news along the pike

June 17, 1996

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Center for Drug Evaluation and Research

Tough Security Measures Set For Parklawn

Limited Road Access and Entry Planned

By Ruth Clements

In a government-wide effort to improve security for federal employees, significant changes are underway at the Parklawn building. The changes are in response to recommendations made by the Department of Justice and come in the wake of the bombings of Oklahoma City's Alfred P. Murrah federal build-ing, New York's World Trade Center, and other terrorist threats in recent years.

The changes improve security for the parking garages and areas immediately adjacent to the Parklawn building, and the lobbies used to enter and exit the building. The remodeling is being performed to bring Parklawn up to the same standards as the newer FDA buildings.

Many CDER employees are already familiar with the MDI (Monitor Dynamics Incorporated) access cards used to enter CDER buildings like Woodmont and Corporate Boulevard. This same system will be installed in the Parklawn building later this year. CDER employees working in Parklawn who do not currently have a badge with a magnetic stripe will be issued new badges before the system goes online.

Another feature of the MDI system will be the installation of controlled access gates for entrance and exit from the garages and the Healthy Beginnings Daycare Center. There will be gates and guard booths installed at the end of Fishers Lane near the back entrance to the Parklawn Cemetery. These gates will be the control point for the only access to the daycare center and the second and third level

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Debra Birnkrant Wins 1995 Flemming Award for Science

By Jeffrey Yorke

She was spreading peanut butter on bread, making sandwiches for her three sons when the telephone rang. The woman on the other end wanted to speak with Dr. Birnkrant.

"Nine times out of ten it's the other Dr. Birnkrant," mused Debra B. Birnkrant, M.D., referring to her husband, Alan, an obstetrician/gynecologist at Columbia Women's Hospital.

But this time it was for her and the caller had good news.

Birnkrant was being officially notified that she was one of the 1995 winners of the prestigious Arthur S. Flemming Award in the scientific category. The award honors "outstanding young [under 40 years-old] men and women in the Federal Government." Judges consider specific accomplishments, actions that result in material improvements, substantial financial savings or significant social or technological progress; general accomplishments; and community involvement.

Birnkrant, a medical reviewer in CDER's Division of Antiviral Drug Products, made the judges' jobs easy. They

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Dr. Birnkrant

New Book Details Drug Development

An explosion in transplantation immunology, molecular biology and technology advances in the pharmaceutical sciences has stimulated unprecedented discovery, research and development of promising new therapeutic agents for controlling graft rejection and treating autoimmune disorders.

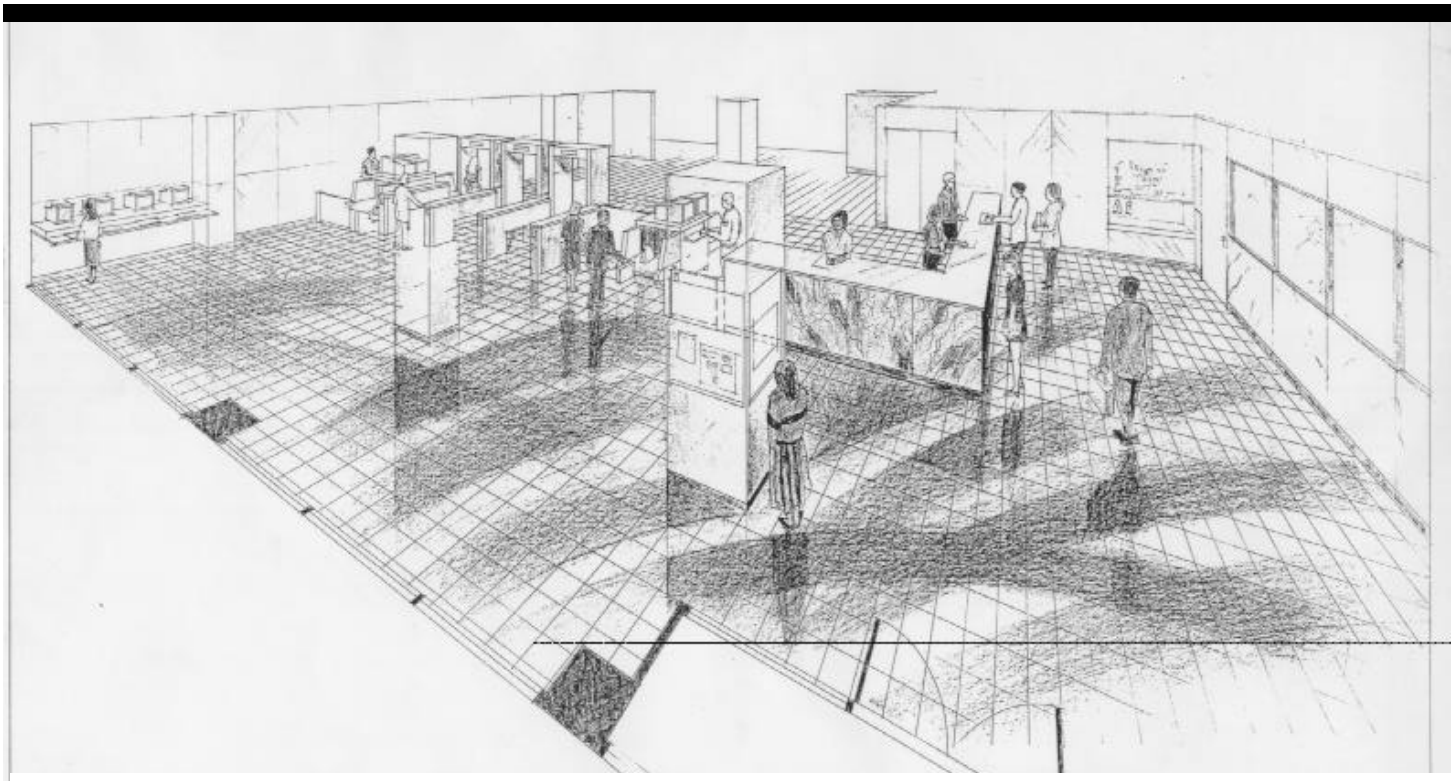
This revolution in immunology, biotechnology and the emerging regulatory science of drug development has been captured in detail and clarity in "Principles of Drug Development in Transplantation & Autoimmunity." Edited by FDA's Ronald Lieberman, M.D., and Asoke Mukherjee, M.D., the book was written by experts from the pharmaceutical industry, academia and FDA, and has just been published by Chapman & Hall, New York.

