news along the pike

Center for Drug Evaluation and Research

August 28, 1996

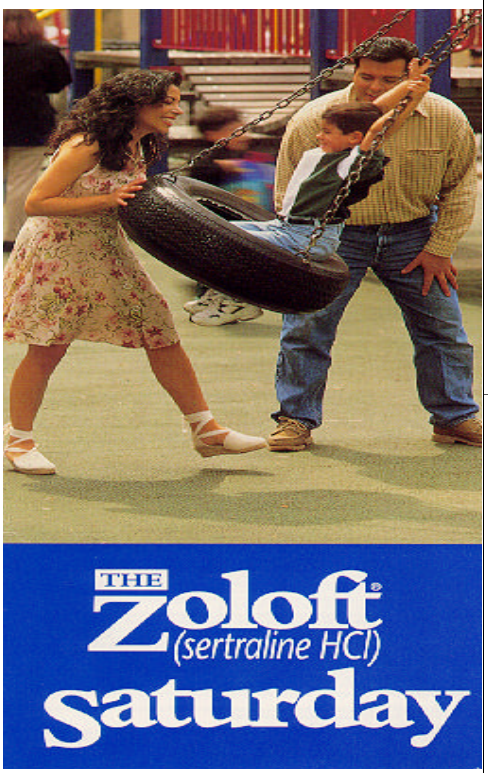
Volume 2 Issue 8

Pfizer's Zoloft Nets DDMAC Warning Letter

Firm Advertised Unapproved Claims

By Lisa L. Stockbridge

The Division of Drug Marketing, Advertising and Communications (DDMAC) issued a Warning Letter to Pfizer for disseminating advertising materials for Zoloft (sertraline HCl)



tablets that promoted the product for unapproved uses and contained other false and misleading statements. In a letter dated Aug. 1, the Center asked Pfizer to respond to the charges with a plan of action to

(Continued on page 4)

MedWatch/CDER Labeling Summary Will Tell Health Care Community What We Know

By Stephen A. Goldman, M.D.

A drug's safety profile evolves over its lifetime on the market. The public health is enhanced by effective postmarketing surveillance coupled with a reviewing division's efforts in making safety-related labeling changes. Yet, if you have ever wondered how aware the health care community is of new labeling changes, you are not alone.

In that spirit, MedWatch and CDER are pleased to announce an unprecedented initiative to disseminate safety-related drug information. MedWatch, the educational/promotional arm for all FDA postmarketing surveillance programs, will use information generated by the CDER reviewing divisions to heighten health professionals' awareness of the extent of drug-induced disease.

What does this project involve, and how will it work?

MedWatch receives copies of approval letters detailing new labeling supplements to original NDAs. These letters and their attachments will be the foundation for summaries detailing safety-related labeling change(s). Monthly summaries will cover the labeling changes approved by CDER during that time period.

What would be considered a safety-related labeling change?

A boxed warning, or any change in clinical pharmacology, contraindications, warnings, precautions, adverse reactions or overdosage, are considered labeling changes.

How many such changes are made by CDER?

Over one three-month period (September-November 1995), there were 47 safety-related labeling changes (ranging from 11-24 per month).

How important is the degree to which the labeling change being made is de

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3 CDER Staffers Pen Article on Fetus Risks From Paternal Drugs

Certain drugs are known to carry a substantial risk of fetal harm, if administered to a pregnant woman. Much less is known about the risks to a fetus (if any) when drugs are administered to men. In theory, drugs could adversely affect spermatogenesis, or drugs transmitted in seminal fluid might cause fetal harm.

Data from animal studies provide some support for these concepts. Three members of the CDER staff Robert DeLap (HFD-150), Jean Fourcroy (HFD-580), and G. A. Fleming (HFD-510), recently authored a paper on this subject, which reviewed the scientific data, identified situations in which there might be a risk, and provided suggestions for management of potential risks. The article, "Fetal Harm Due to Paternal Drug Exposure: A Potential Issue in Drug Development," was a project of the Women's Health Subcommittee of the CDER Medical Policy Coordinating Committee, and appeared in the Drug Information Journal, volume 30, number 2, pp 359-364.

— Robert DeLap

inside...

MedWatch Labeling Summary Will Spread CDER Information

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tailed in the approval letter/attachment?

Very Important. As the summaries will be directly based on the hard copies of the approval letters/attachments, providing enough information to ensure an easy understanding of the difference between the old and new labeling is crucial. If the letter itself does not provide this information, an attached revised package insert that highlights the revision(s), or an attached old package insert that strikes out the text to be deleted and prints the new text adjacent to its planned insertion would be very helpful.

What will be the format for the summaries?

