approaches. These are statistics that incorporate prior knowledge and accumulated experience into probability calculations.
- Research and training needs: The industrialization dimension of the *Critical Path Initiative* (July *Pike).*
- Moving towards the "desired state": Manufacturing science and quality by design as a basis for risk-based review of chemistry, manufacturing and controls (CMC).
- Update on pharmaceutical industry practices research study.
- Pilot model for prioritizing selection of manufacturing sites for cGMP inspection.
- cGMPs for the production of Phase I investigational new drugs.
- Applying manufacturing science and knowledge: Regulatory horizons—current steps relative to PAT, comparability protocols and changes without prior approval.

On the first day of the meeting, discussions focused on the evolving CMC review paradigm within the Office of New Drug Chemistry and the Office of Generic Drugs. Each office provided its own perspective. The meeting started with a lively debate on defining the amount of production development data to be submitted with an application that would assist the Agency in understanding the manufacturing process. The members agreed that process understanding, as additional pharmaceutical development information becomes available, would lead to greater regulatory flexibility.

The subcommittee discussed establishing a working group to assist in defining the level of developmental data to be submitted with applications and to determine what incentives might be appropriate. After an OGD presentation, the subcommittee expressed an interest in seeing approval times shortened, while maintaining the quality of review, which will benefit both the public health and the industry.

Both presentations discussed "gaps" in the knowledge of manufacturing processes. The subcommittee suggested that another working group could be formed to assist in developing an educational program for both Agency and industry staff to strengthen their knowledge of process understanding.

On the second day, the Office of Compliance presented its first public rollout of a pilot model being developed to prioritize the selection of manufacturing facilities for cGMP inspection. **David Horowitz,** the office director, said that we wanted to "look at determining whether FDA resources are being used most effectively and efficiently to address the most significant public health risks." He also said that "in order to provide the most effective public health protection, we should match the level of effort against the magnitude of the risk."

Discussion was centered on:

- The suggestion to distinguish between different risks associated with the products and the processing lines.
- The suggestion to use a decision tree to prioritize sites.
- The recommendation that the distribution of sites selected by the model should represent a balance between generic and innovator sites and between biotech and conventional manufacturing sites.
- The concern that a high volume of production should not be given too much weight as a criterion to prioritize sites for inspection.
- A suggestion that there should be a "volume-risk index" that would fully take into account factors that mitigate risks, some of which may be associated with high-volume production.
- The historical inconsistency among investigator findings that might limit the use of such findings in prioritizing sites for inspection. These inconsistencies should become less problematic over time as the new Pharmaceutical Inspectorate program is implemented.
- Ensuring that the proposed model for selecting cGMP inspection sites would promote the correct incentives to encourage robust quality systems, continued availability of medically important drugs and continuous improvement.

Full information on the meeting, including copies of the presentations, is available at http://www.fda.gov/ohrms/dockets/ac/cder04.html#PharmScience.

The subcommittee is part of FDA's strong advisory committee system which complements the Agency's scientific expertise. This system brings the latest research together with patient and caregiver concerns, and industry and consumer advocacy viewpoints for discussion, recommendation, and input to strategic planning activities and decision-making processes.

Subcommittee members are: Judy Boehlert, Ph.D., (chair), Patrick DeLuca, Ph.D. (also a member of ACPS), Daniel Gold, Ph.D., Kenneth Morris, Ph.D., Thomas Layloff, Jr., Ph.D. [not in attendance], Garnet Peck, Ph.D., Joseph Phillips, G.K. Raju, Ph.D., Nozer Singpurwalla, Ph.D. (also a member of ACPS). Also in attendance as non-voting industry members were Gerry Migliaccio, Ph.D., and Paul Fackler, Ph.D.

Robert King is a special assistant for science in OPS.

CDER presents 56 individual awards at spring honors ceremony

(Continued from page 1)

oMelodi McNeil, R.PH.

Thomas J. Permutt, Ph.D.

Mia Y. Prather

Jacquelyn Barber Washington

Division of Library and Information Services Management Team: **Carol S. Cavanaugh, Karen M. Kapust, Kathryn W. Kruse, Kathrin L. McConnell** and **Nancy L. Muir.**

Pharmocogenomics Group: **Atiqur Rahman, Ph.D.,** and **Lei Zhang, Ph.D.**

FDA Group Recognition Award

CDER/CBER Risk Management Working Group: **Susan S. Allen, M.D., Mark I. Avigan, M.D., Christine M. Bechtel, Julie G. Beitz, M.D., Jonca C. Bull, M.D., Min Chu Chen, Muriel N. Cherry, Lois G. Chester, David S. Cho, Ph.D., Aileen Ciampa, Edward M. Cox, M.D., Jerome C. Davis, Richard D. Diamond, M.D., Theresa Finn, Ph.D., David Graham, M.D., Mark Goldberger, M.D., MPH, Bette Goldman, Barbara Gould, Donna Griebel, M.D., Patrick Guinn, Brain Harvey, M.D., Ph.D., Toni Piazza-Hepp, Pharm.D., Florence Houn, M.D., MPH, Claudia Karwoski, Pharm.D., Mary Beth Jacobs, Ph.D., Ider Peter Lee, Deborah Leiderman, M.D., Zili Li, M.D., Susan Lu, R.Ph., Melodi McNeil, R.PH., Robert Meyer, M.D., Kathy Miracco, Janice Newcomb, Colleen Pritchard, Judy Racoosin, M.D., George Rochester, Ph.D., Patricia Rohan, M.D., Ralph Schmid, Daniel Shames, M.D., Jeff Siegel, M.D., Nancy Smith, Ph.D., Judy Staffa, Ph.D., R.Ph., Toni Stifano, Robert Temple, M.D., Yi Tsong, Ph.D., Joyce Weaver, Pharm.D., Mark Weinstein, Ph.D.,** and **Mary Willy, M.D.** PHS officers nominated for companion award: **CAPT Miles M. Braun, CDR Carol A. Holquist, CAPT Elizabeth J. McCarthy, CAPT Thomas G. Phillips, CAPT Denise P. Toyer, CAPT Anne E. Trontell, CDR Kathleen Uhl, CDR Ellis F. Unger** and **CDR Robert P. Wise.**