Topics in the 787-page book include: the molecular actions of recently approved immunomodulators; the status of new immunomodulators; the role of animal models and clinical pharmacology in the rational development of new agents; clinical endpoints; practical issues in trial design and analysis; pharmacoeconomics of drug development; structure-based drug design; induction of tolerance by donor specific cell therapy; and oral antigenic tolerization to genetically engineered pigs and cell transplants for diabetes and Parkinsonism.

In his foreword, FDA Commissioner David A. Kessler, M.D., notes that the

(Continued on page 2)

inside...



Artist's drawing of Fishers Lane-side of Parklawn lobby after security system is installed

Tough Security Measures Set For Parklawn Building, Street

(Continued from page 1)

garage areas. A permanent guard booth will be installed on Fishers Lane between the B & C wings. This location will be responsible for preventing vehicles from parking on Fishers Lane in front of the building. There will also be gates and guard booths installed on the Parklawn Drive side of the building for access to the first-level garage. The area around the loading dock will be significantly restricted with delivery vehicles parking across the driveway from the actual dock area.

If you've been to the Parklawn building recently, you've probably noticed the x-ray machines already in place in the lobby areas. Another significant change will be the expansion of the 5B lobby, into the space formerly occupied by First Union Bank, to accommodate new security equipment. Right now, visitor packages and deliveries are being x-rayed. Once the lobbies are reconfigured to accommodate additional security equipment, all items will be x-rayed. In addition to the x-ray machines, metal detectors are also being installed. Although the card access will not be operational right away, the guards posted at the 1B, 3B, and 5B lobbies will continue to check ID's, and will begin to require employees to walk through the metal detectors and send their packages, handbags, and briefcases through the x-ray equipment. The guards will be equipped with hand-held metal detectors for employees who use a wheelchair. Guards will also use an x-ray machine and a hand-held metal detector to perform random checks of employees, and of packages, in the garage-level elevator lobbies. These checks will not be announced.

Employees will be seeing signs of all of these improvements during the summer. Although it is anticipated that the card access system will not be functioning by the end of the year, construction is already underway in the lobby areas and employees will be seeing changes soon in the way they enter and exit the Parklawn building. For CDER employees located in other buildings, don't feel left out; there are surveys underway to determine security improvements needed to bring all federal buildings up to the highest possible level of security and safety. All of these changes are being made to improve the safety and security of employees working in the Parklawn building.

The writer is the director of the Division of Management Services, Office of Management.

Editor's Note: Additional security information packets are available from OTCOM, 301/827-1243.

CDER Authors Detail Drug Development

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book "clearly underscores the vital interplay between the three traditional pillars of our biomedical research complex -- the government, the pharmaceutical industry and academia -- as well as the emerging importance of direct public input -- for the successful and timely translation of basic science discoveries into new and effective therapies."

The book is broken into four, easy-to-use sections: Basic Principles and Essential Concepts; New Drug and Biologic Product Development; Managing the Drug Development Process; and Future Directions in Drug and Biological Development.

The book, ISBN# 0412100614, costs $150 and can be purchased by calling Chapman & Hall, 1-800-842-3636.

Editor's Note: Ronald Lieberman, M.D., will join the National Cancer Institute (NCI) as a medical officer/clinical pharmacologist (Medical Director) on July 1. He will oversee the design, development, and overall management of Phase 1-3 clinical trials of chemoprevention programs in the U.S and abroad. Dr. Lieberman will also serve as a liaison with academia, CDER, and other FDA centers and will develop collaborative programs involving clinical investigator/clinical pharmacology training.