The summaries will include 1) drug proprietary and generic names, 2) section(s) on the labeling change(s), and 3) brief—one paragraph or less—description of the labeling change(s). The length of descriptions will vary depending on complexity.

What do the reviewing divisions have to do?

Send MedWatch all appropriate approval letters/attachments clearly delineating the labeling change(s).

Divisions will also be asked to review the summaries for accuracy via the mechanism used to clear the MedWatch FDA Medical Bulletin column. A master list of summaries for that month will be sent to the supervisory consumer safety officer in each of the reviewing divisions whose drug(s) are included. Since the summaries cover letters/attachments with divisional clearance, review should be easy, just as with the MedWatch column.

How are the summaries going to be used?

After division pass-through, the summaries will be sent to the MedWatch Partners for dissemination. The MedWatch Partners program involves over 100 health professional organizations who formally sign up as Partners and help promote postmarketing surveillance, as well as inform their members about safety-related issues through organizational journals, newsletters, or other vehicles.

Each summary will include a notation that health professionals should contact the appropriate company for a copy of the full labeling.

Compiled summaries will also be published in the FDA Medical Bulletin. Given space limitations and the number of anticipated summaries, it is unlikely that most of the completed summaries will be printed. Still, a published list of drugs and their respective affected sections would be a great improvement over what is currently available regarding labeling changes without the issuance of a "Dear Health Professional" letter.

When will the project start?

The project is expected to begin by early September.

Whom should I contact if I have any further questions regarding this labeling summarization project?

Feel free to call me at (301) 827-3699, or e-mail me (SGOLDMAN@FDAEM-@SSWMBX@FDAOC).

Whom should I contact if I have any further questions/ suggestions regarding the MEDWATCH Partner program?

Call Gale White, M.S., R.N., Deputy Director of MEDWATCH and Coordinator of the MEDWATCH Partner program, at (301) 443-0117, or by e-mail, (GWHITE-@FDAEM@SSWMBX@FDAOC. You can also contact me. We are always looking for new Partners, and would appreciate any assistance in recruiting organizations that focus on your respective specialties/expertise.

We have high hopes for this project designed to provide a valuable public health service through the dissemination of important new safety information generated by dedicated CDER staff.

The writer is Associate Director for Medicine, MedWatch, Office of the Commissioner.

For First Time, CDER Eliminates NDA Backlog

By Kevin L. Ropp

The Center for Drug Evaluation and Research (CDER) has eliminated its original new drug application (NDA) backlog for the first time since enactment of the Prescription Drug User Fee Act in 1992.

At the end of July 1996, all NDAs pending at the Center were still within the PDUFA-established due date for taking a complete action (for example, “not overdue”).

“CDER and the pharmaceutical industry have been working diligently to ensure faster, more efficient, yet high quality reviews of new drug applications. These figures indicate that this teamwork has paid off and American consumers will benefit,” said Janet Woodcock, CDER director.

According to Murray Lumpkin, M.D., deputy Center director for review management, “all of the original applications in the fiscal year 1993 and 1994 cohorts have received their first cycle action. For comparison: 6 months ago we had 9 original NDAs overdue and 1 original NDA resubmission overdue; 1 year ago we had 18 overdue original NDAs and no overdue NDA resubmissions. At the end of July we were 0 and 0.”

Because of the faster review times and improved applications, CDER has cut the average total time to approval needed for an NDA by nearly 50 percent over the past three years--from a high in 1992 of over 26 months to a record low in 1995 of 16.5 months.

Under PDUFA, Congress set review performance standards that required the Center by 1997 to review and act on standard original NDAs within 12 months and priority NDAs within 6 months. In addition, similar standards were set for reviewing and acting on effectiveness supplements. The performance standard for reviewing and acting on NDA resubmissions and manufacturing supplements has been 6 months throughout the program.

The law also set a phased-in performance goal schedule for each of the four review categories. In 1995, CDER

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Reviewers' Corner

Grassroots Proposal: DSI Audit of Reviewer-Selected Electronic NDA Data

By Grant Williams, M.D.

Problem: The present system for auditing clinical data is limited.

The present system does not routinely provide an audit of the electronic data the sponsor submits.

The present system may not routinely focus on data that is most central to the claim of efficacy and/or safety.

Concept: A grass-roots group of reviewers from Pulmonary, Oncology, Biometrics, and the Division of Scientific Investigations (DSI) has been meeting periodically to discuss the facilitation of this audit process. One of the products constructed with input from this group is an application in MSAccess that will retrieve specified measurements from the sponsor's electronic datasets and create various report forms for DSI to use in the audit process. This application is intended to guide the reviewer through the retrieving of:

- retrieving specific endpoint measurements of investigational sites to be audited;
- selecting an appropriate report format;
- printing out reports for audit.

