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

Date: March 2, 2001

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: 2001 NAPM Annual Meeting & Educational Conference

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: 2001 NAPM Annual Meeting & Educational Conference

Presented for: NAPM

Date Presented: January 31, 2001

Presented by: Gary Buehler, Acting Director
Office of Generic Drugs

Number of Pages: 14

Melissa Lamb

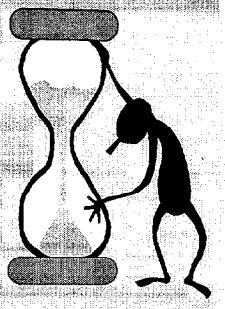
Attachment

90S-0308

M695

2001 NAPM Annual Meeting & Educational Conference

"A Decade Later"

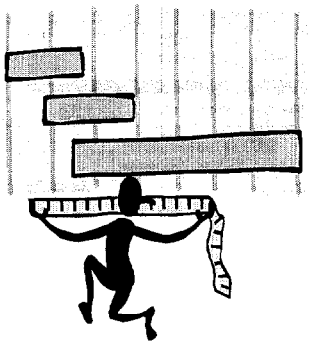


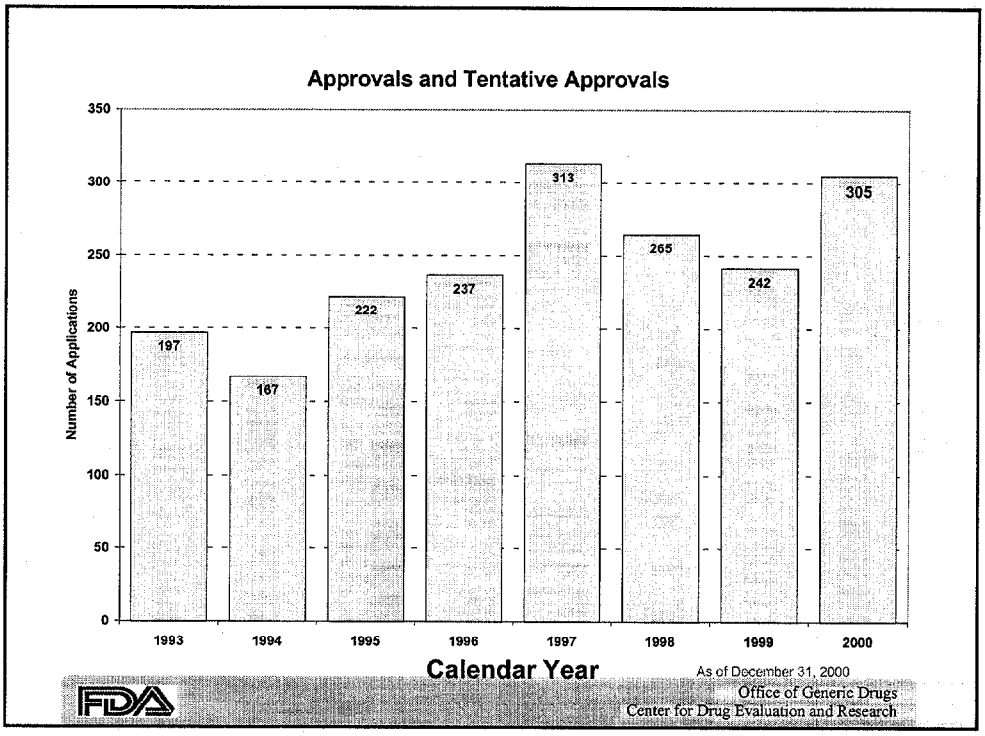
Gary J. Buehler
Acting Director
Office of Generic Drugs
CDER/FDA