Ombudsman's Corner

TheTimes, They Are A-Changin'

By Jim Morrison

In the ombudsman business, you take your victories when you can. Since I am exposed to CDER's problems every day, I find it refreshing to see areas where people are more satisfied today than they were yesterday.

You may recall that I reported last month that recently hired CDER employees had expressed dissatisfaction with the way the recruitment and orientation process was handled at the local level. They complained of entering their new offices with a feeling that management didn't care about their arrival and without such handy items as furniture, personal computers, telephones, and the like.

At the end of May, I had another opportunity to poll new hires as I addressed the CDER New Employees Orientation. People in these sessions have been newly hired since the last session, generally no more than two months earlier. As usual, I concluded my remarks with an informal survey of those present concerning how satisfied they were with the way that they were brought on board (whether they had an adequate working environment, were welcomed by supervisors, etc.).

At the previous session in early March, at least one third of the people expressed dissatisfaction and offered examples of problems. This time, no one raised any complaints, and the group expressed general satisfaction. I might have thought that this was an especially docile group or a statistical fluke, except for a statement by one of the new hires who had been hired by the Center some years ago, left, and was returning. She commented that the difference in the recruitment and initial work environment between her two entries into CDER was like "night and day."

I am not so much of a Pollyanna as to proclaim that all our recruitment and orientation problems are solved! But I think this apparent shift in the attitudes of new hires is real and shows that the efforts of the many individuals who have been working to make CDER a more hospitable environment for newcomers are paying off.

So those of you who have contributed to this "day for night" transformation, please give yourselves a pat on the back! For those who didn't have a chance to participate in this effort, there will be many more opportunities to contribute your talents. There are many changes occurring in CDER that are being led by Center Director Janet Woodcock, M.D., and the Change Team consisting of senior managers. You will be hearing more about these changes in meetings with your offices, and there will be ample opportunities for you to participate actively in suggesting and implementing changes that you think are needed to make CDER the kind of organization that we all want it to be.

The writer is CDER's Ombudsman.

Pediatric Guide Issued to Industry

The "Content and Format for Pediatric Use Supplements" industry guidance, detailed in an article in the May issue of The Pike, was published in the May 24 Federal Register.

This document is intended to provide guidance on the format and content of "pediatric use" labeling supplements to approved applications for drugs and licensed biological products. This labeling information is intended to provide practitioners with sufficient "pediatric use" information upon which to base a decision to prescribe a drug for use in pediatric patients.

Reviewers' Corner

Regulatory Forum Set For Fall

By Debbie Henderson

Controversy: *"A dispute, especially a lengthy and public one, between sides holding opposing views." (American Heritage Dictionary)*

In an environment of increased focus on containing health care costs, what role does FDA play in considering the economic impact of approving diagnostic agents that impose significant costs with no proven clinical benefit?

These are the sorts of questions that have the making for a lively debate. In fact, they will be the foundation of a series of such discussions billed "Regulatory Controversies" set for September.

The idea was spawned from the clear need for a forum where regulation of human drugs could be debated and resolved. This vehicle is not designed to address the nitty-gritty scientific questions unique to specific NDAs, but instead to focus on issues related to regulatory policy or regulatory philosophy that are generally applicable to a broad range of drug products or classes.

For example, the first debate will tackle the long-standing issue of appropriate efficacy standards for diagnostic imaging agents -- an area of currently inconsistent regulatory philosophy within and across CDER, CBER and CDRH. Should efficacy be defined as imaging as claimed or must clinical benefit be demonstrated?

Topics proposed for subsequent debate include: the adequate representation of women and other special populations in clinical trials; the role of scientific literature in support of efficacy supplements; and the appropriateness and validity of quality of life measurements in clinical trials and a lengthy list of biostatistical controversies.

Although the precise format of the regulatory controversies has not been finalized, the creation of a panel of experts -- the regulatory equivalent of "Supreme Court" -- could be in the offing. The panel would be charged with hearing the evidence and developing a position on controversial issues.

As an initiative of the Good Review Practices (GRPs) Track 2, the "continuous improvement" arm of the GRP initiative, this series aims to foster solid policy decisions that would be incorporated and embraced as good review practices.

If you're intrigued by this, Track 2 is in search of interested volunteers to contribute to the regulatory controversies series. Contact me, Debbie Henderson, via e-mail (HENDERSOND) or 301/594-6779 with topics, suggestions, or, hopefully, with your offer to help!

The writer is director of the Executive Operations Staff.

New CDER Division

The Division of Reproductive and Urologic Drug Products (HFD-580), has been formed as a new review divsion in ODE II. It is comprised of part of the present Division of Metabolism and Endocrine Drug Products (DMEDP). **Lisa Rarick, M.D.**, is acting division director. The remaining part of DMEDP will be renamed the Division of Metabolic and Endocrine Drug Products. That division will remain HFD-510. All of the divisions will report to ODE II Director **James Bilstad, M.D.**

Epidemiology and Biostatistics

After 25 Years, First Changes In Biometrics Program Are Not A "Random Event"

By Charles Anello, Sc.D.