The reports are clear, concise forms with investigator information printed across the top and patient information printed in columns for the auditor to verify using the case report forms at the sites.

Proposed steps in process:

After reviewing the protocol and case report form, medical and statistical reviewers identify the priority data elements for audit.

In conjunction with DSI, investigational sites are selected for audit.

Using the application in MSAccess, data from priority data elements are extracted from the electronic database for the sites which are to be audited; data for each site is then presented in a format convenient for audit.

A comparison of selected data to primary source documents is performed by DSI site personnel.

The review division receives feedback regarding the validity of the data for the priority data elements.

Potential advantages of process:

One concern regarding the routine audit of only the case report form to the primary data is that there is no assurance that errors have not been made in translation of the case report form data to the electronic data upon which applicant and FDA analyses are performed, and ultimately, upon which decisions regarding drug approval are often made. The proposed process enables validation of the data from the earliest (primary source) to the latest (electronic) form of primary data. In the past, attempting to address this problem, some reviewers compared data from case report forms to data tabulations; with the proposed process this would no longer be necessary. In addition, medical and statistical reviewers who are using electronic data to perform analyses could be certain that their findings are grounded in the primary source data.

Another concern is to focus on the audit process. Often reviewers are concerned primarily about the quality of data for a few key endpoints. Even if the global quality of data in a trial were substandard, one might, especially with high-priority drugs, want to know about the quality of data for elements most central to the claim of efficacy and/or safety. After review of the case report form and protocol, the medical officer and statistician can determine which are the primary analyses, and which are the key data elements supporting these analyses. Identifying these elements should allow the auditor to focus the audit and the report on the quality of this data; perhaps such focus would allow audit of more charts and a better estimate of data quality.

This proposed process should:

Allow for an audit of the full scope of data flow, from source documents to electronic data.

Allow reviewers to focus the audit on most relevant data.

At some point in the future, speed the audit process by facilitating transmission of electronic data to the field for audit. This process has been used for several NDA applications in both the Pulmonary and Oncology review divisions. Several of the applications have involved data which has been submitted in MSAccess format.

The writer is a medical reviewer in the Division of Oncology.

CDER Eliminates NDA Backlog

(Continued from page 2)

agreed to review 70 percent of all applications, resubmissions and supplements by the congressionally-set review deadlines. Calendar year 1995 figures indicate that the Center has easily surpassed its goal. Thus far, CDER has reviewed 81 percent of original NDAs within the allotted time (this could go as high as 99 percent on-time if all those remaining are acted upon before their due date); 97 percent of NDA resubmissions; 86 percent of effectiveness supplements; and 90 percent of manufacturing supplements (this could go as high as 96 percent on-time if those remaining are acted upon before their due date).

"This represents a tremendous amount of work by a lot of people over the past several years to get 'caught up'--at least with original NDAs and resubmissions of original NDAs," Lumpkin said. "Clearly the challenge now will be to stay 'caught up.' I honestly believe we are far on our way to doing so and I think we can really sense a fundamental belief in and commitment to performing quality reviews on time."

In addition to eliminating the NDA review backlog, the Center has significantly reduced and is on its way to eliminating the backlog in the two other review categories—effectiveness and manufacturing supplements.

The writer is an editor in the Office of Training and Communications and on the staff of The Pike.

Zoloft Nets Warning Letter

(Continued from page 1)
cease the dissemination of all violative materials.

Zoloft is only indicated for the treatment of depression, defined as a "major depressive disorder" in the DSM-III. However, Pfizer has recently begun two widespread campaigns, "Reaching Out" and "The Zoloft Smile," to promote Zoloft for off-label uses such as dysthymia, premenstrual dysphoric disorder, postpartum disorders and obsessive-compulsive disorder. Further, Zoloft is being promoted for use in groups for which the safety has not been adequately studied, such as patients with post-myocardial infarction and the elderly. Use in patients who have suffered a heart attack (or post-myocardial infarction) is particularly worrisome because of the cardiovascular adverse events that were observed during clinical trials in healthy, depressed individuals.

Zoloft belongs to a group of anti-depressants known as the serotonin-selective reuptake inhibitors, or SSRIs. Other drugs in this class include Prozac (Eli Lilly), Paxil (SmithKline Beecham), and Serzone (Bristol-Myers Squibb). Prozac and Paxil have already been approved for obsessive-compulsive disorder. None of the drugs have been approved for the other off-label uses. The SSRIs are relatively new in the anti-depressant marketplace which was formerly dominated by the tricyclic anti-depressants such as clomipramine, imipramine, and amitriptyline. It is a competitive market and DDMAC is continuing to examine the promotional activities of other firms for violations.

