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M E M O R A N D U M

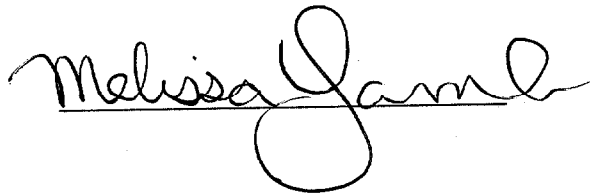
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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Date: March 6, 2001  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs  
Subject: Current Regulatory Issues

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

Title of Presentation: Current Regulatory Issues Concerning the  
Generic Drug Industry  
Presented for: NAPM  
Date Presented: May 15, 2000  
Presented by: Gary Buehler, Acting Director  
Office of Generic Drugs  
Number of Pages: 21



Attachment

90S-0308

M704



# Current Regulatory Issues Concerning the Generic Drug Industry

NAPM Mid-Year Meeting and  
Educational Conference

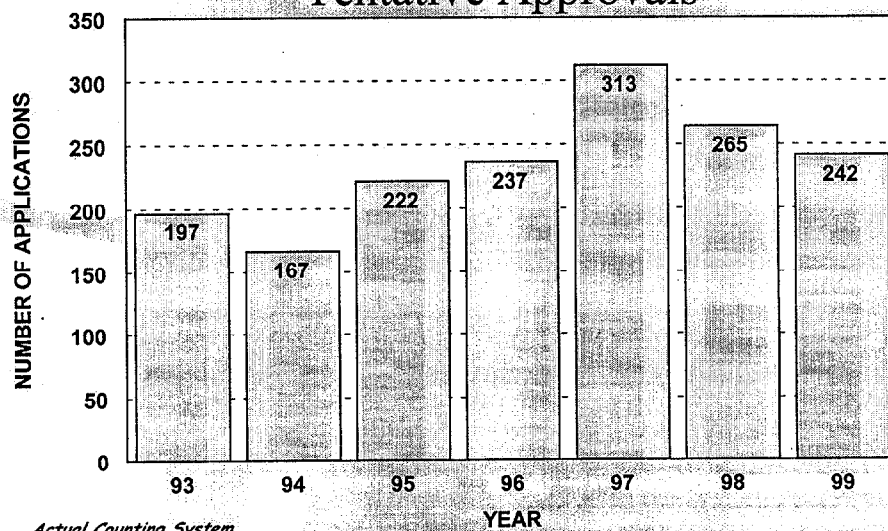
May 15, 2000  
Newark, NJ

Gary Buehler, Acting Director  
Office of Generic Drugs

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## Calendar Year Approvals and Tentative Approvals

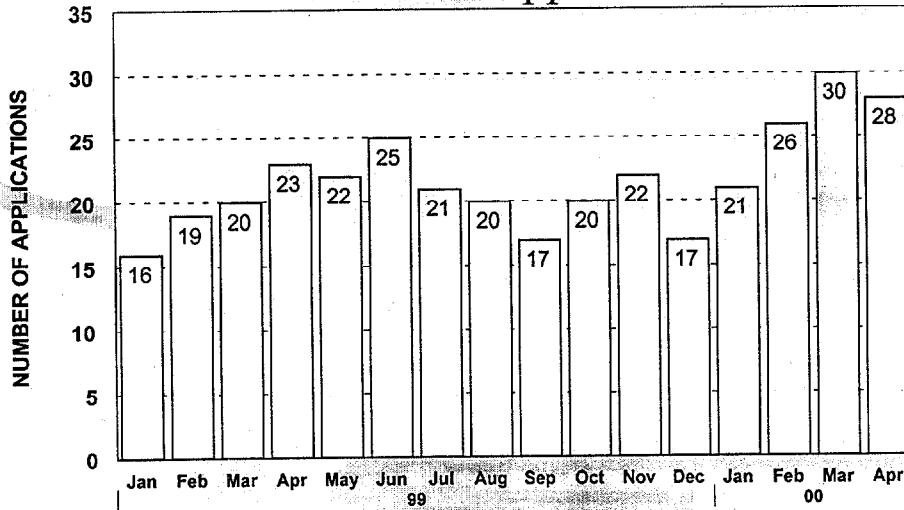


*Actual Counting System*

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## Calendar Year Approvals and Tentative Approvals