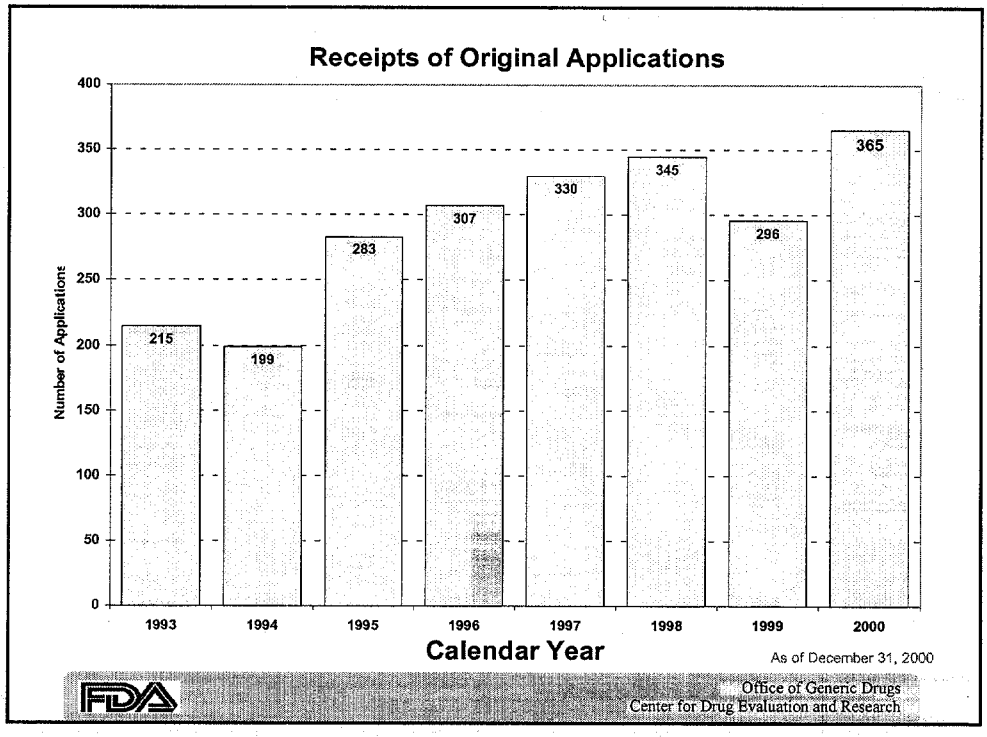
January 31, 2001

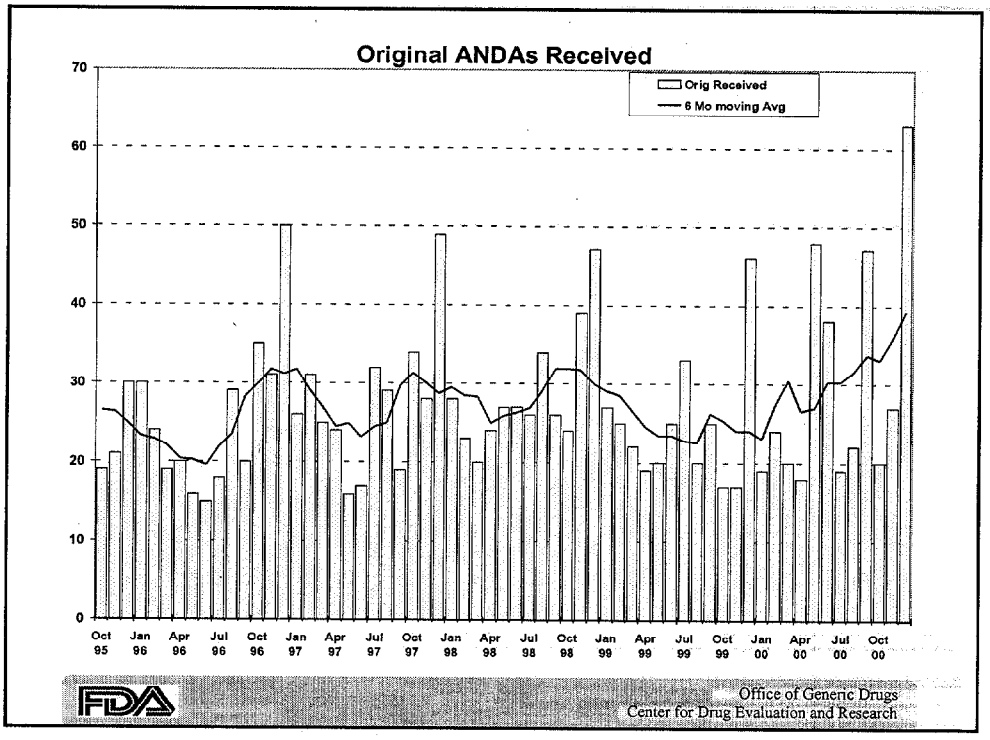
Topics

- Productivity Update
- Methods Validation Changes
- Staffing
- Proposed Review Changes