The first major organizational change for the Biometrics Program in a quarter of a century has occurred in CDER. The Office of Epidemiology and Biostatistics has completed an important restructuring from a one-division organization to a four-division program. This change was a deliberate move on the part of OEB management to provide the new Office of Review Management and the Office of Pharmaceutical Science with more effective biostatistical and computational support in a manner consistent with CDER's changing structure.

As the Center has expanded its resources to meet the Prescription Drug User Fee Act (PDUFA) goals, there has been a proportional increase in the Center's biostatistical and computational resources. Also, the move toward team reviews and easy access to statistical consultations led to a strong demand for colocation of team members. There was also a need to have the statisticians fully integrated into the entire drug development process (i.e., preclinical, clinical and postmarketing).

Thus, the old two-branch Division of Biometrics has been replaced by a new four-division structure without any sub-units. In order to accomplish a smooth transition to this new structure, and to assure consistent application of statistical methodology and regulatory policy across the four biometrics divisions, two Associate Director positions have been established as follows: Associate Director for Biostatistics (Clinical) and Associate Director for Biostatistics (Non-Clinical). Former Branch Chiefs, Dr. Sayta Dubey and Dr. William Fairweather, have assumed these important new roles, respectively, as Associate Directors.

In addition, OEB has renamed it's ***Research and Methodology Planning (RAMP) Staff***, headed by **Dr. Stella Machado**, to the ***Quantitative Methods and Research (QMR) Staff***, with added responsibility for providing statistical support to the Office of Pharmaceutical Science.

The directors in the four new biometrics divisions are as follows:

- Division of Biometrics I (DBI), supports the Office of Drug Evaluation I which consists of the following CDER Review Divisions: Neuropharmacological Drug Products, Cardio-Renal Drug Products, Oncologic Drug Products and Drug Advertising and Communications (DDMAC). The division will be headed by **George Chi, Ph.D.** Dr. Chi earned his Ph.D. in mathematics from Carnegie-Mellon University. He joined FDA in 1983 and has served as a group leader since 1986.
- Division of Biometrics II (DBII), supports the Office of Drug Evaluation II which consists of Metabolism and Endocrine Drug Products and Pulmonary Drug Products. **Edward Nevius**, who earned his Ph.D. from Florida State University, will head the division. Dr. Nevius joined FDA in 1979 and has served as a group leader since 1985.
- Division of Biometrics III (DBIII), supports the Office of Drug Evaluation III which consists of Gastro-Intestinal and Coagulation Drug Products, Medical Imaging and Radiopharmaceutical Drug Products and Aesthetical Care and Addictions Drug Products. **Nancy Smith,** who earned her Ph.D. at the University of Maryland, will head the division. She joined FDA in 1988 and has served as group leader since 1993.
- Division of Biometrics IV (DBIV), supports the Office of Drug Evaluation IV and V and consists of Anti-Infective Drug Products, Anti-Viral Drug Products, Over-the-Counter Drug Products, Dermatology and Dental Product Development and Ophthalmologic Anti-Inflammatory, Analgesic and Drug Products. **Ralph Harkins, Ph.D.** has accepted the top position in the division. Dr. Harkins earned his Ph.D from the University of Oklahoma. He joined FDA in 1986 and has served as group leader since 1990.

The writer is deputy director of the Office of Epidemiology and Biostatistics.

FDA Award Winners in CDER

More than 70 members of the CDER staff picked up awards from the center during a morning ceremony on May 10.

However, that afternoon, still more people from the center were recognized for their efforts at an agency level. The following folks received FDA awards at the DoubleTree Hotel:

Award of Merit
Roger Williams
Donald Hare
Lawrence Lesko
Douglas Ellsworth

SUPAC Group
Suva B. Roy
Allen Rudman
Henry Malinowski
Lawrence Lesko

Reviewer's Ed Subcommittee
Lana Pauls
Charles Ganely
Heidi Jolson
Lydia Martynec
Ruthana Davi
Carol Assouad
See Yam Lam
Janet L. Rose
Daniel Trachewsky
Dale Wilcox
Rose Cunningham
Lisa Rarick
Nancy Smith
Jack Pevenstein
Eileen Parish
Linda Sherman

PHS Commendation
Stephen Wilson
Ron Leiberman
Robert Nelson

Commissioner's Special Citation

Community Health Project Investigative Group
Elsworth Dory
Gerald Hajarian
Betty Jones
George Prager
Angela McDaniels
Lavonia Huff
Frances O. Kelsey

Field Comm/Pilot One Shot Review
Brenda Arwine
Karen Bernard
Manuel Garza

Group Recognition

Thalidomide Review, Regulation Group

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Center Director Janet Woodcock, M.D., left, with Alfreda Burnett, Ph.D., at the CDER awards ceremony on May 10. The FDA awards were presented during an afternoon ceremony.

AMF Corner

Electronic Repository Allows Reviewers To Double-Click Through Years of IND, NDA Data

By David Isom

If tapping into 15 years of voluminous Investigational New Drug (IND) and New Drug Application (NDA) reviews and their supporting documents in searchable image and text format sounds impossible, think again. What was once a CDER goal has now become reality in the Division of Biopharmaceutics.

