

M E M O R A N D U M

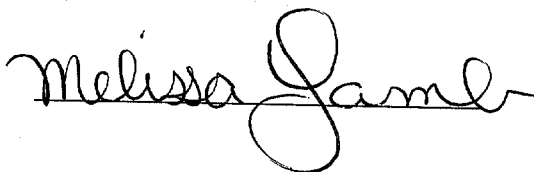
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

0777 '01 MAR -2 11:18

Date: March 6, 2001  
To: Dockets Management Branch (HFA-305)  
From: Melissa Lamb  
Office of Generic Drugs  
Subject: Update from the Office of Generic Drugs

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: Update from the Office of Generic Drugs  
Presented for: GPIA Science Committee Meeting  
Date Presented: June 19, 2000  
Presented by: Gary Buehler, Acting Director  
Office of Generic Drugs  
Number of Pages: 22



Attachment

90S-0308

M706



# Update from the Office of Generic Drugs

GPIA Science Committee  
Meeting

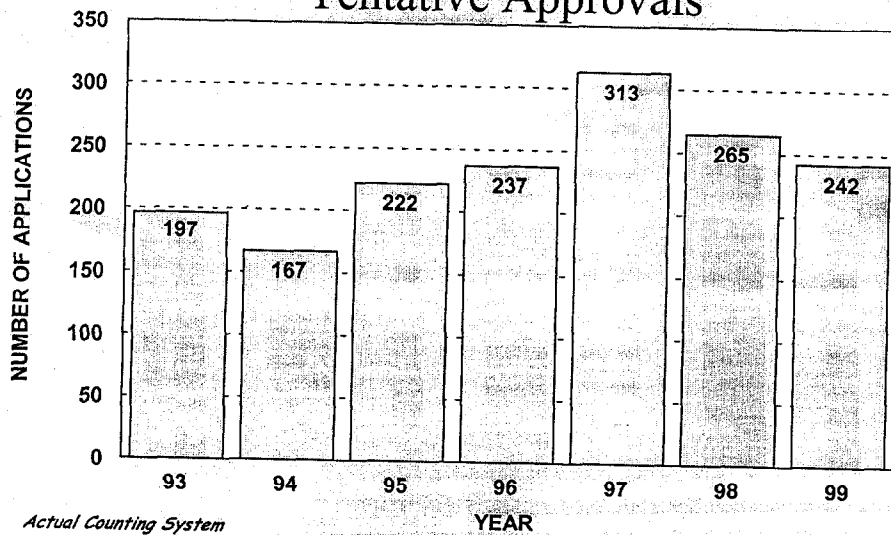
June 19, 2000  
Newark, NJ

Gary Buehler, Acting Director  
Office of Generic Drugs

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## Calendar Year Approvals and Tentative Approvals