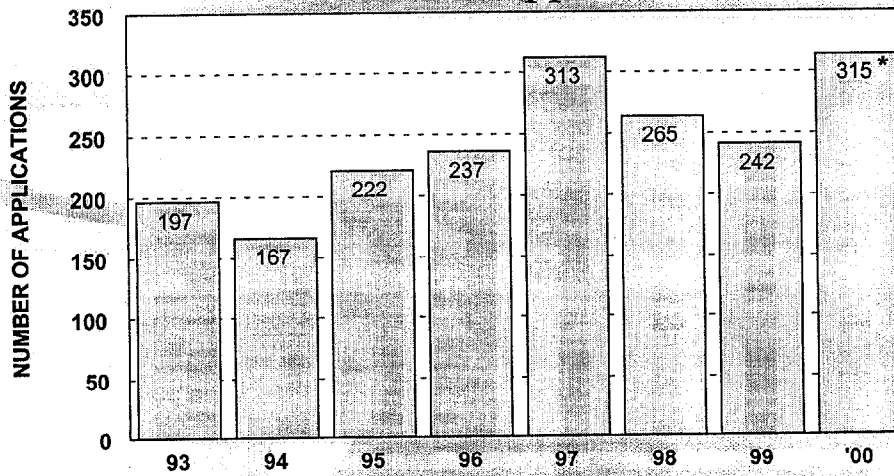
Actual Counting System

YEAR

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## Calendar Year Approvals and Tentative Approvals