This is the first Warning Letter issued by DDMAC in 18 months. DDMAC sends Advisory Letters and untitled letters (notices of violation or NOVs) on a regular basis to help industry stay in compliance with the Federal Food, Drug, and Cosmetic Act. Warning Letters are only issued for violations of regulatory significance (violations that can lead to enforcement action) and serve as the principal means of giving industry prior notice of violations requiring prompt voluntary correction. Failure to take corrective action and prevent future repetition of the violation may result in an administrative and/or enforcement action without further notice.

The writer is a regulatory reviewer in the Division of Drug Marketing, Advertising and Communications.

Fellows *Program to Foster Leadership, Change*

"People who invest themselves in being what they can be, and more important, people that invest themselves in helping others be what they can be, are involved in the single most important work on this earth."

— Eric Hoffer

By Lori A. Frederick

More than two dozen medical officers, reviewers, pharmacologists, consumer safety officers and other CDER staffers have embarked on a year-long program aimed at developing vision and commitment, and building leadership skills.

The CDER Leadership Fellows Program, announced earlier this year by Center Director Janet Woodcock, M.D., was designed by CDER senior management in partnership with the Council for Excellence in Government, to play an integral part of the CDER change process. The program will help foster and develop CDER's current and future leaders and mold their collective sense of mission, vision, values and alignment.

These skills will enable the Fellows to contribute greatly to the Center by working closely with the Senior Management Team (SMT) throughout the change process. The Fellows will also contribute to CDER's mission by originating and completing individual prejects designed to help and/or improve CDER in various areas such as performance measurement and regulatory compliance.

A unique aspect of CDER's program is that it allows participants to remain productive in their work units during the year-long Fellows commitment while simultaneously engaging in outside activities such as skill-building retreats and benchmarking site visits. For example, Fellows will be given the opportunity to meet with executives from "best-in-class" organizations to learn first-hand how the business practices of these successful individuals might be applied to FDA and CDER.

As part of the competitive process, the Fellows applicants produced high-quality applications and participated in rigorous interviews conducted by panels of representatives from the Council. The D.C.-based Council is a prestigious non-profit, non-partisan organization committed to improving the government performance by building partnerships among the private and public sectors ands its members.

The CDER program is being administered by the Office of Training and Communications in conjunction with the Center's senior leadership. It represents the ongoing efforts by the Center's management to appreciate and recognize the many contributions performed daily by staff at all levels. CDER believes this initiative will produce important results through the support and development of leadership skills among the selected Fellows.

Upcoming events include an "Opening Retreat" in mid-August, followed by a "Go-Away" with the Senior Change Team in late September. The retreat will feature presentations and welcoming remarks by deputy Center directors Murray Lumpkin, M.D., and Roger Williams, M.D.

The inaugural group of Fellows are:

Timothy Ames	Generic Drugs
Carol Assouad	Medical Library
Sue Bell	Epi & Biostatistics
Laurie Burke	Drug Evaluation 1
Joseph Doleski	Manufacturing/Quality
John Emelio	Management
Luigi Girardi	Drug Evaluation 4
Clare Gnecco	Epi & Biostatistics
Kenneth Hastings	Drug Evaluation 4
Robert Hopkins	Drug Evaluation 4
Ajaz Hussain	Testing and Research
Susan Johnson	Drug Evaluation 2
Lisa Kammerman	Epi & Biostatistics
Michael Klein	Drug Evaluation 3
Joyce Korvick	Drug Evaluation 4
Cheung Kwong	Drug Evaluation 2
Mary Lambert	Drug Evaluation 3
Karen Lechter	Drug Evaluation I
Marianne Mann	Drug Evaluation 4
Cynthia McCormick	Drug Evaluation 1
Nancy Ostrove	Drug Evaluation 1
Lori Paserchia	Drug Evaluation 3
Robert Seevers	Pharm Sciences
Nancy Smith	Epi & Biostatistics
Janice Soreth	Drug Evaluation 4
Ubrani Venkataram	Generic Drugs
Grant Williams	Drug Evaluation 1
Steven Wilson	Epi & Biostatistics

The writer is an editor in the Office of Training and Communications and is on the staff of The Pike.

AMF Corner

DSS Deployment in Full Swing

New Features Added As System Expands

By David Isom

Many of you have recently received the Automated Management of Files (AMF) Decision Support System (DSS) on your computer. Although we have discussed DSS here before (May 1996), just to recap, the DSS provides a Windows-based interface into the existing Center Office Management Information System (COMIS) database. DSS is similar to the existing Online Retrieval 18 (OLR18) function in COMIS.

However, the system includes enhanced and more user-friendly searching capabilities, plus a variety of new ways to view additional COMIS information. The Division of Information Systems Design (DISD) is currently installing the system on personal computers used by consumer safety officers and chemists in the review divisions, which will allow us to coordinate the installation of the DSS with the Establishment Evaluation System (EES). Other disciplines will soon receive the DSS.

