

M E M O R A N D U M

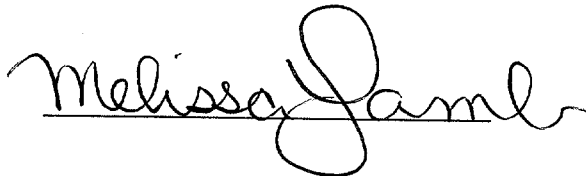
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

0778 '01 MAR -8 AM:18

Date: March 6, 2001
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Trades Association Meeting

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: Trades Association Meeting
Date Presented: June 20, 2000
Presented by: Gary Buehler, Acting Director
Office of Generic Drugs
Number of Pages: 15



Attachment

M707



Update from the Office of Generic Drugs

Trades Association Meeting

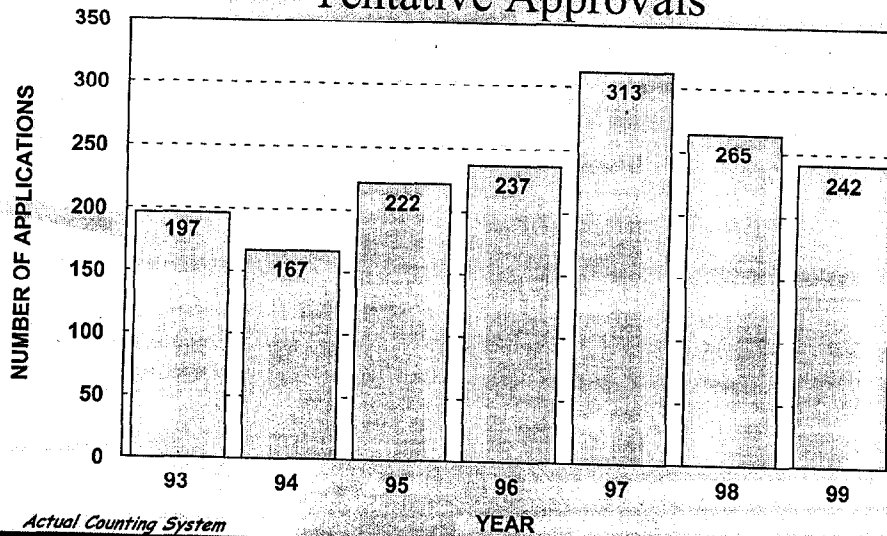
June 20, 2000

Rockville, MD

Gary Buehler, Acting Director
Office of Generic Drugs

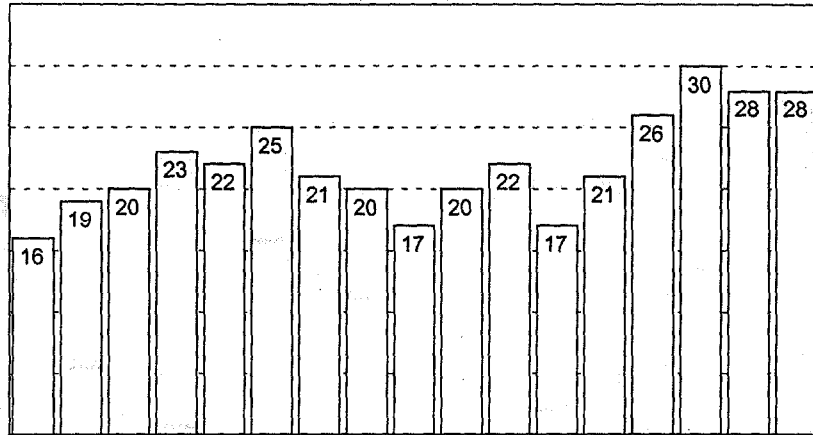


Calendar Year Approvals and Tentative Approvals

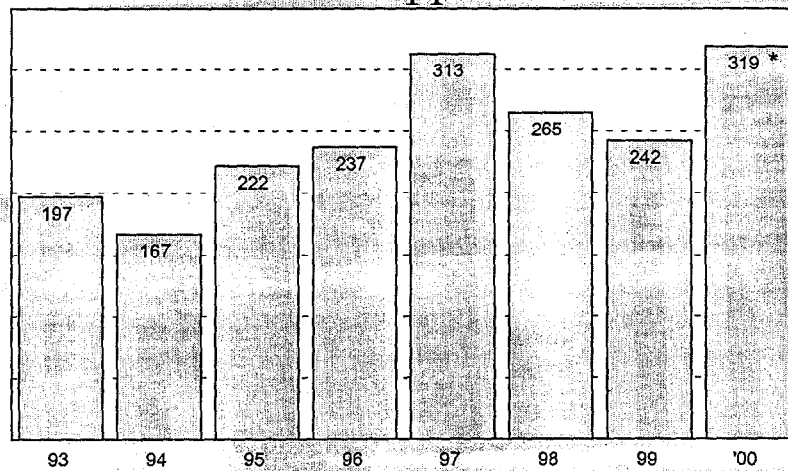




Calendar Year Approvals and Tentative Approvals

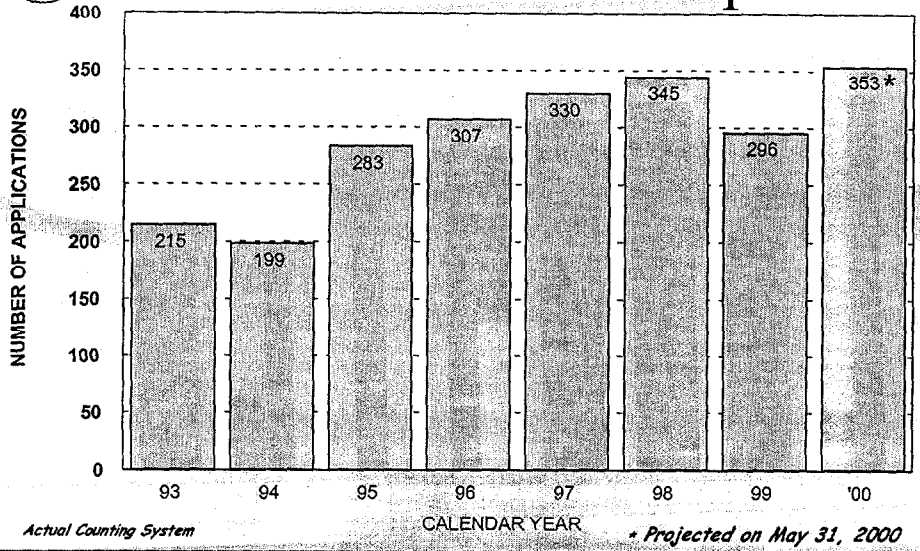


Calendar Year Approvals and Tentative Approvals

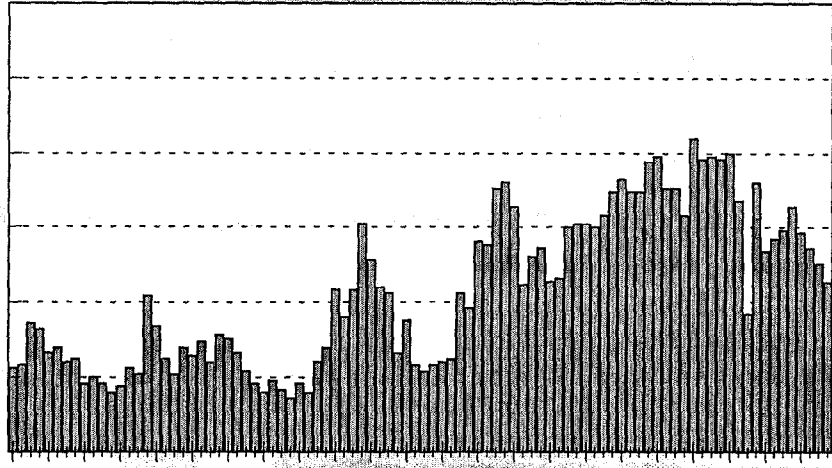




Calendar Year Receipts

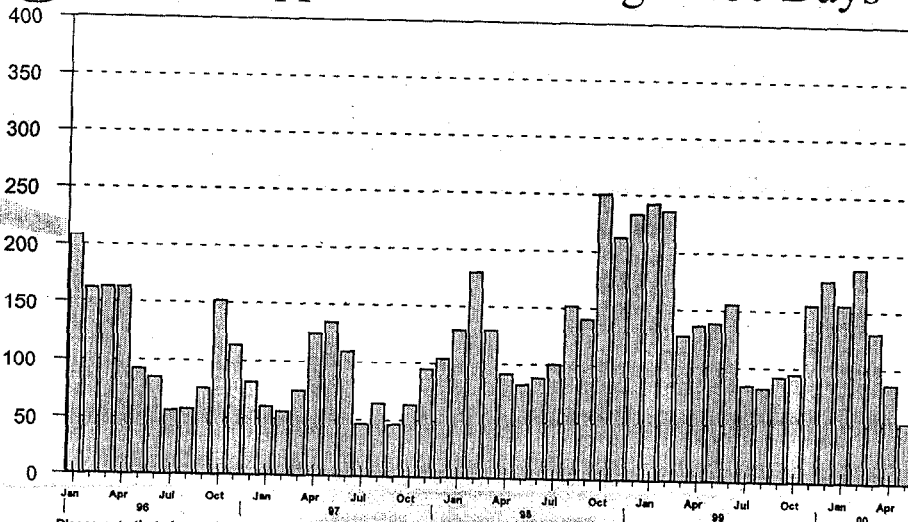


Original ANDAs Pending > 180 Days





CMC Supplements Pending > 180 Days