Billed as the Biopharmaceutics Division File Electronic Repository, this component of the Automated Files Management project has created a way to use imaging software to store the image and text of historical review-related files of an entire division. The development is now fully operational.

The electronic repository has helped the Biopharmaceutics and Bioequivalence staff access data more quickly and efficiently. Users believe that this technology has enhanced the quality of their reviews. User documentation and customized biopharmaceutic training classes have been given to over 85 percent of Biopharmaceutics and Bioequivalence staff. Additional training classes are also being conducted each month for any staff interested in accessing this biopharmaceutic fileroom. Six months after the entire Biopharmaceutics staff is trained, a survey will be taken to assess the effect of the repository on the review process.

The repository will continue to be enhanced. For instance, a Graphic User Interface (GUI) will be added to easily navigate the Management Information Systems (MIS) database and Excalibur repository.

Stored in an Excalibur electronic "fileroom," the data is prospectively maintained by using a combination of scanning (contract and in-house) and electronically stored documents as the Biopharmaceutics Division develops a routine for maintaining the fileroom fully with the final electronic copy of their documents. To request access to this fileroom, send a request through your supervisor to Dave Moss.

Author's Note: Many thanks to the people who have contributed to the success of this component of AMF. In particular, thanks to the entire Biopharmaceutics staff, and also the development team members Paul Hepp, Gayle Hobson, Vikki Levi, Helen Mitchell, Paul Chapman, Barbara Murphy, and Tom Tokoli.

The writer is the AMF Project Manager.

CDER's "Blueprint" Sparks Renewal of Vision

By Jim Morrison

As Center Director Janet Woodcock, M.D., often states, CDER, like all other organizations today, must either renew itself or become irrelevant. There is no middle ground in which the Center can remain unchanged yet still remain a potent force in service to the public health.

The current CDER renewal process began March 17 with a three-day go-away by 30 senior managers at the Lansdowne Resort in Leesburg, Va. That retreat, as were all related activities, was guided by representatives from the Council for Excellence in Government, principally Ron Red-mon and Michelle Hunt. As reported in Dr. Woodcock's March 5 all hands e-mail, go-away participants, now known as the CDER Change Team, began developing new mission, vision and value statements. With the diverse responsibilities of different units in CDER, it is easy to lose sight of the things that bind us together. Therefore, the Change Team believed it essential that a consensus be built in CDER around the three documents, which will state what we do, where we want to go, and what principles we value in getting there.

In order to build a consensus around the mission, vision and values documents, a series of four-day-long "roll-out" sessions are being held with virtually all CDER managers, supervisors and team leaders. The first was held April 19 in Bethesda, and the final one will be held July 3. In addition, the views of non-managers are being sought through smaller discussions with members of the Change Team in such forums as the Reviewer Affairs Committee and in brown bag lunch sessions to be held soon. While all this activity is occurring, CDER offices are holding meetings to further discuss what the process means to them. Based on feedback gained at these meetings, the Change Team will produce what in over-the-counter (OTC) parlance would be termed "tentative final" mission, vision and value statements. The deadline is July 10. On July 11 and 12, the Change Team will again go away (this time to beautiful downtown Rockville) to discuss how to convert the three "blueprint" documents into a concrete plan for renewal.

To prepare for the Rockville go-away, the Change Team engaged in benchmarking on May 20 and 21. At that session, the team had the opportunity to talk with high level managers and entrepreneurs from the private and public sectors to learn how they have effected change in their organizations.

Because the Change Team is comprised of managers who also have full-time responsibilities that limit their ability to do all of the implementation and tracking necessary to the success of CDER's renewal, Dr. Woodcock enlisted help from Julie Carlston in the Commissioner's office. Carlston is no stranger to the Center and has worked closely with many of the staff. She will be devoting about half her time, along with Minna Golden, to this effort. She will also attend the monthly Change Team meetings, lead biweekly meetings of an important subcommittee of the Change Team (the Change Work Group), and be responsible for keeping the entire project on track and moving apace. Julie's outstanding skills, along with those of her staff, will bring welcome relief to those in CDER who were juggling too many tasks with too little time.

CDER renewal is real, gaining momentum, and it has the commitment of senior management. Future go-aways by the Change Team are planned for September and November. It is a long-term project that will never be completed, because renewal, by definition, is a continuous process of change to meet the challenges of a rapidly changing world.

The writer is CDER's Ombudsman.

Health & Fitness

Hey, You! Get Outta the Sun!

By Katharine Freeman

Until recently, suntanned skin was fashionable and considered a sign of good health. Now we know the dangers associated with ultraviolet (UV) radiation from sun exposure We know that damage is cumulative and cannot be repaired. The effects of sun exposure include burning, wrinkling, and premature skin aging, cataracts, immune system suppression, and skin cancers.

Dermatologists have identified six distinct skin types ranging from the type that always burns and never tans, to the type that never burns and is deeply pigmented. Skin type influences a person's susceptibility to cancer from UV radiation, the fairer type being the most susceptible.