Approvals and Tentative Approvals
Number of Applications
350
300
250
200
150
100
50
0
197
167
222
237
313
265
242
305
1993
1994
1995
1996
1997
1998
1999
2000
Calendar Year
As of December 31, 2000
Office of Generic Drugs
Center for Drug Evaluation and Research
FDA


Receipts of Original Applications
Number of Applications
400
350
300
250
200
150
100
50
0
215
199
283
307
330
345
296
365
1993
1994
1995
1996
1997
1998
1999
2000
Calendar Year
As of December 31, 2000
Office of Generic Drugs
Center for Drug Evaluation and Research
FDA


Original ANDAs Received
Orig Received
6 Mo moving Avg
70
60
50
40
30
20
10
0
Oct 95
Jan 96
Apr 96
Jul 96
Oct 96
Jan 97
Apr 97
Jul 97
Oct 97
Jan 98
Apr 98
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Apr 00
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Oct 00
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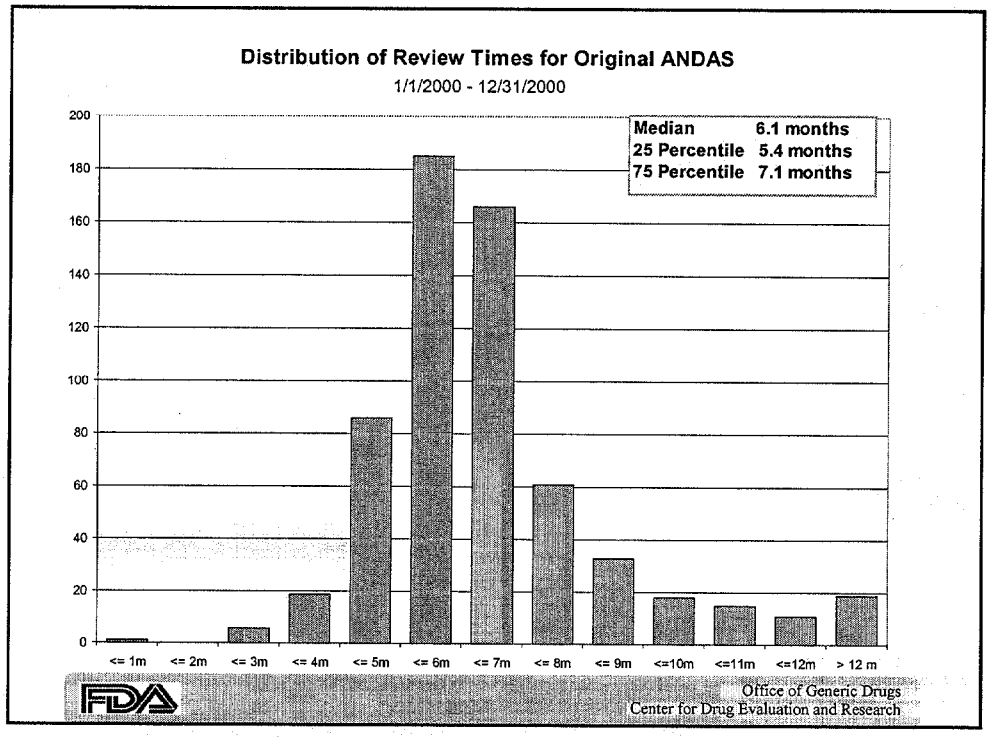
Distribution of Review Times for Original ANDAS
1/1/2000 - 12/31/2000
Median 6.1 months
25 Percentile 5.4 months
75 Percentile 7.1 months
200
180
160
140
120
100
80
60
40
20
0
<= 1m
<= 2m
<= 3m
<= 4m
<= 5m
<= 6m
<= 7m
<= 8m
<= 9m
<=10m
<=11m
<=12m
> 12 m
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Breakdown of Onboard Staff

