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

5128 '01 NOV 30 P1:52

Date: November 27, 2001

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Regulatory Support Branch

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: GphA Technical Committee Fall Workshop

Date Presented: October 29, 2001

Presented by: Gregg Davis
Chief, Regulatory Support Branch
Office of Generic Drugs

Number of Pages: 15

Melissa Lamb

Attachment

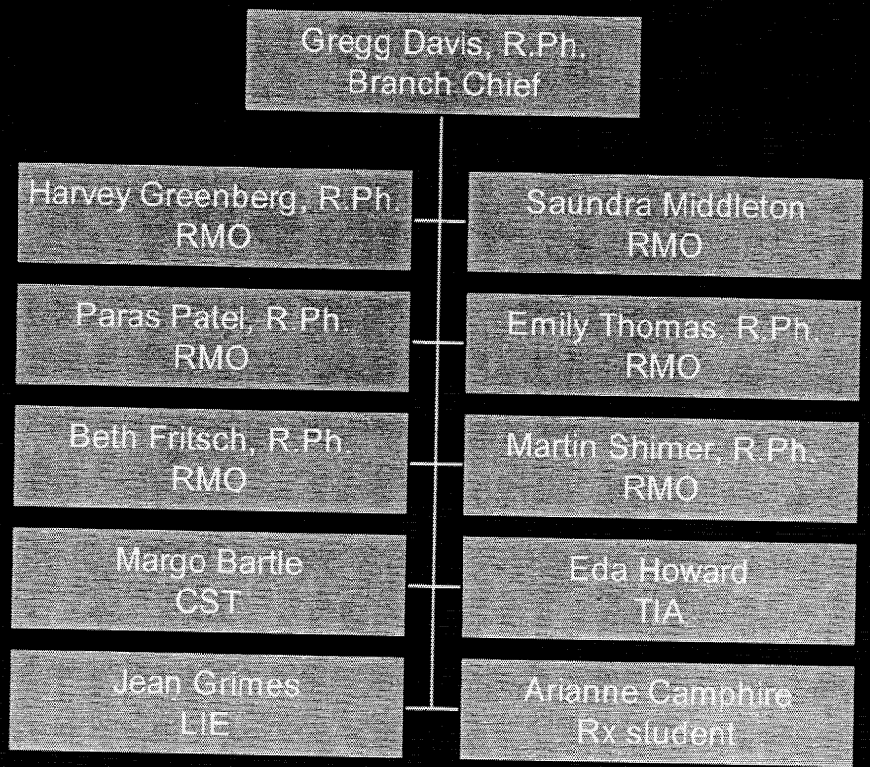
90S-0308

M725

Regulatory Support Updates

Gregg Davis
Chief, Regulatory Support Branch
Office of Generic Drugs

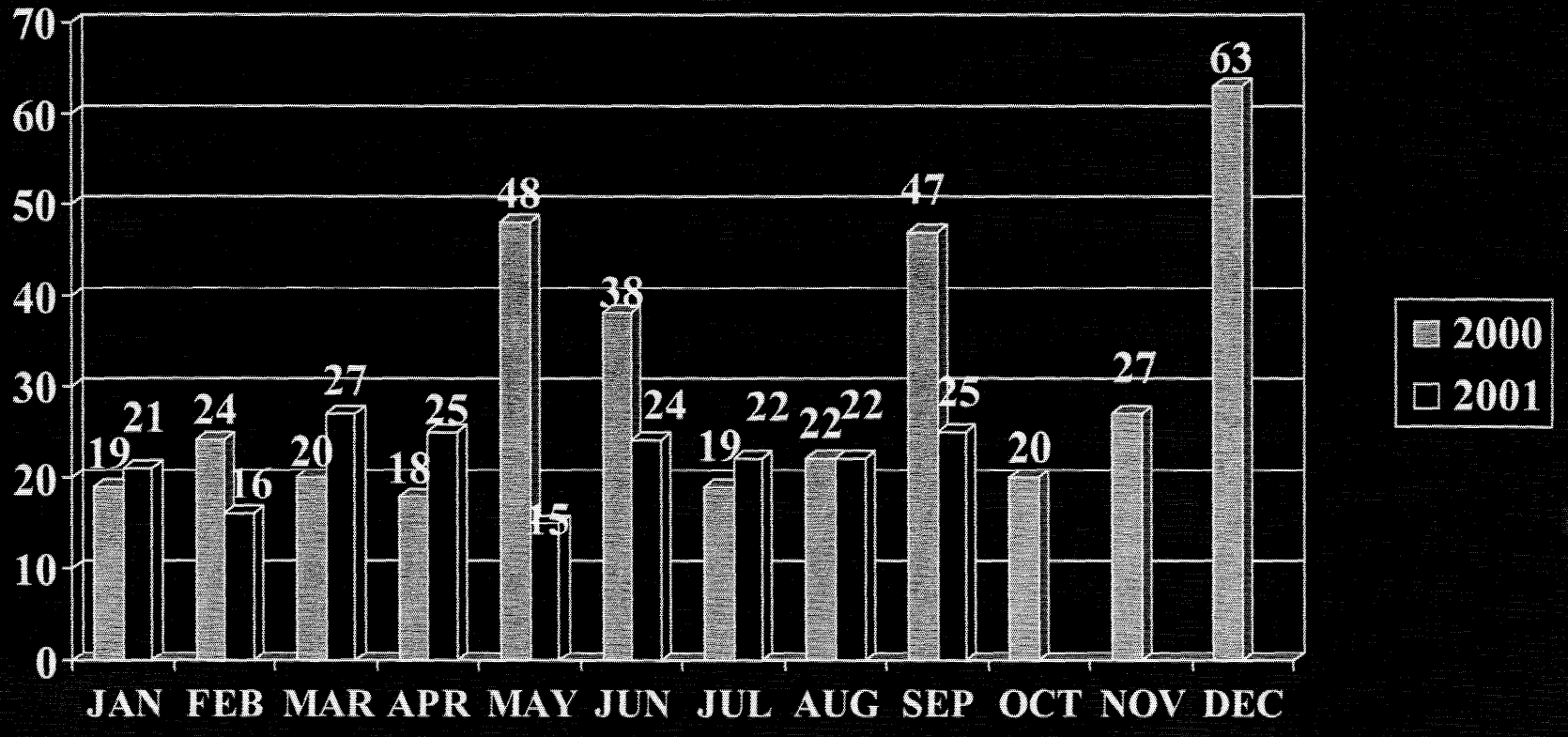
Regulatory Support Staff



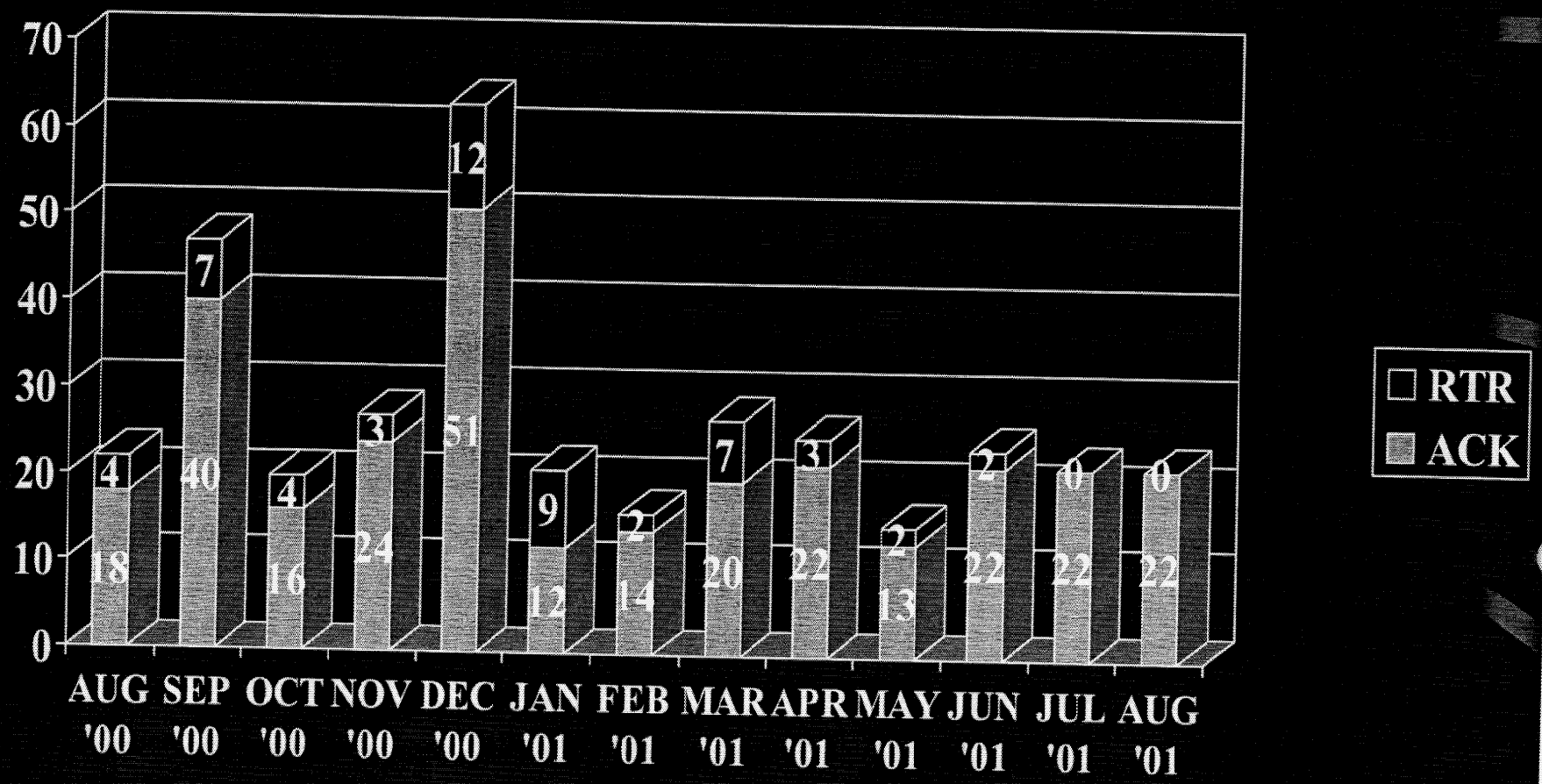
7 things I will not talk about

- Cefuroxime axetil
- Buspirone
- Omeprazole
- Metformin
- Tramadol
- Discontinued Labeling Guidance
- Pediatric Labeling Guidance

Submissions 2000 & 2001



Acks and RTRs