There are several ways to protect yourself from UV radiation; one way is to wear sunglasses, large-brimmed hats, and other protective clothing. Another is to avoid sun exposure from 10:00AM to 4:00PM, sunlamps and tanning parlors. Also, be aware that UV radiation is reflected by water, sand, and snow, and that it passes through windows and clouds. Finally, some drugs can cause an adverse reaction in a person exposed to UV radiation.

Perhaps the first line of defense for most people, certainly "sun bathers," should be the use of sunscreens. Sunscreens are labeled with Sun Protection Factor (SPF) numbers to provide guidance to consumers. The higher the SPF the higher the level of protection. This number generally indicates how much longer a person can be exposed to the sun before a sunburn occurs. For example, if a person starts to sunburn after 15 minutes without a sunscreen, using a sunscreen with an SPF of 15 would allow this person to stay in the sun 15 times longer, or about 3 hours, before burning. However, it is important to use the sunscreen liberally and to reapply often, especially if washed or toweled off.

Although sunscreens protect against sunburn, it is important to know that suncreens may not necessarily protect against cancer. Sunscreens may allow more time in the sun, this means that the total UV exposure is about the same as a shorter exposure to unprotected skin.

Sun protection is especially important for children because most sun exposure occurs before age 20. There is increasing evidence of a link between early UV exposure and skin cancer in adulthood. Dermatologists recommend a sunscreen with an SPF of 15 or higher. Children under 6-months old should not be exposed to the sun.

The writer is a microbiologist in the Division of OTC Drug Products.

Shedding Some Light on the Sun's Rays

By Jonathan Wilkin, M.D.

Although the sun emits a more extensive spectrum of light, thanks to our atmosphere and its ozone, we only have to contend with wavelengths from 290 nanometers (nm) to 700nm. This range includes visible light and the A and B bands of ultraviolet light (UVA and UVB).

Some drugs increase an individual's sensitivity to sun light and may cause a reaction in that person. For a drug, a drug metabolite, or a drug degradation product to have photosensitivity as a side effect, it must absorb light in one of the three bands of light that reach the Earth's surface. In the past, drug companies tested many drugs for photosensitivity which did not absorb light in any of these bands or which absorbed only UVA or UVB. FDA now informs drug sponsors that they should only test for photosensitivity in those drugs that absorb in UVA, UVB, or visible wavelengths. And, they only need to test the band in which absorption occurs.

FDA now accepts absorption spectra for a drug, metabolites, and degradation products that show no absorption from 290nm to 700nm as sufficient evidence of photosensitivity safety. If a drug does absorb within the 290nm to 700nm band, then a patient taking this drug and subsequently exposed to light may experience a photosensitivity reaction.

Photosensitivity reactions fall into two distinct categories: phototoxicity and photosensitivity. Phototoxicity appears as an exaggerated sunburn, and can occur on the very first exposure, and varies in intensity according to the dose of the drug and the "dose" of sunlight. Photosensitivity, or photoallergy, appears as an eczematous eruption, occurs only after the patient has been "sensitized" during a previous exposure to the same or chemically related drug, and, in its most severe manifestations, occurs after only a small dose of the drug and subsequent sun exposure.

Drugs can have adverse consequences on the skin's natural abilities to protect against ultraviolet A or B by reducing the epidermal density filter, interfering with the excision and repair of photo-damaged DNA, or eliminating the surveillance function of Langerhans cells that help recognize and eliminate precancerous epidermal cells. In such ways, drugs can facilitate photocarcinogenesis even though they don't absorb light. We currently require photocarcinogenicity testing of all drugs to be used chronically on sun-exposed skin regardless of their absorption spectra.

Photocarcinogenicity tests of drugs would be so identified in the label along with advice to avoid sun exposure. Current photocarcinogenicity testing is expensive and affects approval decisions for drugs intended for use in the sun, for example, sunscreens. Thus, we are interested in less expensive and shorter methods to assess the risk of photocarcinogenicity.

Patients should always check the label of any drug they are taking before being exposed to the sun for extended periods.

The writer is director of the Division of Dermatologic and Ophthalmologic Drug Products.

Picking The Right Sunscreen

Sunburn and Tanning History	Recommended SPF*
Always burns easily; rarely tans	20 to 30
Always burns easily; tans minimally	12 to under 20
Burns moderately; tans gradually	8 to under 12
Burns minimally; always tans well	4 to under 8
Rarely burns, tans profusely	2 to under 4

**Sun protection factor*

(Source: FDA's 1993 tentative final monograph on sunscreen drug products.)

Birnkrant Wins Flemming Award for FDA, Community Work in Science and Medicine

(Continued from page 1)

recognized her for "her excellent work in public health in promoting the development of potentially life-saving drugs while protecting the public health and advancing the interests of scientific research in women."

The panel specifically noted that "her achievements with the Thalidomide Working Group have been marked by her excellent scientific leadership in a complex and sensitive area and by her skills as a group leader and facilitator in working with professionals in diverse backgrounds."