CDER/CBER Transition Team: **Wendy Aaronson, Tanya L. Abbott, Kim M. Colangelo, Rose E. Cunningham, Roger D. Eastep, Deborah J. Henderson, Glen D. Jones, Ph.D., Amy S. Rosenberg, M.D., Edward M. Sherwood, Keith O. Webber, Ph.D., Karen D. Weiss, M.D., Anne E. Wilcox, Helen N. Winkle** and **Barbara A. Witczak** PHS officers nominated for companion award: **CAPT Sandra L. Kweder, CAPT Anna M. Myers** and **CAPT Cathie L. Schumaker.**

Controlled Substance Staff:, **Dannette M. Alpern, Katherine R. Bonson, Ph.D., Silvia N. Calderon, Ph.D., Michael Klein, Ph.D., Deborah B. Leiderman, M.D., Corinne P. Moody** PHS officer nominated for companion award: **CAPT James R. Hunter.**

Counterterrorism Radiation Group: **Thomas J. Christl, Larry W. Cress, Jan Davis, Denise K. Gavin, Joseph E. Gootenberg, M.D., Dave Green, Ph.D., Ethan D. Hausman, M.D., Frederick N. Hyman, John Kelsey, Stanka Kukich, M.D., John K. Leighton, Ph.D., Brad G. Leissa, M.D., Ralph B. Lillie, Mary D. Murphy, M.D., Dov H. Pluznik, Ph.D., Kathy M. Robie Suh, M.D., Amy S. Rosenberg, M.D., Alla Shapiro, M.D., Orhan H. Suleiman, Cheryl A. Turner, Sakineh H. Walther** PHS officers nominated for companion award: **LCDR Michael P. Bourg, CDR Mitchell V. Mathias, Jr., CDR Michael A. Noska** and **CAPT Mary E. Purucker.**

CSS EMERGENCY CONTROL TEAM: **Katherine R. Bonson, Ph.D., Jennifer A. Goldstein, J.D., Michael Klein, Ph.D.,** and **Corinne P. Moody.**

OCTAP Advance Relocation Staff: **Thomas J. Christl, Joan S. Flaherty, Raya S. McCree** and **Robin Poole** PHS officer nominated for companion award: **LCDR Michael P. Bourg.**

OGD Mefloquine Quality Assurance Group: **Robert A. Lionberger, Ph.D., Shing Hou Liu, Ph.D., Rashmikant M. Patel, Ph.D., Ramnarayan S. Randad, Ph.D., Andre S. Raw, Ph.D., Paul Schwartz, Ph.D.,** and **Lawrence X. Yu, Ph.D.**

Plenaxis Review Team: **Mark I. Avigan, M.D., Julie G. Beitz, M.D., George S. Benson, M.D., Jeanine A. Best, M.S.N., R.N., PNP, Sandra L. Birdsong, Allen D. Brinker, M.D., Dhruba J. Chatterjee, Ph.D., Min Chu Chen, Wen Jen Chen, Barbara S. Chong, Pharm.D., Bronwyn E. Collier, BSN, Nenita I. Crisostomo, Swapan K. De, Ph.D., Eufrecina P. Deguia, Mary J. Dempsey, Evelyn R. Farinas, R.Ph., MGA, Paula L. Gish, R.Ph., Donna J. Griebel, M.D., Maureen A. Hess, MPH, R.D., Mark S. Hirsch, M.D., Florence Houn, M.D., MPH, Alexander W. Jordan, Ph.D., Margaret M. Kober, R.Ph., Cindy M. Kortepeter, Pharm.D., Carol L. Krueger, Stephen E. Langille, Ph.D., David T. Lin, Ph.D., Katherine B. Meaker, Kathy P. Miracco, Scott E. Monroe, M.D., Ameeta Parekh, Ph.D., Toni D. Piazza-Hepp, Pharm.D., Kathleen K. Quinn, Krishan L. Raheja, D.V.M., Ph.D., Moo Jhong Rhee, Ph.D., Ralph J. Schmid, Daniel A. Shames, M.D., Norman L. Stockbridge, M.D., Ph.D., Suzanne R. Thornton, Ph.D., Khin M. U, M.D., Michael E. Welch, Ph.D.,** and **Mary E. Willy, Ph.D.** PHS officers nominated for companion award: **CDR Sammie G. Beam, CDR Roy A. Blay, LCDR James L. Cobbs, CDR Carol A. Holquist, LCDR Mary E. Kremzner, LT Corrine Kulick, LCDR Charles E. Lee, LCDR Alina Mahmud, LCDR Leslie Stephens** and **CAPT Anne E. Trontell.**

Ribavirin Pregnancy Registry Team: **Melisse Baylor, M.D., Allan Brinker, M.D., Russell Fleischer, PA-C, MPH, Steven Gitterman, M.D., Ph.D., Fraser Smith, Ph.D.** PHS officers nominated for companion award: **CAPT Dianne Kennedy, CDR Kathleen Uhl** and **LT Destry Sillivan.**

Rockwall II Renovation Team: **Mary C. Baucum, Gail E. Becker, Mike Bellusci, Marc J. Bloom, Gene Burnett, Pat Carey, Victoria Convers, John L. Emelio, Carla P. Forehand, Fred H. Goetze, Mary F. Hawthorne, Jamey W. Henneberger, Mary M. Jenison, Richard J. Johnson, John P. Long, Patrick Mattis, Michael Raine** and **Stephanie Weyandt**

(Continued on page 5)

Center recognizes efforts of 73 teams at awards ceremony

(Continued from page 4)

FDA Leveraging/Collaboration Award

Lewis K. Schrager, M.D.