	141	Hires
■ Total		
• Chemists	65	7
• Pharmacologists	15	
• Pharmacists	37	5
• Medical Officer	1	
• Math Statistician	1	
• Microbiologists	4	2
• Computer Specialist	2	
• Admin/Support Staff	16	4

Methods Validation Change

- OGD Requests for Methods Validation
  - Previously 30-Day Wait
  - Now - Approval will not be delayed
    - Consistent with Office of New Drug Chemistry
  - OGD Requesting Validation as Early as Possible

Methods Validation Change

- Industry Obligations
  - Prompt Submission of Samples
  - Commitment to Resolve Any Problem Subsequently Found

Inactive Ingredient Guide Update

- Work by Office of Information Technology - Division of Data Management & Services with contract support
- Phase I completed
  - Selected NDAs
  - Pilot QC Methods
- Phase II started January 16, 2001
  - Taking NDAs in batches
  - New programs written to correct data
- Projected completion September 2001

October 2000 NAPM Meeting
John Rapoza Presentation

- Citizen Petition
- Refusal to Receive (File)
- Blend Uniformity Testing
- Amendment Classification

Citizen Petitions
John Rapoza's Suggestions

- Expedite review of CP so they do not delay ANDA approvals
- Raise scientific standard such that petitioners would need to demonstrate that approval of ANDA would be a threat to public health and safety
- Action:
  - Minimal

Refusal to Receive (File)

John Rapoza's Suggestions

- Call - and allow 10 days for submission of missing information
- Reduce filing review time from 60 to 30 days
- Post RTR reasons monthly on website
- More interaction with industry
- Action:
  - Update IIG
  - Revise RTR Policy, re: Colors, Flavors

Blend Uniformity Testing

John Rapoza's Suggestions

- Use as a development tool and as part of validation process
- Once validate - use mixing time
- 2nd level of acceptance testing
- Accept and approve supplements to delete
- Action:
  - Guidance being revised
  - Supplement allowed to remove BUA testing
  - PQRI working on recommendations

Amendment Classification

John Rapoza's Suggestions

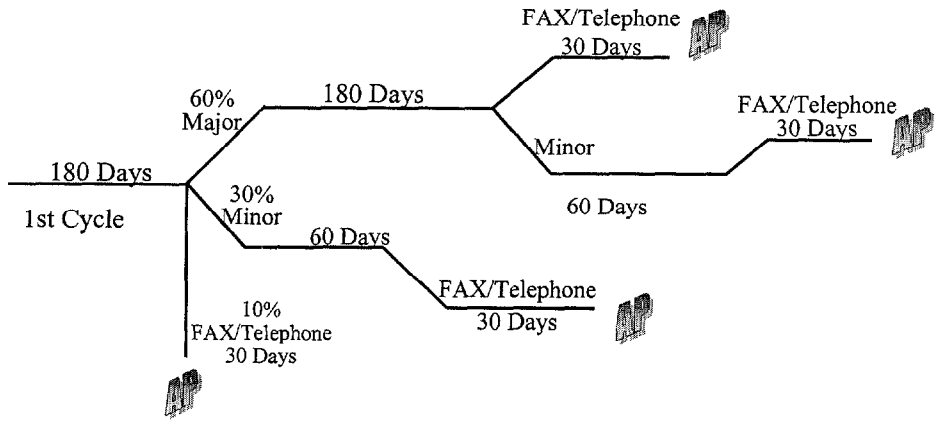
- Criteria for minor amendment needs to be expanded (> 1 hour)
- Do we need FAX and minor amendments? (redundant)
- Should allow industry to address minor deficiencies without causing recycling of application

Inefficiencies Created by the Scandal

- Queue
- Random Assignment
- Limited Communication
  - None during initial review
  - Always with at least 2 people participating in conversation

Original ANDAs

Present Review Path

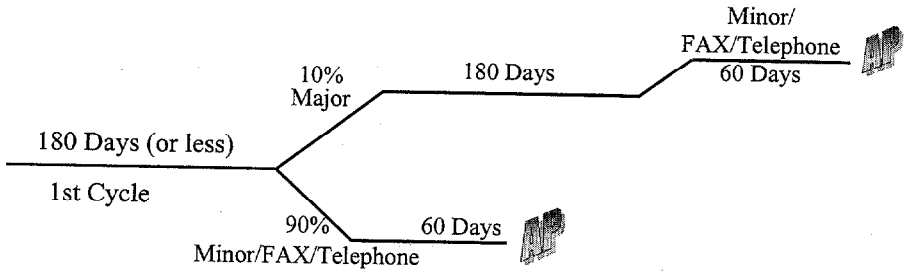


Proposal

- Revise the Major/Minor Amendment Policy
  - Eliminate subjective decisions completely (amount of time need to review)
  - Increase criteria for a minor determination from 1 hour to 4 - 8 hours