With Birnkrant at the helm of the Thalidomide group, coupled with some savvy maneuvering through political quicksand by Center Director Janet Woodcock, M.D., the Antivirals division produced an impressive brochure informing all patients about the general guidelines for thalidomide use. The much-storied drug is not approved for use in the United States, but is being used in a number of investigational trials to treat certain severely debilitating or life-threatening diseases and certain other diseases for which there is no alternative. An extraordinary eye-catching illustration on the brochure's cover features a pregnant woman with an international "no pregnancy" logo striking over her form, warning female patients to avoid pregnancy while taking the drug. Male patients, too, are warned to use condoms during intercourse or abstain from sex altogether. But the drug has shown potential benefit to a number of patients.

"Recognizing the importance of this drug to certain segments of the population, this dynamic FDA group has taken major steps over the past year to increase the availability of thalidomide for the treatment of aphthous ulcers in HIV-infected individuals," wrote Commissioner David A. Kessler, M.D., in a letter of congratulations to Birnkrant. "I think I can speak on their behalf by thanking you for helping to improve their quality of life."

Kessler offered his "special gratitude" for Birnkrant's work in women's health, "specifically your efforts to ensure wider inclusion of women in clinical trials for AIDS drugs."

The commissioner also commended the medical officer, who joined FDA in 1989 as a Staff Fellow, for being one of a few reviewers carrying out joint product reviews with the Canadian Government.

"The value of work with our Canadian counterparts is inestimable, and I want you to know that your past efforts -- as well as your ongoing work in these and so many areas -- is very much appreciated and valued," Kessler said.

Birnkrant received a similar letter of congratulations from Sen. Barbara A. Milkulski (D-Md.) and an invitation to lunch later this month from HHS Secretary Donna Shalala. NBC Nightly News also aired a piece last month about Birnkrant.

But she that perhaps the most rewarding part of getting the award was not the heartwarming adulation from her friends and colleagues, but discovering that Daniel Swern, her organic chemistry professor at Temple University nearly two decades ago, had received the same award in 1954.

"It was a touching moment for me when I found that out," she said. "He was a great teacher, a guru, and was very encouraging to me."

Birnkrant, 39, is also giving back to her community. She continues to work one day a week at the Veterans Affairs Hospital in Washington where she was Chief Medical Resident a decade ago. These days, her responsibilities include patient care and the instruction of medical students, interns and residents. She is involved in her children's school where she delights in teaching elementary-age children about the human body, and she volunteers in a community-based shelter, helping homeless people at her synagogue.

The writer is on the staff of News Along the Pike.

CDER's FDA Award Winners

(Continued from page 4)

Brenda Jarvis Atkins
Rachel Behrman
Ridgely Bennett
Debra Birnkrant
-Harold Jay Blatt
Linda Carter
James Cohen
Wilson DeCamp
Celia DeLawter
Antoine El-Hage
Mark Goldberger
Edward Henderson
Joanne Marie Holmes
Kent Johnson
Sheryl Lard
Maureen Pelosi
Leah Ripper
Janeth Rouzer-Kammeyer
Hilary Sheevers
Brenda Vaughan

PHS Unit Commendation
Matthew Tarosky

Issues in AIDS Clinical Trails
David Feigal
Steven Gitterman
Lisa Kammerman
Kazem Kazempour
Richard Klein
Heidi Marchand
Kimberly Thornton
Lee Zwanziger

PHS Unit Commendation
Kimberly Struble

Restructing Team
Tanya Abbott
Russell Abbott
Jacquelyn Barber
Celeste Buchanan
Charlene Cherry
Ruth Clements
Kristin Crown
Patricia DeSantis
John Emelio
Pam Fagelson
Anita Harrell
Deborah Henderson
Robert Henry
Susan Jafari
Ellen Johnsey
-Cynthia Sayer Marx
Weston Metz
Darryl Patterson
Dave Petak
Khyati Roberts
Janet L. Rose
Rixie Scott
Mira Stanoyevitch
Vanessa Starks
Janet Wildman
Helen Winkle

Synthetic Peptide Subcommittee
Yuan-Yuan Chiu
Helen Davies
Chien-Hua Niu
Eugene Schaefer
Arthur Shaw
James Short
Blair Fraser

PHS Unit Commendation
David Hussong

CDER Awards : Left, Center Director Janet Woodcock, M.D. , with Susan Maloney, M.D. Right, Deputy Center Director Roger Williams, M.D., Dr. Woodcock, and Gary Hollenbeck, Ph.D., during CDER Honor Awards ceremony held last month in Rockville.

Appreciation

Robert Dick Dies

Was FDA "Tea Taster"

By Edward Miracco

Many of you have probably never heard of Robert Hillyer Dick, since this is not a CDER story. Bob never had anything to do with PDUFA (Prescription Drug User Fee Act), drug approvals, regulatory actions, or any of the other issues that keep most of us in the Center hopping. Bob Dick was the "tea taster" in FDA's Northeast Regional Lab. He died May 19, in Albany, N.Y., following a brief illness; he was 82 years old.