Ellen Shapiro

FDA-CHPA Seminar Series Steering Committee: **Abimbola O. Adebowale, Sandra L. Barnes, Robert A. Eshelman, David Hilfiker, Iris D. Khalaf, Karen J. Lechter, Ph.D.,** and **S. Mitchell Weitzman** PHS officer nominated for companion award: **CDR Carmen L. Debellas.**

FDA Quality of Work Life Award

Division of Oncology Drug Products Reviewer Incentives Team: **Kimberly Benson, Ph.D., Peter Bross, M.D., Christy Cottrell, M. Anwar Goheer, Ph.D., Amna Ibrahim, M.D., Richard Lostritto, Ph.D., Roshni Ramchandani, Ph.D., Lilliam Rosario, Ph.D.,** and **S. Leigh Verbois, Ph.D.** PHS officers nominated for companion award: **LT Shelia Ryan** and **CDR Ann Staten.**

PHS Commendation Medal

CDR Frank H. Cross

CAPT Andrea G. Feight

LCDR Melina Griffis

CDR Lisa Mathis

LT Raquel A. Peat

CDR William A. Russell, Jr.

CAPT Anne E. Trontell

CAPT Stephen E. Wilson

Center Director's Special Citation

Guidance Review Team: **Edward M. Cox, M.D.,** and **David L. Roeder.**

Regulatory Science and Review Committee: **Charles Anello, Sc.D., Julie G. Beitz, M.D., George Y. Chi, Ph.D., Eric P. Duffy, Ph.D., Amy L. Ellis, Ph.D., Michael Klein, Ph.D., Peter Lee, Ph.D., Timothy M. Mahoney, Carol T. Norwood, Robert E. Osterberg, Ph.D., Lana L. Pauls, MPH, Kellie S. Reynolds, Pharm.D., Nakissa Sadrieh, Chandrahas G. Sahajwalla, Ph.D.** PHS officers nominated for companion award: **CAPT Paul J. Andreason** and **CAPT Paul J. Seligman.**

RxDepot Team: **Linda E. Silvers, D.V.M., MPH,** and **Melvin F. Szymanski.**

CDER Special Recognition Award

Christine M. Bechtel

Peter E. Coderre, Ph.D.

Daniel Davis, M.D.

Cynthia P. Fitzpatrick

Kathleen S. Fritsch, Ph.D.

Martha R. Heimann, Ph.D.

Joanne M. Holmes

Frederick N. Hyman, D.D.S., MPH

Shiowjen Lee, Ph.D.

Scott E. Monroe, M.D.

Wei Qiu, Ph.D.

Gerlie C. De Los Reyes, Ph.D.

Douglas N. Shaffer, M.D.

Daiva Shetty, M.D.

Harold V. Silver

Sarah J. Singer, R.Ph.

Fraser B. Smith, Ph.D.

Thomas D. Smith, M.D.

Chhagan G. Tele, Ph.D.

Cancer Drug Approval Endpoints Team: **Martin H. Cohen, M.D., Ramzi N. Dagher, M.D., Ann T. Farrell, M.D., Amna Ibrahim, M.D., John R. Johnson, M.D., Richard Pazdur, M.D., Dianne D. Spillman** and **Grant A. Williams, M.D.**

Controlled Substance Staff: **Theresa E. Kehoe, M.D., Michael Klein, Ph.D.,** and **Deborah B. Leiderman, M.D.** PHS officer nominated for companion award: **CAPT David G. Orloff.**

Division of Review Management and Policy Staff: **Wendy Aaronson, Linda K. Burbank, Janet L. Condino, M.Sc., Beverly Conner, R.Ph., Pharm.D., Jeanne M. Delasko, Earl S. Dye, Ph.D., Susan E. Giuliani, Michael G. Harlow, Monica L. Hughes, Pamela D. Hughes, Julie M. Hurley, Glen D. Jones, Ph.D., Karen D. Jones, Mary K. Lee, Paula Lincoln-Smith, Emily L. McFadden, Cathleen B. Michaloski, MPH, Katherine I. Needleman, Connie J. O'Leary, James H. Reese, Ph.D., Diane C. Sartor, Mary J. Schneider, Myrtle C. Shreve, Sharon K. Sickafuse, Dale C. Slavin, Ph.D., Cristi L. Stark, Kelly A. Townsend, Victoria L. Tyson-Medlock** and **Karen D. Winestock.**

Efalizumab for Psoriasis Review Group: **Michelle Y. Clark-Stuart, Clare A. Gnecco, Viola S. Hibbard, Karen D. Jones, Bhanumathi Kanna, Steven Kozlowski, M.D., Elektra J. Papadopoulos, M.D., Anik K. Rajpal, M.D., Carol L. Rehkopf, Dale C. Slavin, Ph.D., Toni M. Stifano** and **Andrea B. Weir, Ph.D.** PHS officers nominated for companion award: **LCDR Craig Doty** and **CDR Joseph L. Johnson.**

Etanercept for Ankylosing Spondylitis Review Group: **Debra E. Bower, Karen D. Jones, Daniel C. Kearns, William B. Tauber, M.D.,** and **Chao Wang, Ph.D.**

Laronidase for MPS-I Review Group: **Howard A. Anderson, Ph.D., Debra E. Bower, Clara S. Chu, Ph.D., Blair A. Fraser, Ph.D., Bradley J. Glasscock, Melanie T. Hartsough, Ph.D., Ilan Irony, M.D., Cynthia L. Kelley, Calvin B. Koerner, Richard D. McFarland, M.D., Katherine I. Needleman, Toni M. Stifano, Marlene G. Swider, Deborah M. Trout** and **Hong Zhao, Ph.D.** PHS officer nominated for companion award: **CAPT Martin D. Green.**