Original ANDAs

Proposed Review Path



Result

- About 90% of all original review would result in minor determinations

  (Increase of 40%)

Advantages

- Improve continuity of review - Less time between amendments
- Decrease total time to approval

- Decrease processing time by decreasing number of cycles
- Decrease (eliminate?) disputes over amendment determinations

Disadvantages

- Decreased incentive for quality applications
- Initially could increase time required for minor amendment reviews
- Initially could increase number of overdue originals (Congressional barometer)

Long-Term Plan

- Allow telephone communication between review chemist/team leader during initial review
- Resolve minor deficiencies through communication resulting in more 1st-cycle approvals

Phase-In

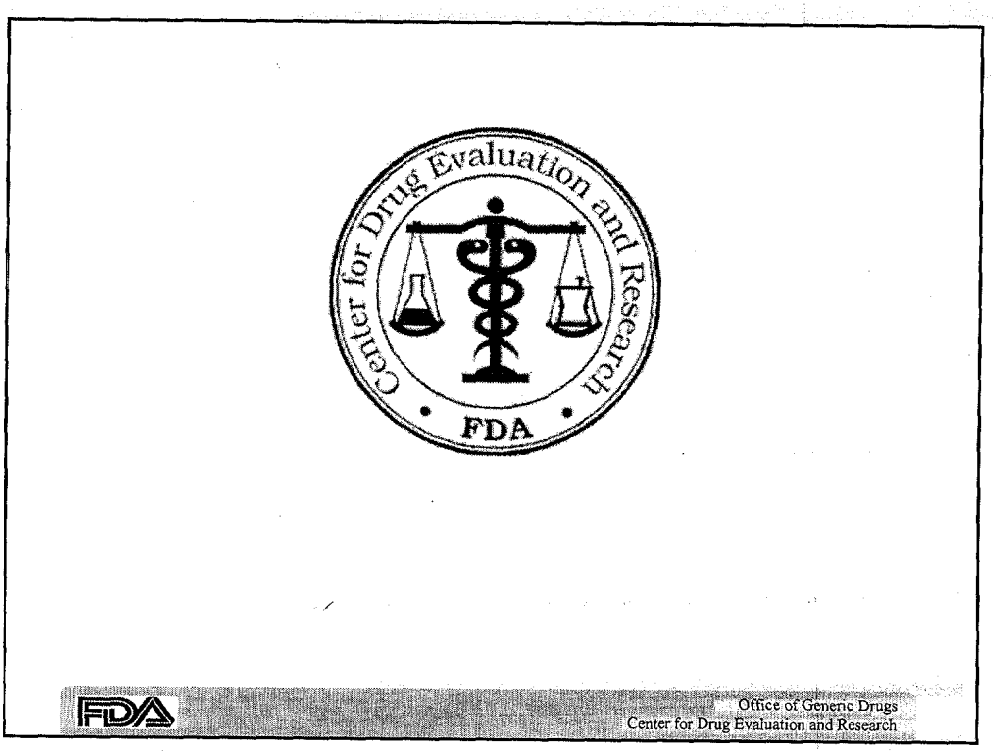
- Liberalize major/minor determinations (when in doubt = minor)
- Increase communication between sponsor and review chemists/team leaders

Industry Cooperation

- Timely response to telephone/FAX communication
- Realization that all chemists are not created equal - some will call more than others
- Understanding during phase-in period
- Initially "minor" reviews may be delayed as well as reviews of originals

Conclusion

- Continue emphasis on communication with industry
  - Next OGD-Industry Meeting >Spring 2001
  - Controlled Correspondence
  - Web Initiatives
- Move forward with review refinements
- Emphasize quality of work life/training for OGD staff
- Focus on Science Base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