Please note that abrupt changes in the level of pending supplements (e.g. the increase in September 1994) are the result of global submissions to all applications held by a single firm. Changes other than these will be



Current Challenges

- Review
- Communication



Chemistry Review

- Current Backlog
- Process Review
- New Staff



Chemistry Review Backlog

Division 1 - 122 Days

Team 1	113 Days
Team 2	162 Days
Team 3	122 Days
Team 4	92 Days



Chemistry Review Backlog

Division 2 - 125 Days

Team 6	118 Days
Team 7	140 Days
Team 8	123 Days
Team 9	120 Days



Process Review

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



New Staff

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

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 PTE due to report	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Estrogens • Gonadotropins • LVPs • Cytotoxic • Antineoplastic • Bronchodialator (MDI) • Surgical-Dental 	Teresa Watkins	Michelle Dillahunt
TEAM 3	Paul Schwartz	Gil Kang Kathy Woodland Nashed Nashed Liang-Lii Huang	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Antipsychotics • Corticosteriods • 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	<ul style="list-style-type: none"> • Antibacterial • Anti Fungal* • Antineoplastic* • Immuno-suppressants* *Fermentation Derived 	Jackie Council	Mark Anderson
		Susan Rosencrance			
		Ruth Ganunis			
		Susan Zuk			
		M. Scott Furness			
TEAM 7	Brenda Arnwine	Karen Bernard	<ul style="list-style-type: none"> • Anti-Ulcer • Anticonvulsants • Antimotility • Anticholinergics • Anorexics 	Koung Lee	Kassandra Sherrod
		Raymond Brown			
		Mahnaz Farahani			
		Ijeoma Nnamani			
		Radhika Rajagopalan			
TEAM 8	Ubrani Venkataram	Sema Basaran	<ul style="list-style-type: none"> • Beta-Blockers • Ca Channel Blockers • Anti-arrhythmics • Anti depressants • Drug Abuse 	Adolph Vezza	Tim Ames
		Bitu Mirzai-Azarin			
		Robert Permsohn			
		Mouna Selvam			
		Lucia Tang			
TEAM 9	Glen Smith	Andrew Langowski	<ul style="list-style-type: none"> • Antiviral • Analgesics • Anesthetics • Narcotic agonists • Anticoagulants 	Chan Park	Jeen Min
		Edwin Ramos			
		Dominick Roselle			
		Mayra Pinedro-Sanchez			
		Tao-chin Wang			