DISD is also offering training on the DSS in CDER's new training room in SRA's building at 5635 Fishers Lane. SRA is CDER's System Management and Review Tracking (SMART) contractor. Training includes hands-on computer instruction, plus a user account, password, training and user's guide. Watch your e-mail for the DSS training schedule.

Although the first version of the DSS is being rolled-out, we are continually updating and refining the DSS based on your comments and feedback. Subsequently, reports have been generated that can be printed by clicking on the new Print Screen button. The reports include:

- A header at the top of every page containing the search criteria you entered in DSS for the query;
- All the information DSS selected for the query, not just the information you can see on the screen; and
- Codes and code descriptions.

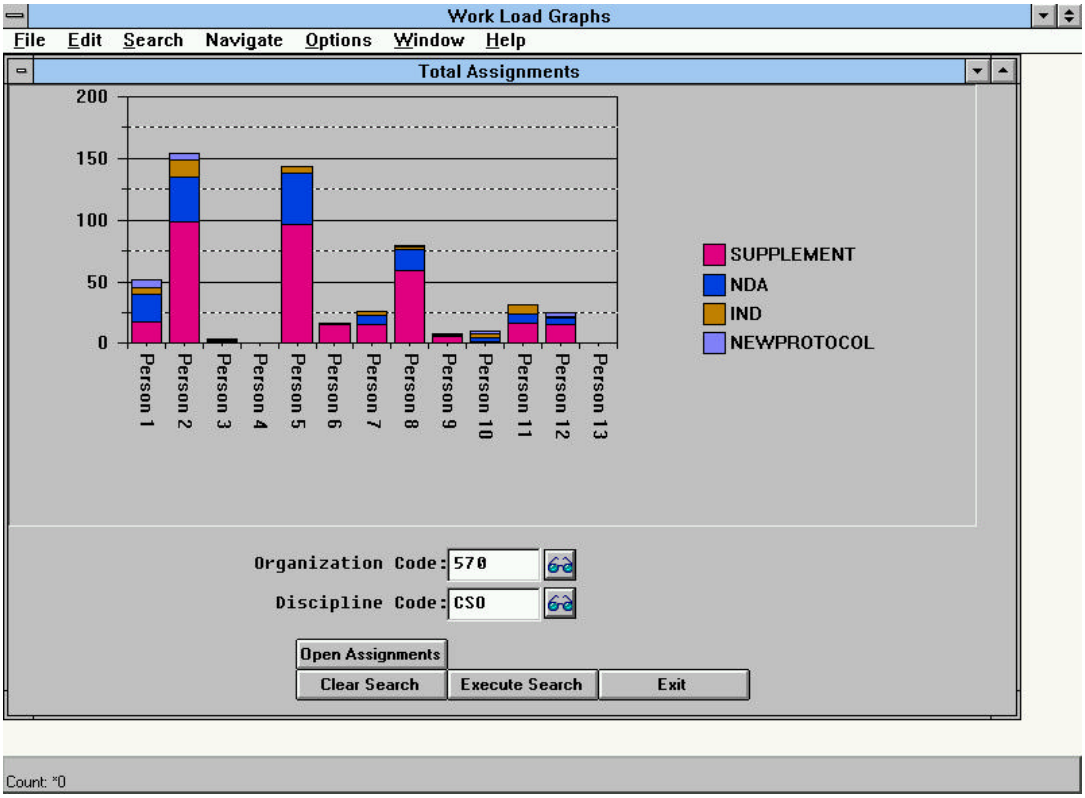
We know how important the print capability is to you, and a new version of the DSS that includes the print capability will be installed on current user's PCs toward the end of August.

We have also been working on a workload graphing feature, DSS Workload Graphs, that will let you view the distribution of work among the members of a division by their disciplines. The DSS Work Load Graphs use a bar graph format to display from COMIS the number of assignments by reviewer name. There are three Work Load Graph windows:

Total Assignments: The Total Assignments window shows all of the supplement, NDA, IND, and new protocol assignments for each member of a division by discipline. A sample Total Assignments window is shown below.

Open Assignments: The Open Assignments window displays all of the open or pending IND, NDA, supplements, and new protocol assignments for each member of a division by discipline.

Supplement Assignments: The Supplement Assignments window displays all open or pending supplement assignments for each member of a division.



We plan to deploy the DSS Workload Graphs to an alpha test group in August. As with the initial version of the DSS, we will enhance the Workload Graphs based on the results of the alpha test. Then we can fully deploy this new feature to all DSS users sometime in the fall. Thanks again to all the people who helped us develop and implement the DSS. We look forward to seeing you at training.