ANDA Withdrawal Program

- Since October 2000, 61 letters sent
- 28 withdrawn by applicants, 9 by FDA
- 14 amended, 9 committed to amend
- 1 other

Refuse to Receive Issues

- Inactive ingredients - [ ], new use, parenterals outside 314.94(a)(9)
- Bioequivalence - fails acceptance criteria
- Sterility Assurance/Filter Validation
- Dissolution - no data and < 12 tablets
- DMF Authorization
- Stability - < 4 accelerated data points

Refuse to Receive Issues

- Packaging/Manufacturing - < minimum # required for the test batch
- Lacks supporting data for each component and composition
- Incomplete GDEA certifications
- U.S. agent authorization

Control Documents

- 125 controls received since October 2000
- 115 have been answered, 10 still pending
- All but 20 were inactive ingredient requests

Control Documents

- Letter, fax, e-mail are all fine
- Fax number - 301-594-1174
- Must have address and phone number for contact

New strengths

- 21 CFR 314.3 defines an abbreviated application as the application described under 314.94, including all amendments and supplements…

New Strengths

- The Regulatory Support Branch is now reviewing ALL new strength amendments and supplements for acceptability
- Processed identically to originals
- Telephone call or refused to receive

New Strengths (cont.)

- Must still follow 314.94 with regard to content and format
- Absolutely requires a new patent certification and notification to the patent owner and application holder

New strengths

- Proposal to place entire application in major status with the submission of a new strength amendment - this will increase time to approval

- However, OGD will allow new strengths to be submitted as separate applications

IIG Update

- 55,664 separate ingredient records
- Available December 2001 via internet
- Searchable
- Will not list range, only highest level