Division of Bioequivalence TEAM Structure

Thursday, May 11, 2000

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

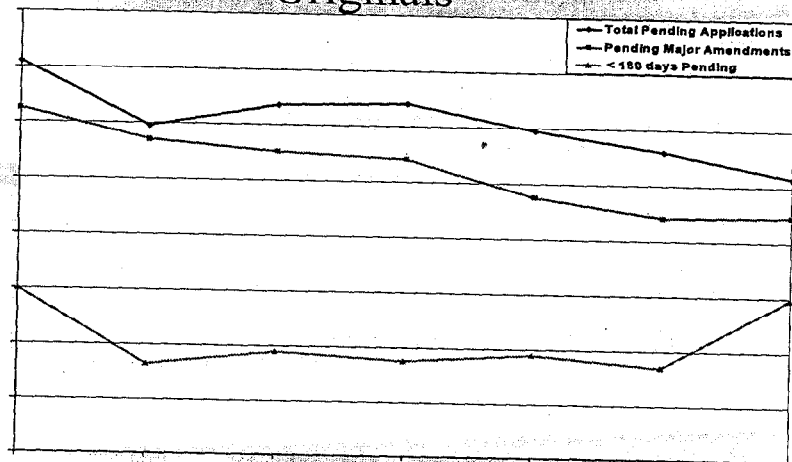


Microbiology Review

- Functioning Unit
- Project Manager Oversight
- Decreasing Numbers

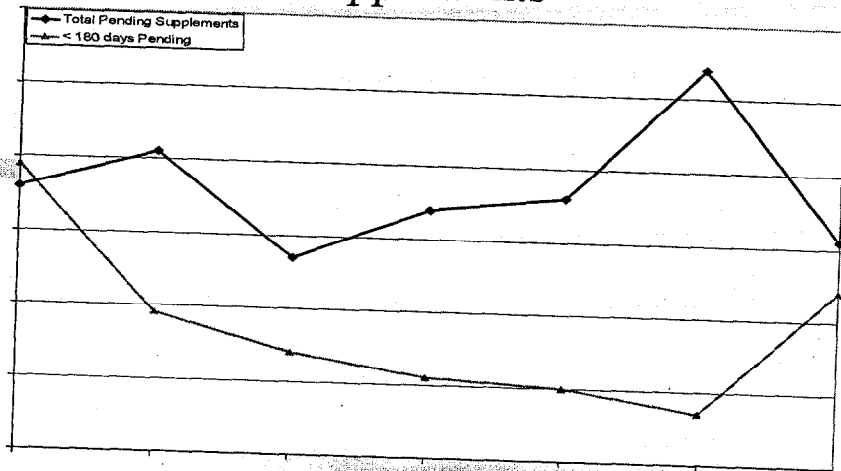


Microbiology Productivity Originals





Microbiology Productivity Supplements



Communication

- Web Initiatives
- Guidances
- Controlled Correspondence



Web Initiatives

Addition	Implementation Status
• 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



Web Initiatives

Addition	Implementation Status
• 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



Guidances

- Inactive Ingredients
 - Revision of Inactive Ingredients Guide (IIG)
- Major-Minor Revision
- Blend Uniformity
- Bioavailability/Bioequivalence