Prexige Review Team: **Hamid R. Amouzadeh, Ph.D., Rafia N. Bhore, Ph.D., Zhou Chen, M.D., Ph.D., Suktae Choi, Hong Lu, Tatiana Ossova, M.D., Rao Puttagunta, Ph.D., Mohammad A. Rahman, Ph.D., Joel Schiffenbauer, M.D., Maria L. Villalba, M.D., Stacey N. Welch** and **James P. Witter, M.D., Ph.D.**

The Industry Meeting Tracking System Development Team: **Wendy Aaronson, Christine A. Aragon, Sandra L. Barnes, George D. Clanton, Kellie Cleland, Kim M. Colangelo, James T. Cross, Michael Cu, Charlene Do, Elizabeth A. Duvall Miller, Gary M. Gensinger, Susan S.**

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CDER presents 56 individual awards at spring honors ceremony

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Johnson, Hemanth Kishore, Michael Lanthier, Eduardo Lim, Colleen L. LoCicero, Jane Lu, Merril J. Mille, David M. Moss, Sally A. Newman, Stacey L. Nichols, Dorothy W. Pease, Xiao Yi Peng, Heather W. Pierce, Colleen Ratcliffe, David L. Roeder, Leslie L. Saveland, Matvey Shkiler, Linda A. Sigg, Binh C. Ta, Sergei A. Tsarev, Frances S. Weiss, and **Jerry Yokoyama** PHS officers nominated for companion award: **LCDR Kellie J. Cleland, LCDR Ellen F. Molinaro,** and **CAPT Anna M. Myers**

CDER Administrative/Program Management Excellence

Debbie S. Begosh

Sandra Van Buskirk

OCPB Management Team: **Susan M. Banks** and **Lenore K. Foley.**

ODE VI Administrative Team: **Shannon M. Freund** and **Anne E. Wilcox.**

OEP Program Management Team: **Amy M. Garvin, Jeremy R. Lowery** and **Jamie M. Metz.**

CDER Excellence in Communication Award

Laura C. Alvey

Larry W. Cress, M.D.

Elaine C. Frost

Lauren Y. Lee, Pharm.D.

Shwu-Luan Lee, Ph.D.

Anthony R. Mire-Sluis, Ph.D.

Dianne D. Spillman

Dorothy J. Wawrose, M.D.

OGD Regulatory Training Group: **Barbara M. Davit, Ph.D., Paul Schwartz, Ph.D., U. V. Venkataram, Ph.D., Ruth A. Warzala** and **Robert L. West** PHS officers nominated for companion award: **LCDR Steven D. Mazzella, CDR Aida L. Sanchez** and **LCDR Martin H. Shimer II.**

CDER Information Technology Excellence Award

Amy B. Mason

eCTD System Team: **Sheila K. Andrew, Donovan F. Duggan II, Kenneth Edmunds, Jr., Gary M. Gensinger, Zei Pao Huang, Thomas J. Selnekovic** and **Barbara A. Witczak.**

CDER Leadership Excellence Award

Julie G. Beitz, M.D.

Rafia N. Bhore, Ph.D.

Barry W. Cherney, Ph.D.

Susan K. Cummins, M.D., MPH

Donna J. Griebel, M.D.

Sally A. Loewke, M.D.

Kathy M. Robie-Suh, M.D., Ph.D.

Guoxing Soon, Ph.D.

James L. Weaver, Ph.D.

Karen D. Weiss, M.D.

Leslie D. Wheelock

Monica A. Unger

CDER Excellence in Mentoring Award

John K. Leighton, Ph.D., DABT

David C. Bostwick

Leah A. Cutter, Ph.D.

Laura A. Governale, Pharm.D.

Gil Jong Kang, Ph.D.

Redactor Mentoring Team: **Roy V. Castle, Jr., Easter C. Doyle, Stephanie A. Mason, Howard Philips, Debra A. Taub** and **Diane F. Walker** PHS officer nominated for companion award: **LT Jeanne Skanchy.**

CDER Project Management Excellence

Jane A. Dean

Corinne P. Moody

Patricia A. Stewart

DCT Project Team: **Thomas J. Christl** and **Joan S. Flaherty, R.N., M.S.**

CDER Regulatory Science Excellence Award

Gerald H. Sokol, M.D.

Project RSR-03-14 Team: **Ted Guo, Ph.D.,** and **John R. Senior, M.D.**

Pharmaceutical Solid Polymorphism Working Group: **Richard C. Adams, M. Scott Furness, Ph.D., Stephen Miller, Ph.D., Nashed E. Nashed, Ph.D., Edwin Ramos, Andre S. Raw, Ph.D., Kathy P. Woodland-Outlaw** and **Lawrence X. Yu, Ph.D.**

CDER Support Staff Excellence Award

Stanley T. Allen

Joan R. Broadwater

Andrea M. Chen

Michael G. Ledley

Eugenie S. Patrick

Lonnie D. Smith

CDER Team Excellence Award

BTSS Transition Team: **Charles Anello, Sc.D., Aloka G. Chakravarty, Ph.D., Japobrata Choudhury, Ph.D. , Satya D. Dubey, Ph.D., Clare A. Gnecco, Ph.D., Ferrin D. Harrison, Ph.D., Hsien Ming J. Hung, Ph.D. , Lisa A. Kammerman, Ph.D., Kallappa M. Koti, Qian H. Li, Ph.D., Satish C. Misra, Ph.D., Anthony G. Mucci, Ph.D., Lillian Patrician, Mahboob Sobhan, Ph.D.,** and **Boguang A. Zhen, Ph.D.**