Actual Counting System

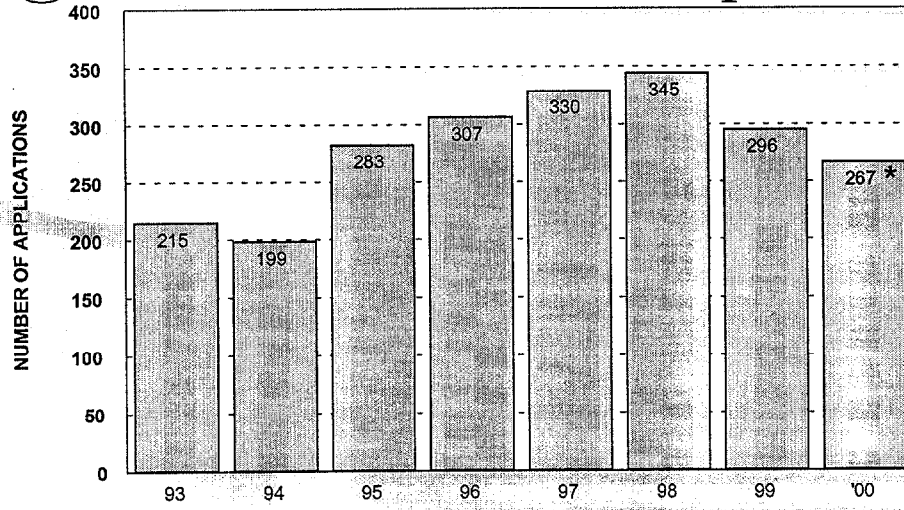
YEAR

\* Projected on April 30, 2000

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# Calendar Year Receipts



Actual Counting System

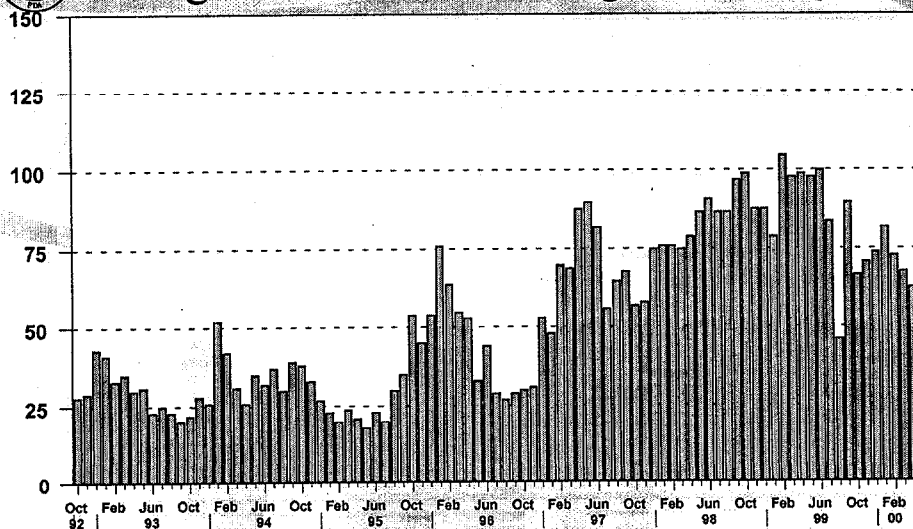
CALENDAR YEAR

\* Projected on April 30, 2000

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# Original ANDAs Pending > 180 Days



Actual Counting System

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## Current Challenges

- Review
- Legal
- Communication

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## Chemistry Review

- Current Backlog
- Process Review
- New Staff

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## Chemistry Review Backlog

### Division 1 - 117 Days

Team 1	126 Days
Team 2	140 Days
Team 3	104 Days
Team 4	98 Days

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## Chemistry Review Backlog

### Division 2 - 126 Days

Team 6	144 Days
Team 7	104 Days
Team 8	130 Days
Team 9	126 Days

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## Process Review

- Increased Internal Communication
- Identify "Roadblocks"
- Improve Quality of Worklife
- Hire More Chemists

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## New Staff

- 3 Chemists Hired in last 6 Months
- 6 Projected Hires

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Division of Chemistry I TEAM Structure			May 9, 2000		
Chemistry I	TEAM Leader	Team Staff	Major Therapeutic Class	Labeling Reviewer	Project Manager
TEAM 1	Albert Mueller	David Cummings Rosario D'Costa James Fan Raj Bykadi FTE due to report	• Antihypertensives • Angiotensin • Diuretics • Radioactive • Radiopaques • NonSteroidal Anti Inflammatories	Jim Barlow	Bonnie McNeal
TEAM 2	Michael Smela	Shirley Brown Ken Furnkranz Mujahid Shaikh Bing Cai Eugene Schaefer	• Estrogens • Gonadotropins • LVPs • Cytotoxic • Antineoplastic • Bronchodialator (MDI) • Surgical-Dental	Teresa Watkins	Michelle Dillahunt
TEAM 3	Paul Schwartz	Gil Kang Kathy Woodland Nashed Nashed Liang-Li Huang	• Anti-anxiety • Sedatives • Dermatologies • Otics • Ophthalmics • Antifungal • Anti-Infectives	Lillie Golson	Elaine Hu
TEAM 4	Dave Gill	Upinder Atwal Shing Liu Steve Sherken Neeru Takiar Robert Trimmer	• Antipsychotics • Corticosteroids • Antihistamines • Cough Prep. • Muscle Relaxant • Contraceptive • Anabolic Steroids • Vitamins	Debbie Catterson	Ruby Yu