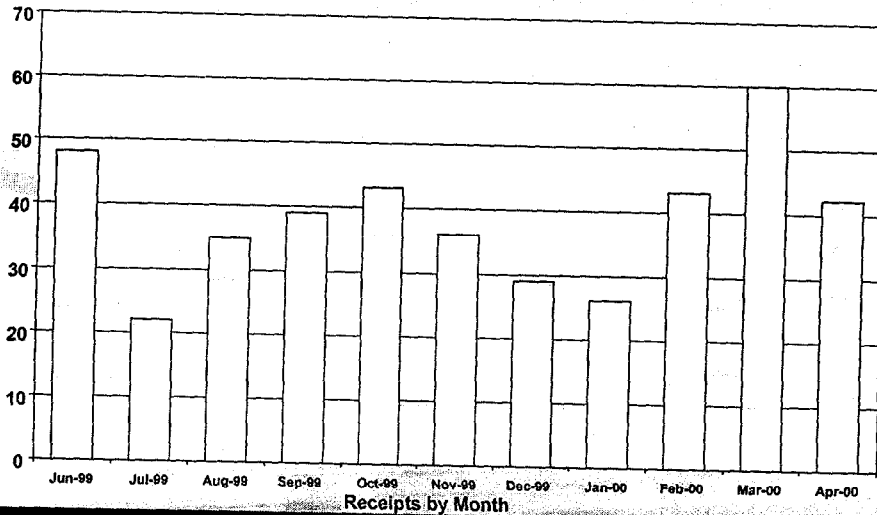


Controlled Correspondence

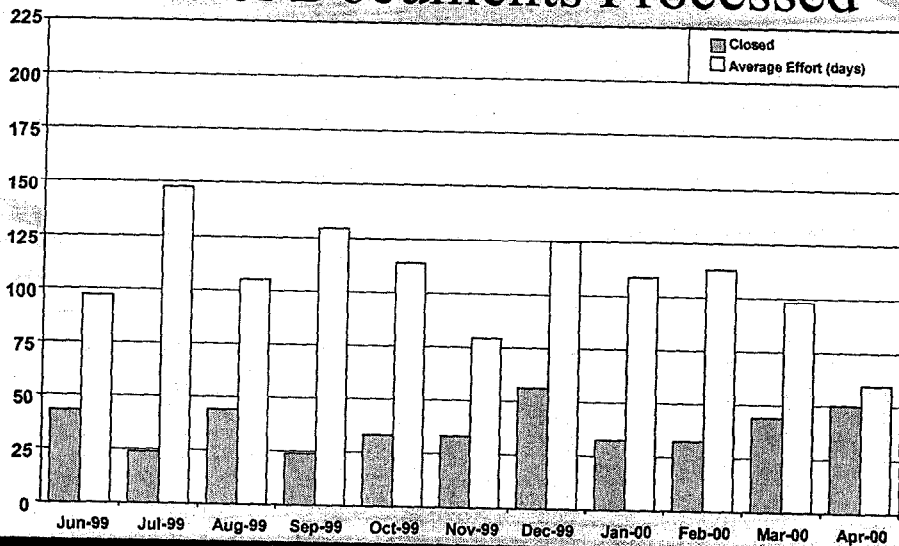
- June 1, 1999 - April 30, 2000
 - = 423 Pieces
 - Bioequivalence Questions
 - = 223 pieces (53%)
 - Remainder = Labeling; Chemistry; Regulatory Support
- Increased Effort to Complete



Control Documents Received

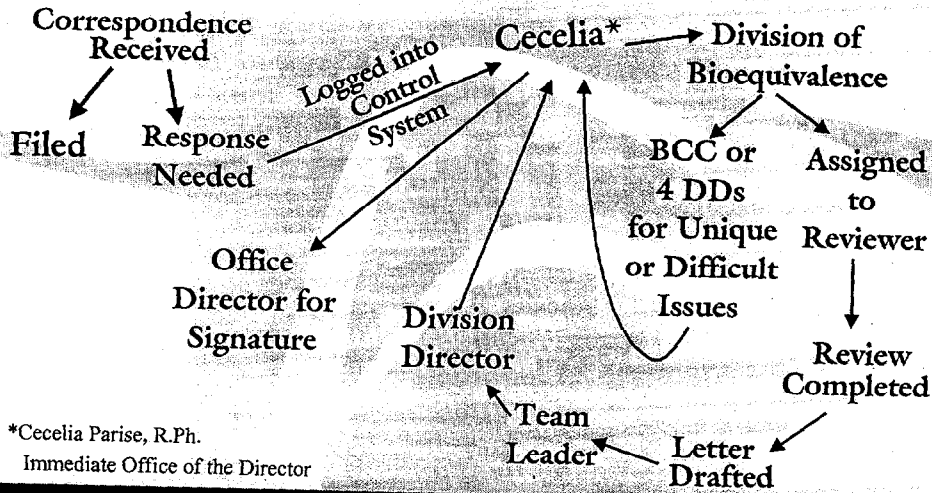


Control Documents Processed





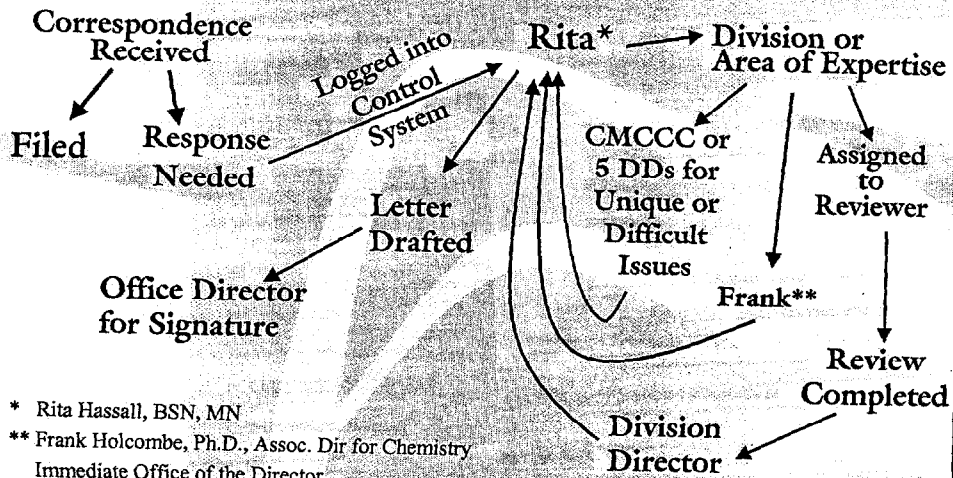
Controlled Correspondence



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



Controlled Correspondence



* Rita Hassall, BSN, MN
** Frank Holcombe, Ph.D., Assoc. Dir for Chemistry
Immediate Office of the Director



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