Controlled Substance Staff: **Dannette M. Alpern, Katherine R. Bonson, Ph.D., Silvia N. Calderon, Ph.D., Michael Klein, Ph.D., Deborah B. Leiderman, M.D., Corinne P. Moody** PHS officer nominated for companion award: **CAPT James R. Hunter.**

Division Of Bioequivalence Review Branch III: **Moheb H. Makary, Ph.D., Farahnaz Nouravarsani, Ph.D., Patrick E. Nwakama, Pharm.D., Gur J. P. Singh, Ph.D.,** and **Zakaria Z. Wahba, Ph.D.** PHS Officer Nominated for the Companion Award **LT Connie T. Jung.**

DSPIDP Labeling Supplement Backlog Team: **Renata Albrecht, M.D. , M. R. Alivisatos, M.D., Matthew A. Bacho, Shukal Bala, Ph.D., Marc W. Cavaille-Coll, M.D., Ph.D. , Dakshina M. Chilukuri, Gerlie C. De Los Reyes, Ph.D., Peter A. Dionne, Arturo Hernandez, M.D., Ekopimo O. Ibia, M.D., MPH, Seong H. Jang, Christine K. Lincoln, Eileen E. Navarro Almario, M.D. ,**

(Continued on page 7)

Center recognizes efforts of 73 teams at awards ceremony

(Continued from page 6)

Rigoberto A. Roca, M.D., Leonard V. Sacks, M.D. , Ramesh K. Sood, Kalavati C. Suvarna, Ph.D., Maureen R. Tierney, M.D., M.Sc., and **Diana M. Willard** PHS officers nominated for companion award: **CAPT Robin E. Anderson, LT Kristen E. Miller, LCDR Ellen F. Molinaro, LCDR Susan R. Peacock, LCDR Jouhayna S. Saliba** and **LT Yon C. Yu.**

Internet Pharmacy Sample Survey Team: **Christopher D. Ellison, Susan Jenney, Richard E. Kolinski, Terra G. Lipe, Sandra J. Logan, Terry W. Moore, Larry K. Revelle, Ph.D., Anjanette P. Smith, John A. Spencer, Ph.D., Kimberly D. Story, Duckhee Y. Toler** and **Benjamin J. Westenberger.**

Lindane Labeling Team: **Julie G. Beitz, M.D., Jeanine A. Best, Gary J. Buehler, Abigail C. Jacobs, Ph.D., John K. Jenkins, M.D., Claudia B. Karwoski, Coralee G. Lemley, Toni D. Piazza Hepp, Pharm.D., Cecelia M. Parise, Marilyn R. Pitts, Kathleen K. Quinn, Terri F. Rumble,** and **Beverly Weitzman** PHS officers nominated for companion award: **CDR Frank H. Cross, Jr., CAPT Mary J. Kozma-Fornaro, CAPT Sandra L. Kweder, CDR Lisa L. Mathis, LCDR Leslie A. Stephens** and **CAPT Anne E. Trontell.**

Medical Imaging Guidances Review Team: **Nancy E. Derr, Florence Houn, M.D., MPH, Kyong A. Kang, Pharm.D., Adebayo A. Laniyonu, Ph.D., Sally A. Loewke, M.D., Lydia O. Martynec, M.D., George Q. Mills, M.D., Brian L. Pendleton, J.D., Ramesh Raman, M.D., Sharon T. Risso, Karen D. Weiss, M.D.,** and **Michael E. Welch, Ph.D.**

Medical Record Data Team: **Katrina S. Garry, David J. Graham, M.D., MPH, Cynthia J. Kornegay, Ph.D., Melodi McNeil, R.Ph.,** and **Judy A. Staffa, Ph.D., R.Ph.**

Office of Drug Safety Longitudinal Electronic Medical Record Data Team: **Katrina S. Garry, David J. Graham, M.D., MPH, Cynthia J. Kornegay, Ph.D., Melodi McNeil, R.Ph.,** and **Judy A. Staffa, Ph.D., R.Ph.**

Omapatrilat Review Team: **Javher V. Advani, Ph.D., Jeanine Best, MSN, PNP, Julie Beitz, M.D., Sandra Birdsong, Allen Brinker, M.D., MPH, Maryann Gordon, M.D., Elizabeth Hausner, D.V.M., Hsien-Ming James Hung, Ph.D., Claudia Karwoski, Pharm.D., John Lawrence, Ph.D., Tim Link, Ph.D., Colleen LoCicero, Zelda McDonald, Juan Carlos Pelayo, M.D., Gabriel Robbie, Ph.D., Judy Staffa, Ph.D., Norman Stockbridge, M.D.,** and **Douglas Throckmorton, M.D.** PHS officers nominated for companion award: **LCDR Andrew Haffer, CAPT Michael F. Johnston** and **CAPT Anne E. Trontell.**

Opioid Risk Management Team: **Mark Avigan, M.D., Lisa Basham-Cruz, Jeanine Best, MSN, PNP, Sandra Birdsong, Silivia Calderon, Ph.D., Suresh Doddapaneni, Ph.D., Lanh Green, R.Ph., Laura Governale, Pharm.D., Sharon Hertz, M.D., Howard Josefberg, M.D., Michael Klein, Ph.D., David Lee, Ph.D., Deborah B. Leiderman, M.D., Carolyn McCloskey, M.D., MPH, Corinne Moody, Rita Ouellet-Hellstrom, Ph.D., MPH, Martin Pollock, R.Ph., Bob Rappaport, M.D., Giana Rigoni, Pharm.D., Judy Staffa, Ph.D., R.Ph., Sara Stradley, Mary Willy, Ph.D., MPH, Celia Winchell, M.D.,** and **Srikanth Nallani, Ph.D.** PHS officers nominated for companion award: **LT Johanna M. Clifford, CDR Scott Dallas, CAPT James Hunter, CAPT Denise Toyer** and **CAPT Anne E. Trontell.**