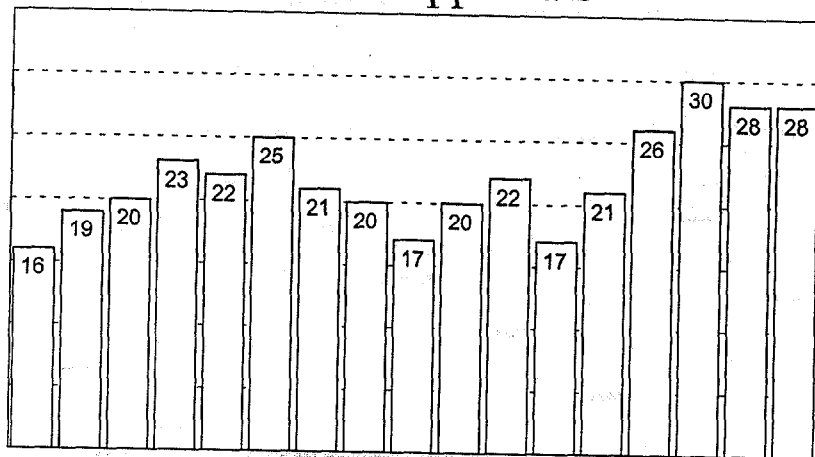


*Actual Counting System*

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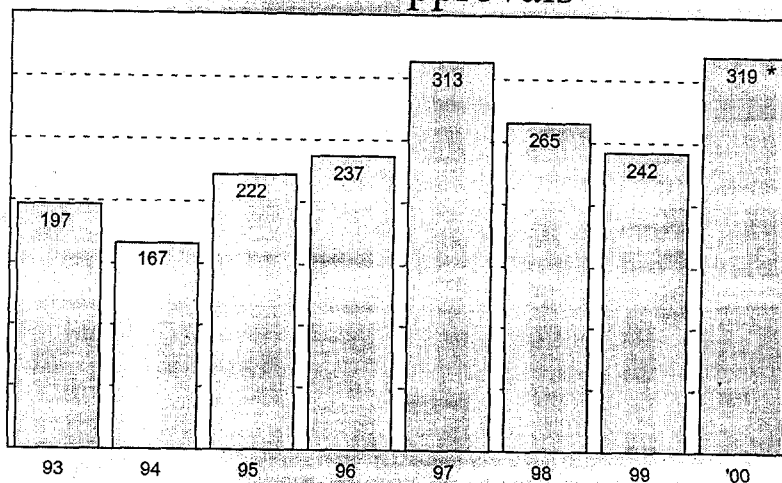
### Calendar Year Approvals and Tentative Approvals



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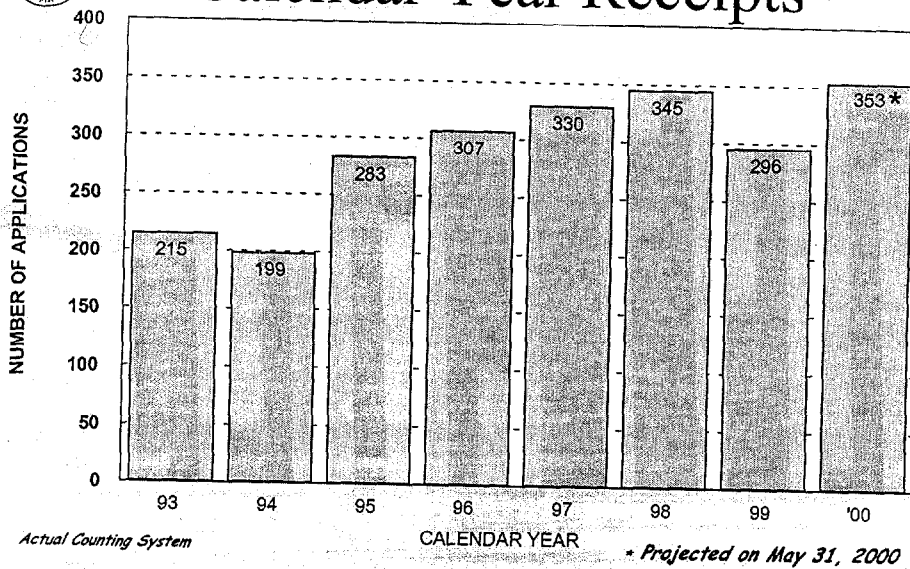


### Calendar Year Approvals and Tentative Approvals





## Calendar Year Receipts



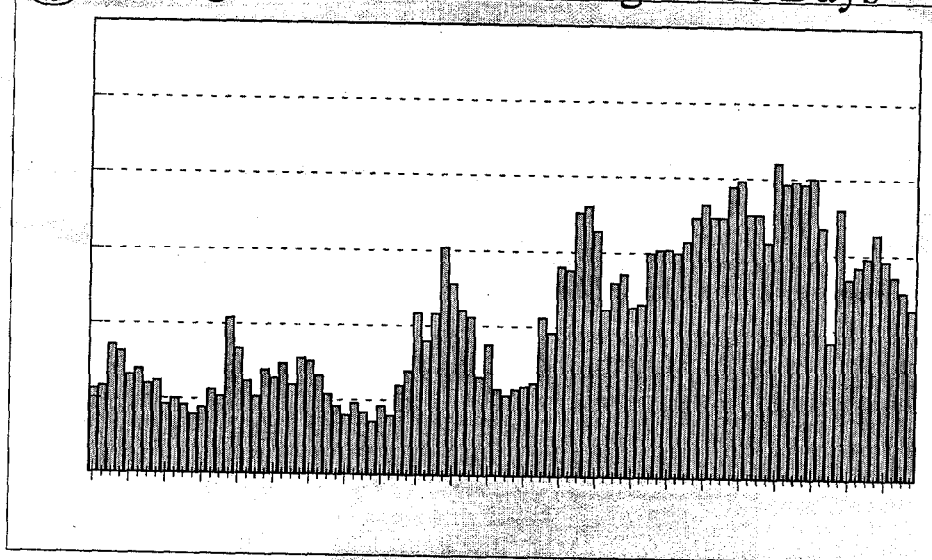
Actual Counting System

\* Projected on May 31, 2000

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## Original ANDAs Pending > 180 Days