The writer is AMF Project Manager.

JRA Workshop Drafts Core Set Of Clinical Outcome Measures

Comments Sought Through Aug. 30

By Lisa G. Rider, M.D.

The pediatric rheumatology community and FDA observed a landmark July 23 when a group of pediatric and adult rheumatologists, as well as other pediatric subspecialists from academia, government and industry, gathered for the FDA Juvenile Rheumatoid Arthritis (JRA) Workshop in Bethesda. These experts provided input on the Draft Rheumatoid Arthritis Guidance Document from the agency's Tricenter Rheumatology Working Group, representing CDER, CBER and CDRH.

JRA, a group of chronic arthritides, afflicts approximately 70,000 children in the United States. While one subset of JRA is identical to adults with rheumatoid arthritis, several other subsets have been well defined and are quite distinct clinically and genetically from adult RA. Whether the proposed licensure claims for adult RA would be applicable to JRA, and if so, what the appropriate outcome measures should be, had to be considered.

One of the meeting's highlights was the development of a core set of clinical outcome measures that could be applied to all JRA subsets, which was similar to the adult RA core set, with appropriate modifications for children with JRA. Limitations in using the core set for the particular and systemic-onset subsets of JRA were discussed, and clinical outcome measures that could be used as secondary endpoints for these subsets were proposed. Additional licensure claims, paralleling those for adult RA, were in principle agreed to, including improvement in function/quality of life, prevention of structural damage, and induction of remission. The status of outcome measures for these claims in JRA were presented.

Fundamental difficulties in doing clinical trials in JRA were highlighted. These include: small markets for sponsors, problems associated with multicenter studies, and the risk of novel drug development in children with nonlethal diseases.The agency is sensitive to these difficulties. Application of the new pediatric labeling regulation should help reduce the number of efficacy studies needed for JRA, particularly in the rheumatoid factor positive subset. Orphan drug status also applies to all agents developed for use in JRA patients.

The Rheumatology Working Group is accepting comments to the draft document until Aug. 30. Based on the workshop and comments received, the current document will be revised and published in the Federal Register. This will allow another opportunity to comment prior to finalization and publication of the Guidance Document.

The writer is a Medical Officer in the Center for Biologics Evaluation and Research.

Where To Go: To get a draft copy of the guidance, call CDER's Rose Cunningham at 301/594-6779, or fax 594-5493.

RAPS: Solving The Regulatory Puzzle

Journey Through Cyberspace Among the Highlights

The Regulatory Affairs Professionals Society's 20th Annual Conference and Exhibition will be held Sept. 9-11 at the Sheraton Washington Hotel, Washington, D.C. The theme of this year's conference is "Solving the Regulatory Puzzle."

The Project Managers Communications Committee's Subcommittee on Communications will represent the Center this year with an extraordinary exhibit as well as fact sheets on CDER information resources.

Lead by Rita Hoffman, Consumer Safety Officer in the Office of Training and Communications, RAPS members will enter a new dimension in the world of cyberspace. Regulatory affairs professionals will provide information on the drug approval process, manufacturing questions, where and how to get guidance documents, and other supporting documentation. CDER Project Managers Susan Cusack, Olga Cintron, Sharon Schmidt, and Chin Koerner will join Hoffman to explain how the project manager function has facilitated the timely review of NDAs. The backdrop for this exhibit is CDER's Project Manager's exhibit that was used at the Drug Information Association meeting in San Diego in June (see page 7). CDER's Webmaster, Paul Stauffer, along with the Division of Information Systems Design Technical Advisor Debbie Yaplee, will be giving hands-on demonstrations of the CDER home page. Kevin Ropp, of the Office of Training and Comunications, will add an artistic touch to materials prepared for this event.

Drug Highlights include:

- FDA Center Director Briefing with CDER's Janet Woodcock, M.D., CDRH's Bruce Burlington, M.D., and CBER's Kathryn Zoon, Ph.D.
- Current Issues in Drug Advertising and Promotion
- Drug Submission Process
- Electronic Submissions for Drugs: What's New?
- The Role of Pharmacoeconomics in Drug Development
- Labeling Negotiations: Science and Policy
- Strategic Importance for Validation
- Role of the Regulatory Affairs Professional on Global Development Teams.

To Register: Call the RAPs Conference Coordinator by Aug. 23 at 301-770-2920, ext. 234.

— Rita Hoffman

CDER's Message Is A Hit at DIA

CDER staff contributed significantly toward enhancing industry/agency communications during the annual Drug Information Association (DIA) meeting in June.