Oxycontin Team: **Thomas W. Abrams, Carol H. Barstow, Debbie S. Begosh, Lesley R. Frank, Joan C. Fuschetto, Guyann V. Toliver** PHS officers nominated for companion award: **CDR Mark W. Askine, CDR Brenda Marques** and **CDR Spencer S. Salis.**

Phonetic Orthographic Computer Analysis Team: **Gary M. Anderson, Melissa L. Bates, Kathleen K. Farhat Sabet, Katrina S. Garry, Yi Huang, Martha L. O'Connor** and **Lynette Swartz** PHS officers nominated for companion award: **CDR Sammie Beam, CDR Carol Holquist, CAPT Jerry Phillips** and **CDR John Quinn.**

Plan B Advisory Committee Team: **Karen M. Anderson, Jin Chen, M.D., Helen Cothran, Susan M. Cruzan, Daniel Davis, Tia Frazier, Donna J. Griebel, M.D., Myong Jin Kim, Karen J. Lechter, Ph.D., Coralee G. Lemley, Scott E. Monroe, M.D., Ameeta Parekh, Ph.D., Jayne E. Peterson, Curtis Rosebraugh, M.D., R.Ph., Andrea Leonard-Segal, M.D., Sarah J. Singer, R.Ph., Arlene Solbeck** and **Karen Somers.**

Prussian Blue Research Team: **Ebenezer B. Asafu-Adjaye, Ph.D., Charles R. Brownell, Patrick J. Faustino, Ph.D., Robbe C. Lyon, Ph.D., Nakissa Sadrieh** and **Yongsheng Yang, Ph.D.**

Thiola Drug Shortage Team**: Lorene M. Kimzey, Kasturi Srinivasachar, Ph.D., Douglas C. Throckmorton, M.D.,** and **Michael J. Verdi** PHS officers nominated for companion award: **CDR Daryl L. Allis, CAPT James D. Bona, CAPT Harvey Greenberg, LCDR Valerie E. Jensen** and **LCDR Alisea R. Sermon.**

Topical Microbicides Working Group: **Rafia N. Bhore, Ph.D., Debra B. Birnkrant, M.D., Daniel Davis, M.D., Dorota M. Matecka, Ph.D., Julian J. O'Rear, Ph.D., Guoxing Soon, Ph.D.,** and **Teresa C. Wu, M.D.** PHS officer nominated for companion award: **LCDR Sylvia D. Lynche.**

VELCADE TEAM: **Sophia S. Abraham, Ph.D., Kimberly A. Benson, Ph.D., Peter F. Bross, M.D., Margaret E. Brower, Ph.D., Ann T. Farrell, M.D., Jogarao V. Gobburu, Ph.D., M. Anwar Goheer, Ph.D., Robert C. Kane, M.D., Shwu-Luan Lee, Ph.D., John K. Leighton, PhD., DABT, Ning Li, M.D., Ph.D., Cheng Yi Liang, Richard T. Lostritto, Ph.D., William D. McGuinn, Ph.D., DABT, David E. Morse, Ph.D., Richard Pazdur, M.D., Atiqur Rahman, Ph.D., Lilliam A. Rosario, Ph.D., S. Leigh Verbois, Ph.D.,** and **Yong C. Wang, Ph.D.** PHS officer nominated for companion award: **LCDR Sean K. Bradley.**

(Continued on page 8)

ICH looks at ways to enhance global cooperation, transparency

The steering committee for International Conference on Harmonization and its expert working groups met in Tysons Corner in June.

The committee continued a discussion initiated in Osaka, Japan, in November, on how to manage the ICH process in the future. It focused on how to:

- Streamline and optimize working practices.
- Better monitor the implementation of existing guidelines.
- Better evaluate proposed new topics.
- Improve transparency and communication.

The ICH Global Cooperation Group held its first meeting with participants from six non-ICH regional harmonization initiatives: the Asia-Pacific Economic Cooperation, the Association of Southeast Asian Nations, the Gulf Cooperation Council, the Pan American Network for Drug Regulatory Harmonization and the Southern African Development Community.

Janet Woodcock, M.D., FDA's acting deputy commissioner for operations, updated the committee on the status activities related to a risk-based approach to drug product quality and good manufacturing practices for pharmaceutical products.

Collaboration and interaction with the ICH process to harmonize product quality globally is one of FDA's key priorities, Dr. Woodcock said.

Parking passes needed to visit Corporate Blvd.

BY DANA SCHUHLY AND CHRIS BENTON

Starting Aug. 22, employees and visitors to CDER offices at Corporate Boulevard will be required to display a CDER parking hang tag in their vehicles from 9:30 a.m. to 3:30 p.m. on weekdays. Between Aug. 22 and Sept. 22, warnings will be distributed. After that, all vehicles without a hang tag risk being towed.

If you are visiting Corporate for a meeting, conference or IT training, the person scheduling the meeting or training will e-mail you a temporary hang tag good for the period of your visit.

There is no designated visitor parking at Corporate II. Government vehicles do not require a hang tag to park at the building. We recommend that visitors to Corporate II use a government vehicle whenever possible. Also, motorcycles do not need a hang tag, but we ask that you provide us your license number.

Also, you will be able to borrow a Corporate II parking hang tag from designated individuals in each of CDER's buildings.

Please contact us for any assistance.

Dana Schuhly and Chris Benton are coordinating the parking hang tag program.