Division of Chemistry II TEAM Structure			May 9, 2000		
Chemistry II	TEAM Leader	Team Staff	Major Therapeutic Class	Labeling Reviewer	Project Manager
TEAM 6	Richard Adams	Maria Shih Susan Rosencrance Ruth Ganunis Susan Zuk M. Scott Furness	• Antibacterial • Anti Fungal* • Antineoplastic* • Immuno-suppressants* *Fermentation Derived	Jackie Council	Mark Anderson
TEAM 7	Brenda Arnwine	Karen Bernard Raymond Brown Mahnaz Farahani Ijeoma Nnamani Radhika Rajagopalan	• Anti-Ulcer • Anticonvulsants • Antimotility • Anticholinergics • Anorexics	Koung Lee	Kassandra Sherrod
TEAM 8	Ubrani Venkataram	Sena Basaran Bita Mirzai-Azarm Robert Permisohn Mouna Selvam Lucia Tang	• Beta-Blockers • Ca Channel Blockers • Anti-arrhythmics • Anti depressants • Drug Abuse	Adolph Veza	Tim Ames
TEAM 9	Glen Smith	Andrew Langowski Edwin Ramos Dominick Roselle Mayra Pineiro-Sanchez Tao-chin Wang	• Antiviral • Analgesics • Anesthetics • Narcotic agonists • Anticoagulants	Chan Park	Jeen Min



	TEAM Leader	Team Staff	Project Manager
<b>TEAM I</b>	<b>Yih-Chain Huang</b>	<b>James Chaney</b>	<b>Krista Scardina</b>
		<b>Lin Whei Chuang</b>	
		<b>Hoainhon Nguyen</b>	
		<b>Chaurasia Chandra</b>	
		<b>Andre Jackson</b>	
		<b>Sikta Pradhan</b>	
		<b>Pradeep Sathe</b>	
<b>TEAM II</b>	<b>Shriniwas Nerurkar</b>	<b>Jenny Lee</b>	<b>Jennifer Fan</b>
		<b>Kuldeep Dhariwal</b>	
		<b>Patrick Nwakama</b>	
		<b>Surendra Shrivastava</b>	
		<b>Gur-Jai Pal Singh</b>	
		<b>Nhan Tran</b>	
<b>TEAM III</b>	<b>Barbara Davit</b>	<b>Mamata Gokhale</b>	<b>Patty Nguyen</b>
		<b>Carol Kim</b>	
		<b>Moheb Makary</b>	
		<b>Zakaria Wahba</b>	

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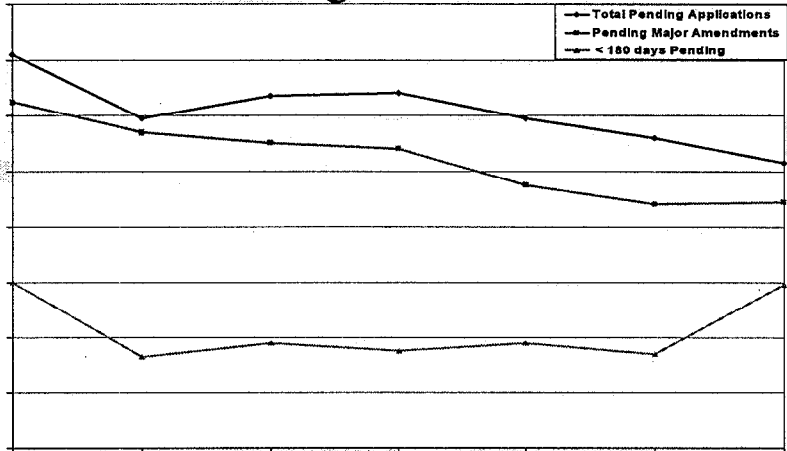
## Microbiology Review

- Functioning Unit
- Project Manager Oversight
- Decreasing Numbers

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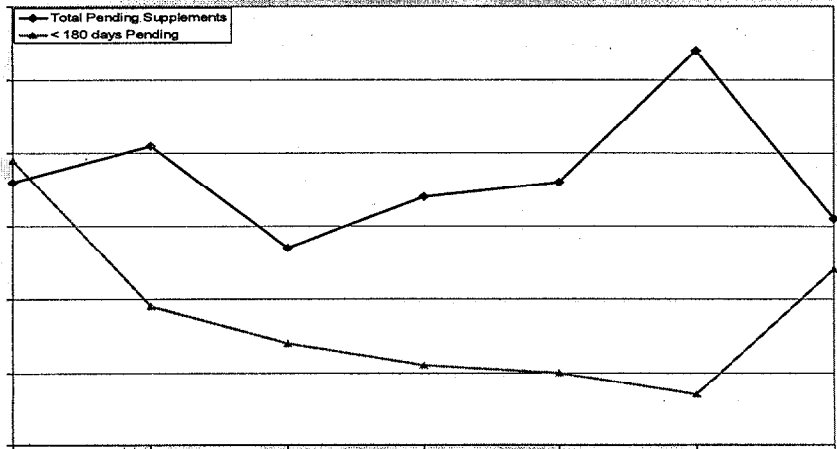
# Microbiology Productivity Originals