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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	<ul style="list-style-type: none"> <li>• Antihypertensives</li> <li>• Angiotensin</li> <li>• Diuretics</li> <li>• Radioactive</li> <li>• Radiopaques</li> <li>• NonSteroidal Anti Inflammatories</li> </ul>	Jim Barlow	Bonnie McNeal
TEAM 2	Michael Smela	Shirley Brown Ken Furnkranz Mujahid Shaikh Bing Cai Eugene Schaefer	<ul style="list-style-type: none"> <li>• Estrogens</li> <li>• Gonadotropins</li> <li>• LVPs</li> <li>• Cytotoxic</li> <li>• Antineoplastic</li> <li>• Bronchodialator (MDI)</li> <li>• Surgical-Dental</li> </ul>	Teresa Watkins	Michelle Dillahunt
TEAM 3	Paul Schwartz	Gil Kang Kathy Woodland Nashed Nashed Liang-Lii Huang	<ul style="list-style-type: none"> <li>• Anti-anxiety</li> <li>• Sedatives</li> <li>• Dermatologics</li> <li>• Otics</li> <li>• Ophthalmics</li> <li>• Antifungal</li> <li>• Anti-Infectives</li> </ul>	Lillie Golson	Elaine Hu
TEAM 4	Dave Gill	Upinder Atwal Shing Liu Steve Sherken Neeru Takiar Robert Trimmer	<ul style="list-style-type: none"> <li>• Antipsychotics</li> <li>• Corticosteroids</li> <li>• Antihistamines</li> <li>• -Cough Prep.</li> <li>• Muscle Relaxant</li> <li>• Contraceptive</li> <li>• Anabolic Steroids</li> <li>• Vitamins</li> </ul>	Debbie Catterson	Ruby Yu



## 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	Implemented
• First Generic Drug Product List	Implemented
• 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
- Blend Uniformity
- Bioavailability/Bioequivalence

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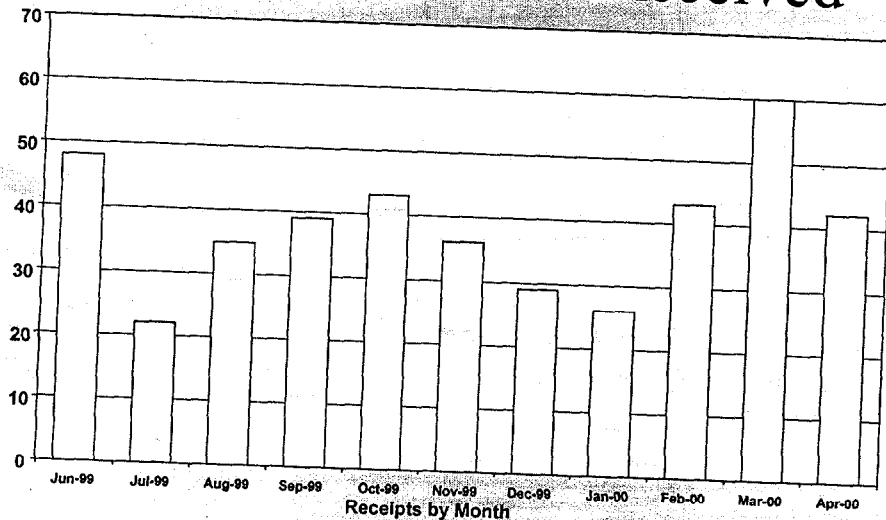
## Controlled Correspondence