In 2 ceremonies, Agency honors work of 12 individuals, 5 groups

(Continued from page 7)

Agency ceremony awards

Commissioner's Special Citation

ICH Q-76A Guidance Expert Working Group: **John Defoe, Malcolm Dixon, Alan Duff, John A. Eltermann, Jr., Stephen Fairchild, Norman Franklin, Betsy P. Fritschel, Sultan Ghani, Stephanie R. Gray, Shoichiro Hamano, Lothar Hartmann, Yuichi Kato, Michel Keller, Sabine Koop, Max S. Lazar, Kiyotoshi Matsumura, Gordon Munro, Tomonori Nakayama, Takayuki Ob, Satoshi Okada, Joseph X. Phillips, Joyce Ramsbotham, Edwin Rivera Martinez, Paolo Romagnoli, Bernard Scherz, Bernadette Sinclair-Jenkins, Tsuyoshi Tanimoto, Robert W. Tribe, Thomas X. White** and **Fumi Yamamoto.**

Quality Systems Framework Subcommittee: **Jerome R. Cordts, Ed.D., Carolyn L. Hommel, Deborah L. Jansen, Sheryl L. Lard Whiteford, Ph.D., Patricia Maroney-Benassi, Ph.D., Leo J. McNamara, Lana L. Pauls, MPH, Sherry L. Purvis Wynn, Michael D. Smedley, Katherine P. Weld, Ph.D., Cheryll J. Wells, Janet Woodcock, M.D.,** and **Stan W. Woollen.**

FDA Award of Merit

Brad G. Leissa, M.D.

Richard Pazdur, M.D.

Sharon T. Risso

SARS Response Team: **Melisse S. Baylor, M.D., Debra B. Birnkrant, M.D., Lorene M. Kimzey, Jeff D. O'Neill, Julian J. O'Rear, Ph.D., Janice A. Shelton** and **Barbara Styrt, M.D.** PHS officers nominated for companion award: **CDR Valerie E. Jensen** and **LCDR Jouhayna S. Saliba.**

FDA Group Recognition Award

cGMP Steering Committee: **John Eyraud, Elaine C. Frost, Barbara J. Giganti, Deborah J. Henderson, Maureen A. Hess, Patricia Maroney-Benassi, Kathleen A. McEvoy, Lana L. Pauls, Glenn M. Scimonelli, Aylin Sertkaya, Carolyn L. Staples, Melanie N. Whalen** and **Geoffrey K. Wong.**

PHS Outstanding Service Medals

RADM Steven K. Galson

CDR Joseph L. Johnson

Length of Service Recognition: 40 years

David C. Bostwick

James S. Bower

Richard E. Kolinski

Ernest G. Pappas

Robert C. Permisohn

Science Forum awards

Excellence in Analytical Science

DNDP Suicide Rates in Trials of Antidepressants Team: **Tarek A. Hammad, M.D., Ph.D.,, Andrew D. Mosholder, M.D., MPH, Gerard Boehm, M.D., MPH, Paul A. David, R.Ph., Judith A. Racoosin, M.D., MPH,** and **Thomas P. Laughren, M.D.**

Excellence in Review Science

Erica Brittain, Ph.D.

Daphne Lin, Ph.D.

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

FDA approves treatments for exposure to radioactive isotopes

(Continued from page 1)

example of FDA's readiness and commitment to protecting Americans against all terrorist threats," said Acting FDA Commissioner **Lester M. Crawford, DVM, Ph.D.**

The two drugs have been used for several decades as investigational drugs to treat patients in radiation contamination emergencies.

In order to encourage manufacturers to submit new drug applications for these products, we announced in September 2003 specific conditions and findings under which the two drugs could be approved through new drug applications. Until these approvals, there had been no approved drug products for the treatment of internal contamination with plutonium, americium or curium.

Internal contamination with plutonium, americium or curium can occur through a variety of routes including ingestion, inhalation or direct contact through wounds.

The goal of treatment with the intravenous chelators is to enhance the removal of these radioactive contaminants and, therefore, reduce the risk of possible future biological effects including the development of certain cancers, which may occur years after exposure.

Release of plutonium, americium and curium could occur from laboratory or industrial accidents; or through terrorist attacks using a radiation dispersal device, commonly known as a "dirty bomb."

The chelators Ca-DTPA and Zn-DTPA should not be administered simultaneously. If both products are available, Ca-DTPA should be given as the first dose.

If additional treatment is needed, treatment should be switched to Zn-DTPA. This treatment sequence is recommended because Ca-DTPA is more effective than Zn-DTPA during the first 24 hours after internal contamination. After the initial 24 hours, Zn-DTPA and Ca-DTPA are similarly effective. Ca-DTPA and Zn-DTPA are usually administered into the blood stream; however, in people whose contamination is only by inhalation, Ca-DTPA or Zn-DTPA can be administered by nebulized inhalation.

The main side effect of Ca-DTPA is the loss of certain essential nutritional metals such as zinc, which can be replaced by taking oral zinc supplements. Although Zn-DTPA may also decrease the levels of certain nutritional metals, the effect is less than with Ca-DTPA.

More information about FDA's efforts to counteract bioterrorism is available on FDA's website at http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html.

Center's import, export Web page helpful to small businesses, others

By Ron Wilson

CDER now has a new Web page on laws and regulations governing the import and export of human drugs and biologics.

The Web page was created for small pharmaceutical business so there would be one place for clear and comprehensive information on imports and exports. It is available by clicking on the Small Business link at the bottom right of the Center's home page or directly at http://www.fda.gov/cder/about/smallbiz/importExportInfo.htm.

Steven Silverman, Margaret O'Rourke and **Ada Irizzary** in the Office of Compliance helped Small Business Assistance in the creation of the Web page. In addition to information on imports and exports, there are many links to various offices and people within the Agency that can provide additional information.

Many will probably be surprised to learn that there are 19 import program managers in the regional and field offices of FDA who are available to provide assistance. The name of each is listed in the Web page along with his or her location and phone number.