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# Microbiology Productivity Supplements



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## Legal Challenges

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## Mylan I - Terazosin

- *Mylan Pharmaceuticals Inc. v. Donna Shalala*
- Civil Action No. 99-2995
- Richard W. Roberts - U.S. District Judge
- January 4, 2000

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## Mylan I - Terazosin

- Agency's Court Decision Trigger  
(the court that enters final judgement from which no appeal can or has been taken)
  - Inconsistent with plain meaning of statute
  - 314.107(e) invalid interpretation of "a decision of a court."

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## Mylan I - Terazosin

- Outcome - "a decision of a court"
  - district court
    - ◆ includes the decision of a United States district court
    - ◆ regardless of whether the decision is appealed
  - appellate court
  - one of the two

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## Mylan I - Terazosin

- Mylan denied relief
- Equitable considerations
- Geneva relied upon FDA's interpretation

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## Guidance for Industry

- Issued March 2000
- Includes concepts from
  - *TorPharm, Inc v. Shalala*
  - *Mylan Pharmaceuticals, Inc v. Shalala*

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## Guidance for Industry

- Court
  - first court that renders a decision finding the patent at issue invalid, unenforceable, or not infringed.
  - Includes district court decision
    - ◆ stay, reversal will have no effect on
      - the beginning of exclusivity
      - or continued running of exclusivity.

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## Guidance for Industry

- Approvals - can be made effective on the date of the court decision.
- Exclusivity - begins on the date of a decision of a court.

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## Guidance for Industry

- Implementation
  - New ANDA's submitted after 3/30/2000
    - ◆ containing a PIV certification
    - ◆ no other ANDA submitted with a PIV certification for the drug.

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## Mylan II - Tamoxifen

- *Mylan Pharmaceuticals, Inc and Pharmachemie B.V. Inc v. Jane E. Henney, Donna E. Shalala, Barr Laboratories, Inc.*
- Civil Action No. 99-cv-862, 99-cv-801
- Ricardo M. Urbina, U.S. District Judge
- March 31, 2000

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## Mylan II - Tamoxifen

- Vacates FDA's response to CP 98P-0493
  - March 2, 1999
  - Stayed effective date of approval of any ANDA for Tamoxifen Citrate other than Barr Laboratories until -
    - ♦ 180 days after first commercial marketing of Barr's Tamoxifen
    - ♦ or date of final decision of a court

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## Communication

- Web Initiatives
- Guidances
- Controlled Correspondence

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## Web Initiatives

<b>Addition</b>	<b>Implementation Status</b>
• New, Improved Generic Drug Approval List	Under Construction
• First Generic Drug Product List	Under Construction
• Para. IV Drug Products Received	Under Construction
• Chemistry Team/Therapeutic Class List	Under Construction

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## Web Initiatives

<b>Addition</b>	<b>Implementation Status</b>
• OGD "What's New" Section	Planned
• Expanded ANDA Submission Information	Under Construction
• Useful Links	Planned
• OGD Contact Directory Guide	Planned
• Presentations by OGD Staff	Planned

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## Guidances

- Inactive Ingredients
  - Revision of Inactive Ingredients Guide (IIG)
- Major-Minor Revision