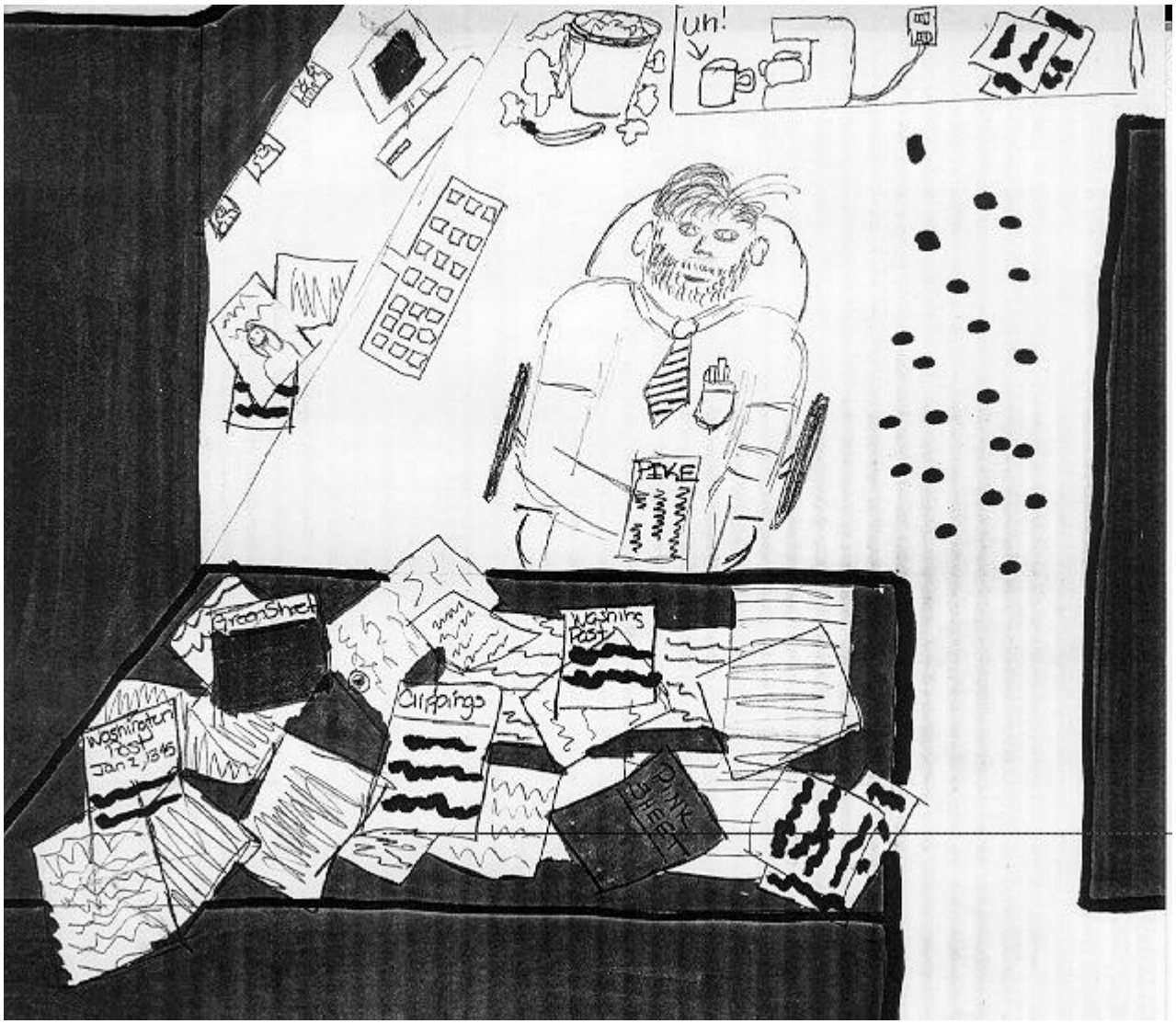
In addition to presentations by CDER keynote speakers such as Center Deputy Directors Murray Lumpkin, M.D., Roger Williams, M.D. and Associate Director Robert Temple, M.D., the Project Management Coordinating Committee (PMCC) orchestrated the afternoon Project Management Track session on June 12th. Speakers included Jean Yager, Bronwyn Collier, Tricia DeSantis, Toni Nearing and Susan Kummerer.

The presentations provided information related to Center project management advances, case studies of successful approaches to expediting application reviews, suggested methods by which industry can assist the review process, and new CDER communications initiatives designed to enhance relations with industry and the public.

The session was well received. Attendees learned that significant improvements had been implemented at CDER and congratulated the speakers. In addition to the presentations, Russell Williams and Tom Perez orchestrated the development and set-up of a CDER Project Management Exhibit (see page 6) which was displayed in the DIA Conference Center. The exhibit also included a demonstration of the CDER World Wide Web home page (CDER Library's Webmaster Paul Stauffer helped with the setup and training for the web demonstration). The exhibit was visited by many of the conference attendees, and several hundred copies of guidance documents and new MaPPs were distributed. The home page was a great hit!