Links are also provided to several other federal agencies involved in imports and exports, such as Department of Agriculture, the Drug Enforcement Administration, the U.S. Export Assistance Centers and the Bureau of Customs and Border Protection.

Import and export issues can be challenging as they sometimes involve the coordination with more than one Federal agency.

Ron Wilson runs the Center's Small Business Assistance Program.

Pike's Puzzler: Matching test

By Tony Chite, P.D.

Match the numbered term with the lettered definition. One letter does not have a number to match.

1. Parenchyma	a. pain resulting from a non-noxious stimulus to normal skin
2. Lithotripsy	b. designates the functional elements of an organ as distinguished from its framework
3. Dystocia	c. having borne one or more viable offspring
4. Nulliparous	d. crushing of a calculus within the urinary system or gallbladder, followed at once by the washing out of fragments
5. Phocomelia	e. hyperpigmentation over cheeks and forehead, also called the "mask of pregnancy"
6. Melasma	f. absence of the proximal portion of a limb
7. Parous	g. having never given birth to a viable infant
8. Allodynia	h. abnormal or difficult labor
	i. pertaining to the zygomatic bone

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

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

Partnerships help spread CDER's consumer information messages

(Continued from page 1)

the right time. While our division coordinates the partnerships, our Center's experts in the Office of New Drugs and the Office of Generic Drugs are key players in developing timely and relevant messages."

Some recent campaigns in which we partnered to develop the messages and materials include:

- *Medicines and* Aging. The Council on Family Health (now defunct) and the Administration on Aging. DPA coordinator: Ayse Hisim.
- As You Age. The Substance Abuse and Mental Health Services Administration and the Administration on Aging. DPA coordinator: Ayse Hisim.
- Antibiotics and Antibiotic Resistance. The Centers for Disease Control and Prevention. DPA coordinator: Sherunda Lister.
- Over-the-Counter Pain Relievers. The National Consumer's League and the National Council on Patient Education and Information. DPA coordinator: **Mandy Eisemann.**

Examples of campaigns that involve the "co-branding," or the authorized use of FDA's logo with an other organization's logo, include:

- *Generic Drug Quality Awareness.* Partners included pharmacy benefit companies and major pharmacy chains. DPA coordinator: Ayse Hisim.
- *Looks Can Be Deceiving*, which outlines the risks of purchasing medicines outside of FDA's regulatory scope. Partnered with 13 state pharmacists' associations and resulted in distribution of 10 million pieces of information. DPA coordinator: **Cindi Fitzpatrick.**

Some of the important placements for our public service announcements include television, radio, national and specialty publications, posters, pamphlets and even information attached to prescription bags at retail pharmacies.

A leading provider of consumer medication information distributed with prescriptions dispensed at 20,000 U.S. pharmacies frequently includes our health promotion messages. "Our messages have been included on information sheets stapled to nearly 180 million prescription bags in the last two years," Fitzpatrick said.

"From August through December of last year, our antibiotic resistance television public service announcement was broadcast more than 4,000 times in 108 markets," Lister said.

"If we had to pay for that amount of coverage, it would have cost more than $345,000." Radio public service announcements were played during that same time period in 213 cities at an estimated value of more than $1.1 million.

Eisemann has coordinated the placement of several public service announcements in national magazines. "The West Coast edition of one national publication carried one of the OTC public service announcements reaching a possible audience of almost 3 million people," Eisemann said. And 152 grassroots newspapers with a projected readership of 7.3 million picked up a news release explaining the campaign.

> "More importantly, our partnerships help ensure the messages in our public health campaigns reach the right audience at the right time."
>
> —Ellen Shapiro

"We're also working with the New York State Health Department on a plan for them to use posters of one of the announcements in all 4,000 of their pharmacies and hundreds of hospital pharmacies," Eisemann said.

The *Looks Can Be Deceiving* campaign uses posters, prescription bag inserts, fliers and tabletop displays to remind pharmacy customers in straightforward language that imported drugs pose a safety risk.

A major pharmacy benefit company, which represents more than 40 million Americans, has been using educational materials from the Generic Drug Quality Awareness campaign. After using the items, the company reported that generic drug use reached an all-time high.

Hisim also has a roster of pharmacy chains that use the generic campaign material. "They often have monthly or bimonthly newsletters, and they'll put an ad or article relating to our message in them," Hisim said. "We put out a good health message, and they see additional value in associating with FDA."

All CDER campaigns and co-sponsored campaigns are available on the Center's Web site at http://www.fda.gov/cder/consumerinfo/DPAdefault.htm. At the top of the page, there is a link to subscribe to a service that will send you an e-mail when our campaigns are updated. The e-mail address for more information about partnering is dpapubs@cder.fda.gov.

Our educational materials are in the public domain and can be used as they are by anyone. However, to co-brand or co-develop items, organizations need a signed a co-sponsorship agreement.

"The agreement spells out that the product is in the public domain and can be shared with interested organizations and individuals," Eisemann said. "The FDA Ethics Office reviews initial agreements, which are usually good for two years."

To foster partnerships, employees in the Division of Public Affairs "take their show on the road."

They set up and staff a display booth of educational materials at different organizations' annual meetings or conventions and make new contacts who are interested in using some of the material or forging a partnership.

The division also exhibits at medical professional events ranging from the Association of Clinical Research Professionals to the American Society of Consultant Pharmacists.

The division's staff also attend some consumer meetings such as those of the AARP or the National Urban League.

Shapiro, who recently received an FDA Leveraging/Collaboration Award, is always looking for new partners and innovative ways to disseminate CDER's messages about the safe and wise use of medicines.

"We don't have a big promotional budget, so we have to find creative ways to get these important messages out. Forming partnerships is key to our success," she said.