Prior to this years's repeal of the Tea Importation Act of 1897, Bob, officially described as the "Supervisory Tea Examiner," was responsible for ensuring the quality of tea imported into the United States. Each batch of imported tea had to meet a standard that was set yearly by the Board of Tea Experts, which was a group of seven (mostly private-sector) individuals. Bob, as a Board member, was an integral part of setting these standards.

His day-to-day work involved primarily "tasting" imported tea and comparing it to the set standard. The operation consisted of brewing a precise weight of tea for a specific time and at a specific temperature. The tea infusion was poured into approximately a dozen teacups placed along the perimeter of a 42"-diameter rotating table. Then, one by one, as the table was manually turned, each infusion was aspirated. The aspiration consisted of quickly drawing up a mouthful of the hot infusion and swirling it around so that the gustatory and olfactory sensations could be fully realized. The mouthful was then unceremoniously spat into a garboon (spittoon!).

The tea was never drunk.

During his career with FDA, which began in 1937, he wrote several articles describing enforcement of the Tea Importation Act and was a member of the International Standards Organization and the Association of Official Analytical Chemists. He was also the subject of many articles appearing in newspapers such as the Wall Street Journal and New York Times. He became the Supervisory Tea Examiner in 1953, and was only the third person to hold this title in the history of the Tea Importation Act.

I will always remember "Mr. Dick," which is what we all called him out of both respect and admiration, as a soft-spoken gentleman with a positive attitude, a kind word for all, and a love for his work. Those of us who worked on tea issues and who knew him personally realize that this is the end of an era. His passing, along with the repeal of the Tea Importation Act, reinforces the constant changes we all face and the inevitability of our own mortality. He will be missed.

The writer is a Consumer Safety Officer in the Office of Compliance and former Chairman of the Board of Tea Appeals.

Communiqué

Robert DeLap, M.D. has been named Director of the Division of Oncology Drug Products. He replaces Gregory Burke, M.D., who left FDA 18 months ago for a position in industry.

"Oncology division staff have been reasonably patient and good-humored about the prolonged selection process, but the Division will surely welcome the stability and ability to plan that comes with appointment of a permanent director and the end of the interregnum," said ODE I Director Robert Temple, M.D.

Norman Drezin is the new deputy director, Division of Drug Marketing, Advertising, and Communications (DDMAC). An attorney and a pharmacist, Drezin joined FDA as a PHS pharmacist in 1966 for a two-year tour of duty. He rejoined FDA in November 1991 as Regulatory Counsel.

Dr. Leah Palmer is the new Branch Chief for Marketing Surveillance and Enforcement Branch II in DDMAC. She is a clinical pharmacist and has a B.S. in pharmacy from the U. of Missouri, Kansas City, and a Pharm.D. from Purdue. She joined FDA in 1994 as a Regulatory Review Officer in DDMAC.

Tom Abrams has been named Branch Chief for Marketing Surveillance and Enforcement Branch I of DDMAC. He has a B.S. in Pharmacy from Rutgers and an MBA from Rutgers Graduate School of Management. He joined FDA in 1993 as a Regulatory Review Officer in DDMAC and became Acting Branch Chief in 1995.

Abram's new responsibilities concern the advertising and promotion of oncology, pulmonary, cardio-renal, ophthalmic, radiopharmaceutical, gastrointestinal, anesthetic, muscle relaxants, and abused drugs.

Getting A Fresh Start . . .

Capt. John R. Short, one of the founding members of the Society of FDA Pharmacists, will retire July 1 after more than 20 years in the Commissioned Corps. He will join Sankyo U.S.A. in New York City and will reside in Morris County, N.J.

Mary Richardson, who joined FDA in 1975 as a Consumer Safety Officer in the Newark District Office and who most recently was Deputy Director of the Division of Scientific Investigations, joined Mission Pharmacal, Inc., San Antonio, as Director of Regulatory and Government Affairs.

JRA Workshop

By Rose Cunningham

The Intercenter Rheumatology Working Group, which has representatives from CBER, CDER, and CDRH, is asking for input on their draft guidance document for rheumatoid arthritis (RA) which was first discussed in a public workshop March 27.

A second public workshop to discuss this draft guidance as it pertains to juvenile rheumatoid arthritis (JRA) will be held next month in Bethesda.

The workshop will enable experts in the field of rheumatology clinical trials and interested representatives of industry, academia, and the public to exchange ideas on developing and assessing new treatment modalities for JRA, types of claims that might be reasonably pursued, and evidence necessary to support such claims.

The workshop is free but advance registration is recommended. Fax your registration to me, Rose Cunningham at 301-594-5493. Include name, title, organization, address, and telephone number. Registration will be available on the World Wide Web, *htttp://www.fda.gov/cder/jraworkshop.htm*.

After consideration of all data, information, or views submitted on the draft guidance, FDA will issue a final draft guidance document which will be published in the Federal Register with another comment period prior to finalization of the document.

When &Where To Go: July 23 at 8 a.m., Holiday Inn Bethesda, 8120 Wisconsin Ave., Versailles III and IV.

news along the pike

Have ideas, news, or photographs to contribute? Please contact:

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