- 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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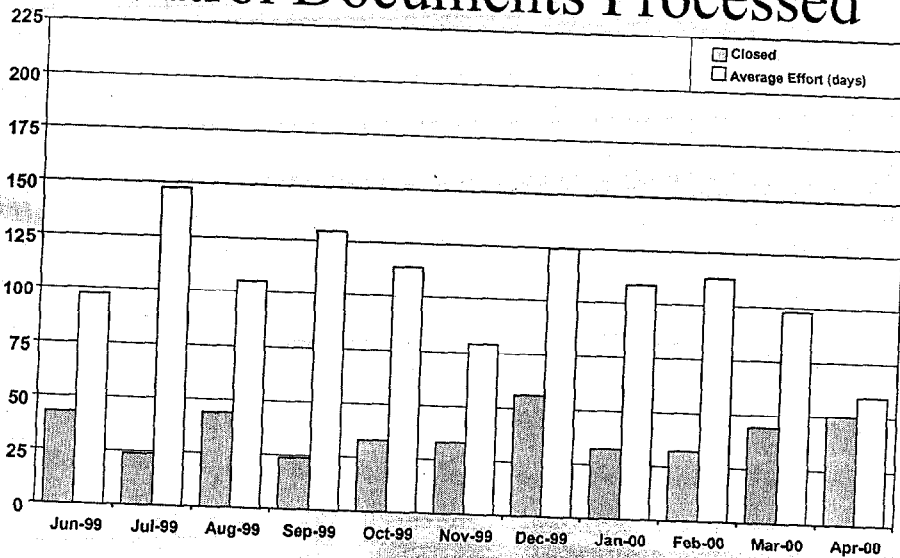
## Control Documents Received



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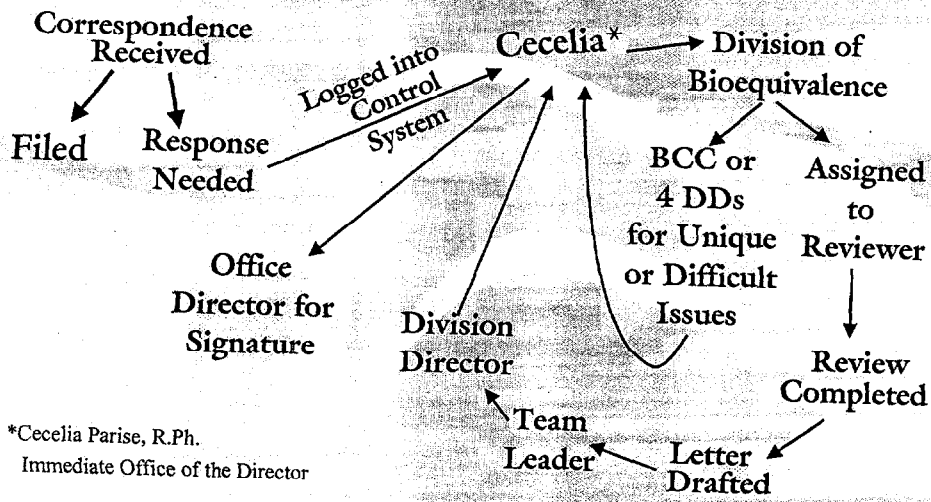
# Control Documents Processed



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# Controlled Correspondence

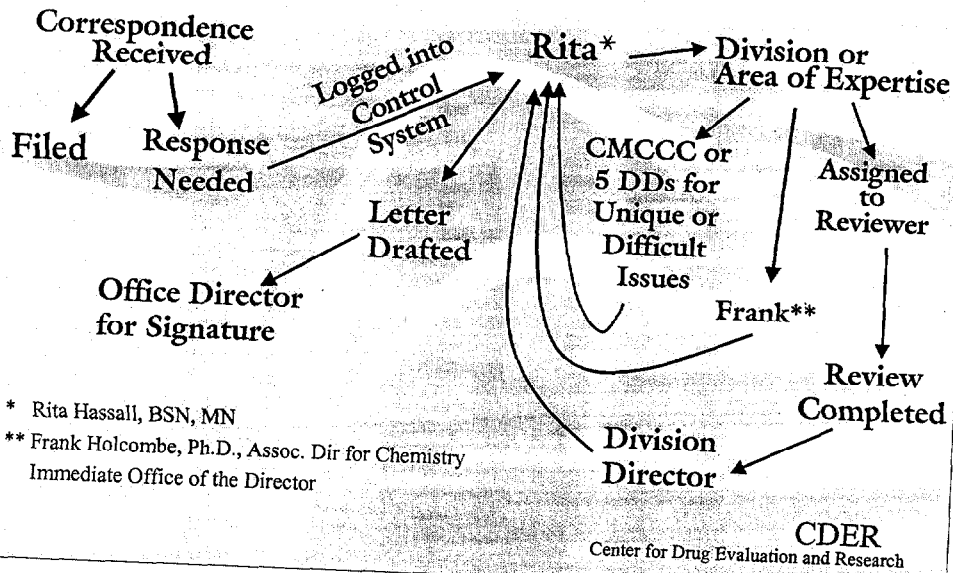


\*Cecelia Parise, R.Ph.  
Immediate Office of the Director

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# 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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