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: October 6, 2000

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Regulatory Support Updates

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: Regulatory Support Updates

Presented for: RAPS 2000 Annual Conference & Exhibition

Date Presented: November 20, 2000

Presented by: Gregg Davis

Number of Pages: 14

Melissa Lamb

Attachment

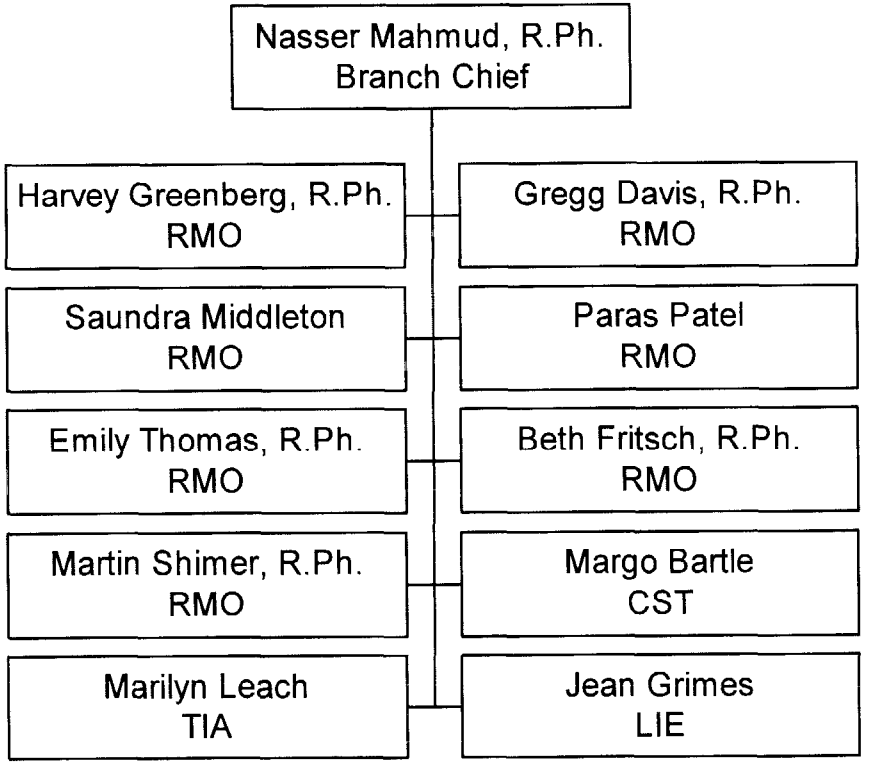
90S-0308

M688

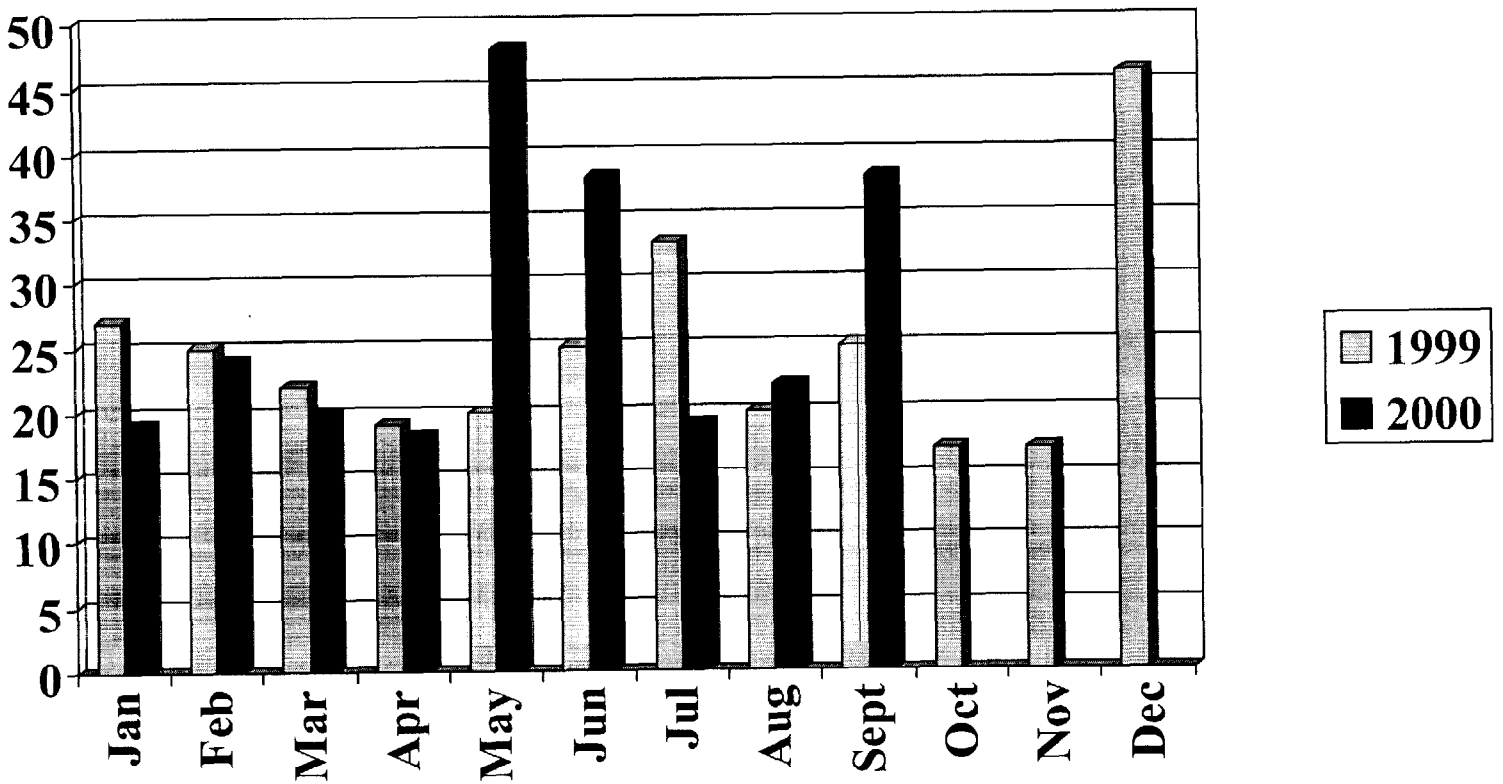
Regulatory Support Updates

Gregg Davis, R.Ph.
Regulatory Management Officer
Office of Generic Drugs

Regulatory Support Staff



Submissions 1999 & 2000



Filing Issues

- Patent/Exclusivity
- Bioequivalence
- Inactive ingredients
- Sterility Assurance/Filter Validation
- Batch Reconciliation
- Manufacturing/Contract Facility Addresses
- DMF Authorization

Patent/Exclusivity Issues

- P IV certifications and viii statements
- U.S. registered/certified mail with return receipts
- PATENT AMENDMENTS

Bioequivalence

- Summary of bioequivalence results
- Addresses of clinical/analytical sites
- Forms 3454 and 3455
- Exception excipients

Inactive Ingredients

- Must not affect safety
- Exception excipients
- pH adjuster vs. buffer
- Flavors/Colors

Filter Validation

- Submission of filter validation data is a requirement for aseptically filled products only

- Aseptically filled ANDAs will not be received without sterile filtration validation

Batch Reconciliation

- One page summary of theoretical/actual yields
- Amount of product packaged in each container size
- Extremely helpful for the regulatory review

Manufacturing/Contract Addresses

- Exact addresses for the facilities used in manufacturing, packaging, etc.
- Corporate addresses are frequently submitted in the ANDA
- Common with API addresses

DMF Authorization

- Directly from DMF holder or via authorized agent

- DMF authorization without DMF number

IIG Update

- Personnel and $
- Pre-1996 data not compatible with post-1996 data
- >6000 applications
- Fall 2000
- Accurate, user-friendly and updateable

Pending Rules/Guidances

- 180 day Final Rule
- Discontinued Labeling Guidance?
- Inactive Ingredients Guidance

Internet p IV list

- List of ANDAs received with a p IV patent certification for a particular drug product/strength

- Cumulative list
- Updated and posted once per month
- not intended for 180 day evaluations
- www.fda.gov/cder/ogd