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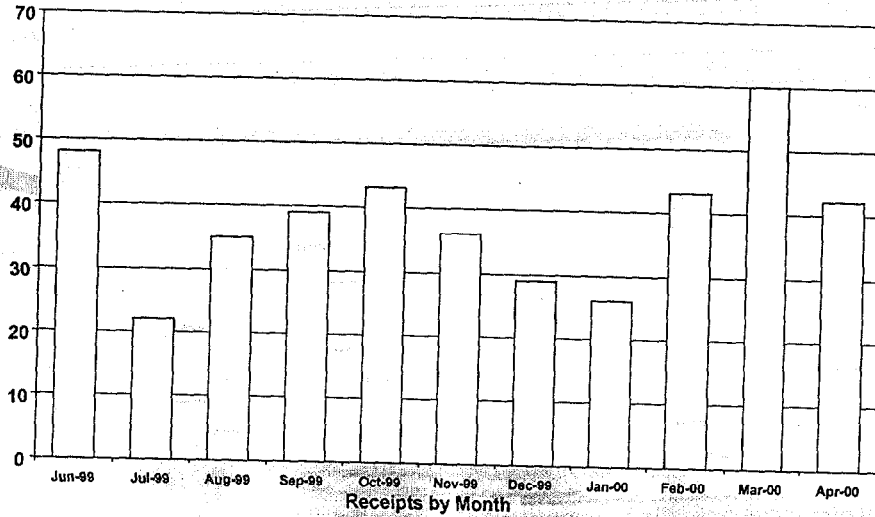
## Controlled Correspondence

- June 1, 1999 - April 30, 2000  
= 423 Pieces
  - Bioequivalence Questions  
= 223 pieces (53%)
  - Remainder = Labeling; Chemistry;  
Regulatory Support
- Increased Effort to Complete

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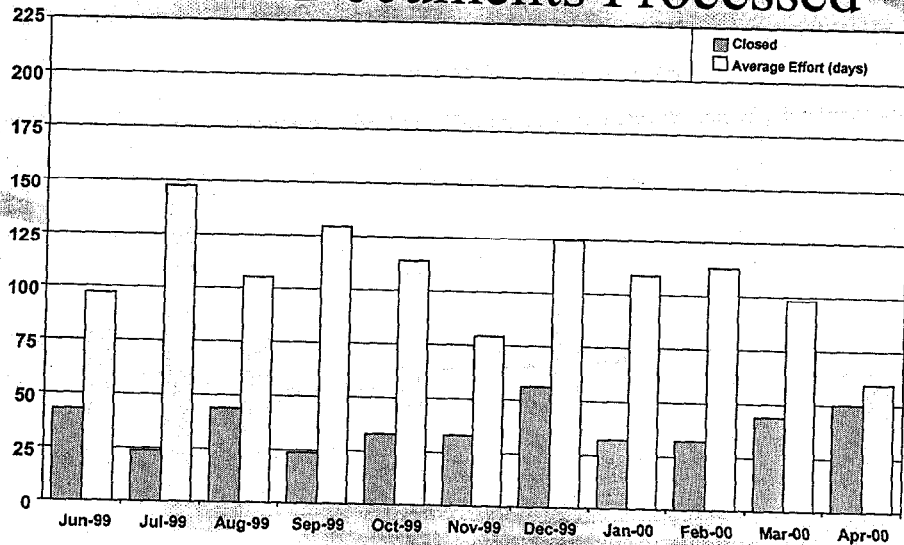
## Control Documents Received