—Jean Yager

. . . Her Dad's World



A drawing of Pike Editor Jeffrey Yorke, by his daughter Audrey, 9. —July 1996

Visiting Faculty Set to Share CDER's Message

By Kevin L. Ropp

The Center's Visiting Faculty Program got underway Aug. 16 when volunteers gathered to begin creating a program that will carry CDER's message to its many external audiences. At this first meeting, volunteers identified presentation topics and intended audiences.

The Visiting Faculty Program is designed to enhance the education of physicians, nurses, pharmacists, physician assistants and regulatory scientists, said Lucy Rose, Office of Training and Communications director.

"Those persons who are a part of the CDER Visiting Faculty Program will use standard materials to speak to groups such as physicians, nurses, pharmacists and other health professionals at medical grand rounds, conferences and meetings. The intent is to educate these groups about CDER and the value it adds to their work during the drug development and post approval processes by facilitating access to safe and effective drugs," Rose said. "The interaction will help build relationships and get feedback from these important constituents as to how we are doing and what their needs are."

Over the next few months, the volunteers will be developing standard slide sets and presentation materials that can be used by any of the Visiting Faculty members. For more information on this program, e-mail Kevin Ropp (Roppk), or call him at 827-3788.

The writer is an editor in the Office of Training and Communications and on the staff of The Pike.

Mentors Corner

The CDER Reviewer Mentoring Program is now coordinated by June Cory in the Division of Training and Development, since Ron Lieberman accepted a position at the National Cancer Institute July 1.

There are about 32 CDER review staff members assigned to mentors, and there are plans to expand the program this year. If you have questions or suggestions about reviewer mentoring at CDER, please contact June Cory by e-mail (coryj) or phone 443-2200.

X (Drive): Where Laurel Meets St. Louis

The insulin, hormone and antibiotic testing groups in the Division of Research and Testing in Laurel have been merged with the Division of Drug Analysis in St. Louis to form the Division of Testing and Applied Analytical Development (DTAAD) under the Office of Testing and Research.

The new X:\ drive address is x:\offices\ops\otr\dtaad, and we have created the following read-only subdirectories:

\mvp*.* (for method validation package status);
\research*.* (for papers published and in progress);
\antibiot*.* (for antibiotic method validation package status);
\manage*.* (which lists key contacts, telephone and FAX numbers, and our mission statement).

The mvp and antibiotic listings are expected to be updated about every two weeks, and the research listing about once a month. The updates in the subdirectories are labelled by the date, e.g., yymmdd.wpc or 96 for the year of 1996, 08 for the month of August and 07 for the day of the month.

To access these files, Tom Layloff has created quick lists in WordPerfect directories:

DTAAD MVPs = x:\offices\ops\otr\dtaad\mvp;
DTAAD Antibiotics = x:\offices\ops\otr\dtaad\antibiot;
DTAAD Research = x:\offices\ops\otr\dtaad\research; and
DTAAD Management = x:\offices\ops\otr\dtaad\manage

Central Document Room Moved

The Central Document Room (CDR) moved Aug. 1 to 12229 Wilkins Ave. It was formerly located in the Park Building. The new phone number is 301-827-4210. All incoming mail sent to the Parklawn mail room will continue to be routed to the Park Building.

However, all express mail services (USP, Federal Express, Airborne, etc.) should be sent directly to Wilkins Avenue.

The Drug Master Files (DMFs) are still located at the Park Building, Room 2-14, 443-0035, until further notice. All incoming mail pertaining to DMFs should continue to be sent to 12420 Parklawn Drive, Rockville, Md. 20852.

For details about the CDR or DMFs, call Mark Gonitzke 827-0537, or Paul Chapman at 827-0535.

Awards to Bell, Sporn

Margaret I. Bell, EEO Manager, and Douglas L. Sporn, director of the Office of Generic Drugs and acting deputy director of the Office of New Drug Chemistry, received "Outstanding Achievement Awards" from the Parklawn Asian Pacific American Community (PAPAC) May 16 "in recognition of their personal leadership and commitment towards equal employment opportunity for the Asian Pacific American Community." The awards were given during the PAPAC program held in the Parklawn building in observance of the Asian Pacific American Heritage Month.

EEO Corner

Hispanic Heritage Month Celebration

CDER will hold its combined EEO Awards Ceremony and the National Hispanic Heritage Month observance on Sept.12 at the Parklawn building. The keynote speaker will be HHS Deputy Director for the Office of Civil Rights Omar Guerrero. Additional details will be announced later.

news along the pike

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

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