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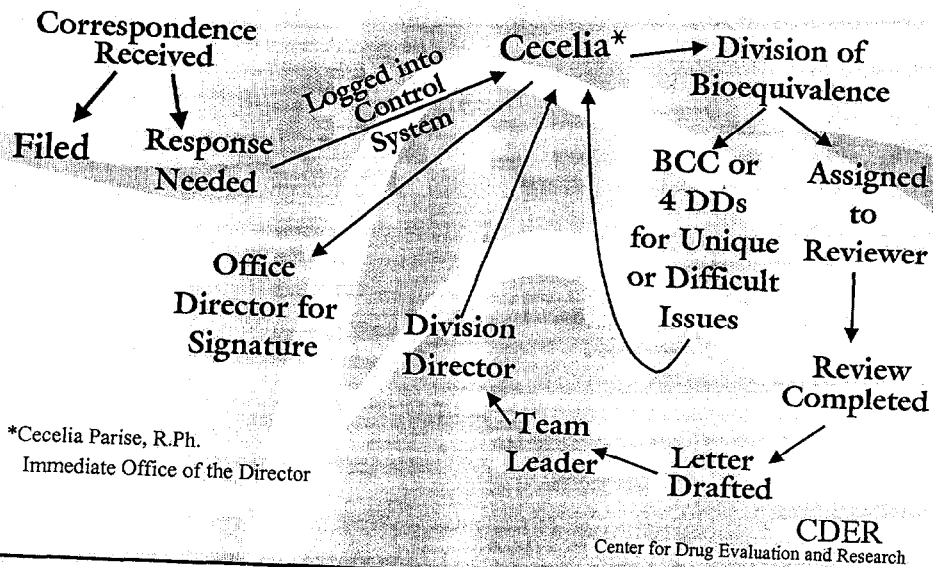
## Control Documents Processed



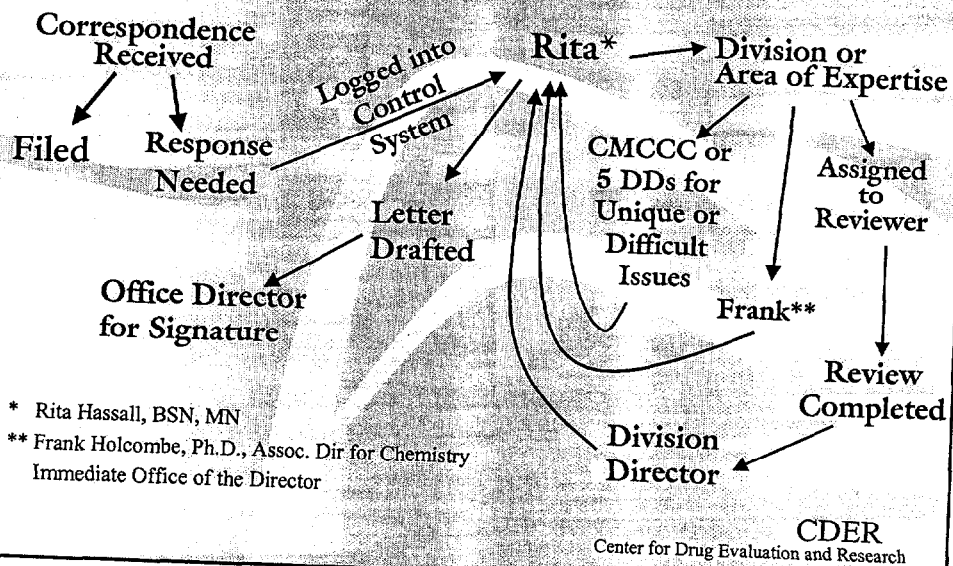
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# Controlled Correspondence



# Controlled Correspondence





## OGD Director Search Search Committee

**Eric Sheinin, Ph.D. - Chair**

Bill Myers - Admin. Support

Paula Bourkland

Yuan Yuan Chiu, Ph.D.

Barbara Davit, Ph.D.

Frank Holcombe, Ph.D.

Larry Lesko, Ph.D.

Wes Metz

Sol Sobel, M.D.

Richard Vengazo

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## OGD Director Search Activities Update

- Drafted Qualifications Statement
- Identified Advertising & Publications
  - New England Journal of Medicine
  - Chemistry & Engineering News
  - AAPS (American Association of Pharmaceutical Scientists)
  - Clinical Pharmacology Therapeutics
  - Federal Publications

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## OGD Director Search

### Activities Update

- Hopeful to get early June publication
- Position will be announced for 60 days
- Interviews to begin in September

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## Summary

- Continue emphasis on application review
- Continue to focus on communication especially through web site
- Address legal issues
- Look for ways to improve the process

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