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

9352 '01 JUN 25 P1:23

Date: June 1, 2001

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Priorities and Process Improvements

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:	Priorities and Process Improvements
Presented for:	FDA/Generic Pharmaceutical Association Workshop
Date Presented:	May 21, 2001
Presented by:	Gary J. Buehler, R. Ph., Acting Director Office of Generic Drugs May 21, 2001
Number of Pages:	23

Melissa Lamb

Attachment

905-0308

M 716

FDA/Generic Pharmaceutical Association Workshop

Priorities and Process Improvements

Gary J. Buehler, R.Ph.
Acting Director,
Office of Generic Drugs
May 21, 2001

February 2000 Priorities

- ✓ Maintain/Increase Productivity
- ✓ Retain Trained Reviewers
- ✓ Improve Quality of Worklife
- ✓ Increase Chemistry Staff

Quality of Worklife Initiatives

- ✓OGD Education Committee
  - – Continuing Education Credits
  - – Internal & External Programs
- ✓Video-Conferencing
- ✓Visits to Pharmaceutical Firms
- ✓Information Technology Upgrades

May 2001 OGD Education Calendar of Events

Sun	*Mon*	*Tue*	*Wed*	*Thu*	*Fri*	*Sat*
		1	2 **CDER Seminar** 1:30-3:00	8:30-10, 1-2:30 3 **Patent & Exclusivity 101** by Greg Davis	4	5
6	7	8	10-11, 11-12 9 **Immediate Office Presentation: Current Patent & Exclusivity Issues** **Scientific Rounds** 1:30-3:00	10	11	12
13	14	15	16 **CDER Seminar** 1:30-3:00	17	18	19
20	1:30-3:00 21 **ONDC Rounds Antisense and Gene Therapy Synthetic Oligonucleotides**	22	11:00-12:00 23 **CMC Brown Bag Antibiotics** by Maria Shih and Others **Scientific Rounds** 1:30-3:00	2:00-3:00 24 **Generic Formulations** presented by TEVA	25	26
27	28 **Memorial Day Holiday**	29	30 **CDER Seminar** 1:30-3:00	31		

Wednesday CDER Seminars/Scientific Rounds, and ONDC Rounds are Satellite Broadcasted to Conference Room B

All Offerings are in Conference Room B unless noted otherwise

Upcoming Events for June...

Colloidal Interfacial Chemistry by Dr. Dianne Burgess, U of Conn.

Day Trip to Pharma Kinetics

Office of Criminal Investigation Presentation

...Details and Dates to follow

- ✓Pharmaceutical Plant Visits
  - Mylan
  - Teva
  - PurePac
  - Abbott
  - 2 - 3 additional visits this year

✓ Presentations by Industry

- Charles River Labs -- Endotoxin Testing
- ESI Lederle -- Generic Drug Marketing
- Abbott Labs -- Sterilization by Irradiation
- TEVA -- Generic Formulations
- To Come:
  - GPhA -- Role of Trade Organization
  - Air Dispersions Limited -- Blow Fill Seal Containers

✓Information Technology Upgrades

- Hardware Upgrades Completed
- Beginning Dual Monitor Capability
- Inactive Ingredient Guide Update Progressing
- Beginning Paperless Division Files System
- Conference Room B Audio/Visual Improvements

Chemistry Staff

- ✔ 9 Chemistry Reviewers Hired Since March 2000
- ✔ No Chemistry Reviewers have left during that period (only Deputy Director, Chem I)

In 2000, we were trying to attain parity with ORM/ONDC reviewers

We now equal or surpass ORM/ONDC reviewers in

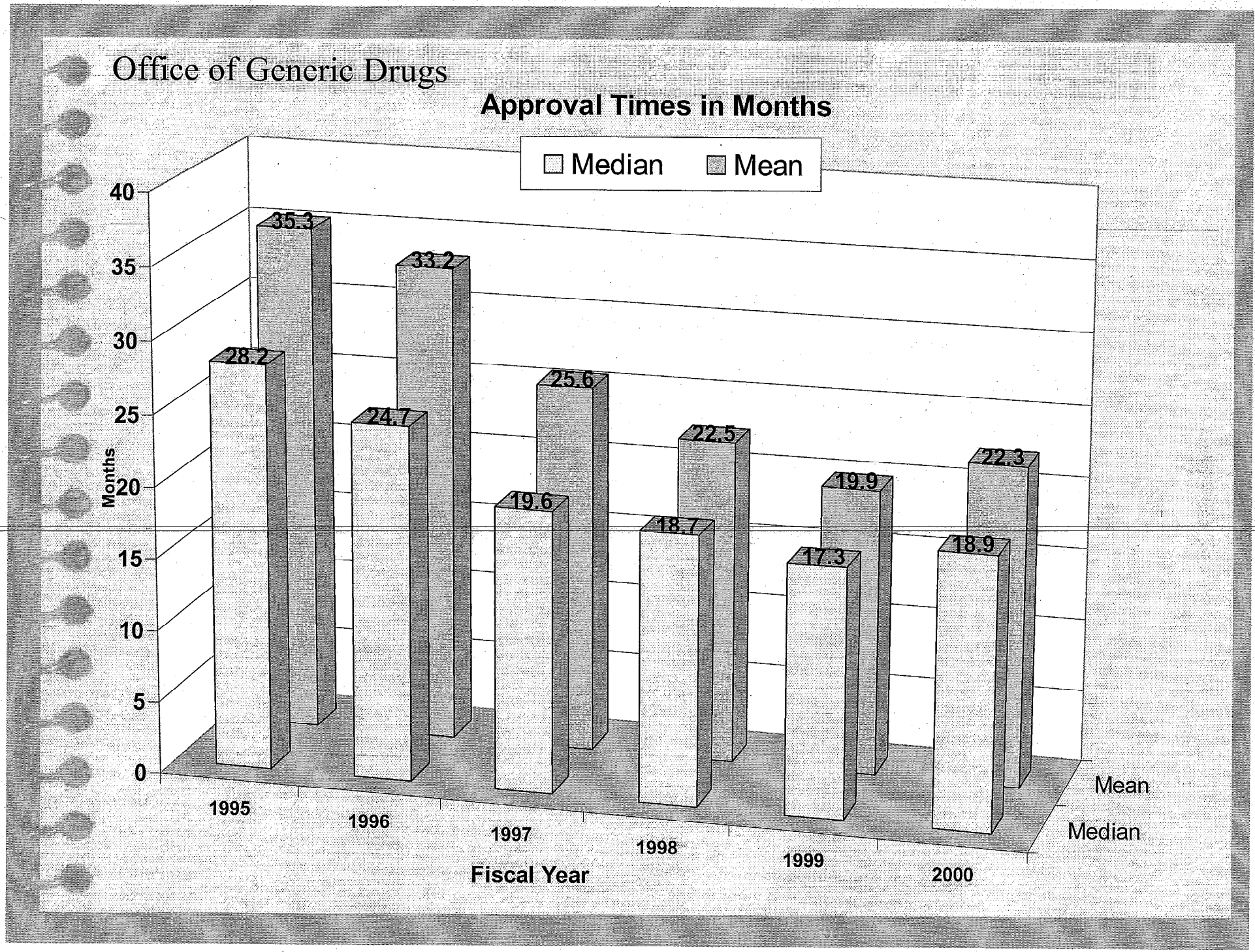
- IT Hardware Capabilities
- Internal Training/Seminar Opportunities

Because of lack of training funds (non-user fee office), we are still behind in external training opportunities

May 2001 Priorities

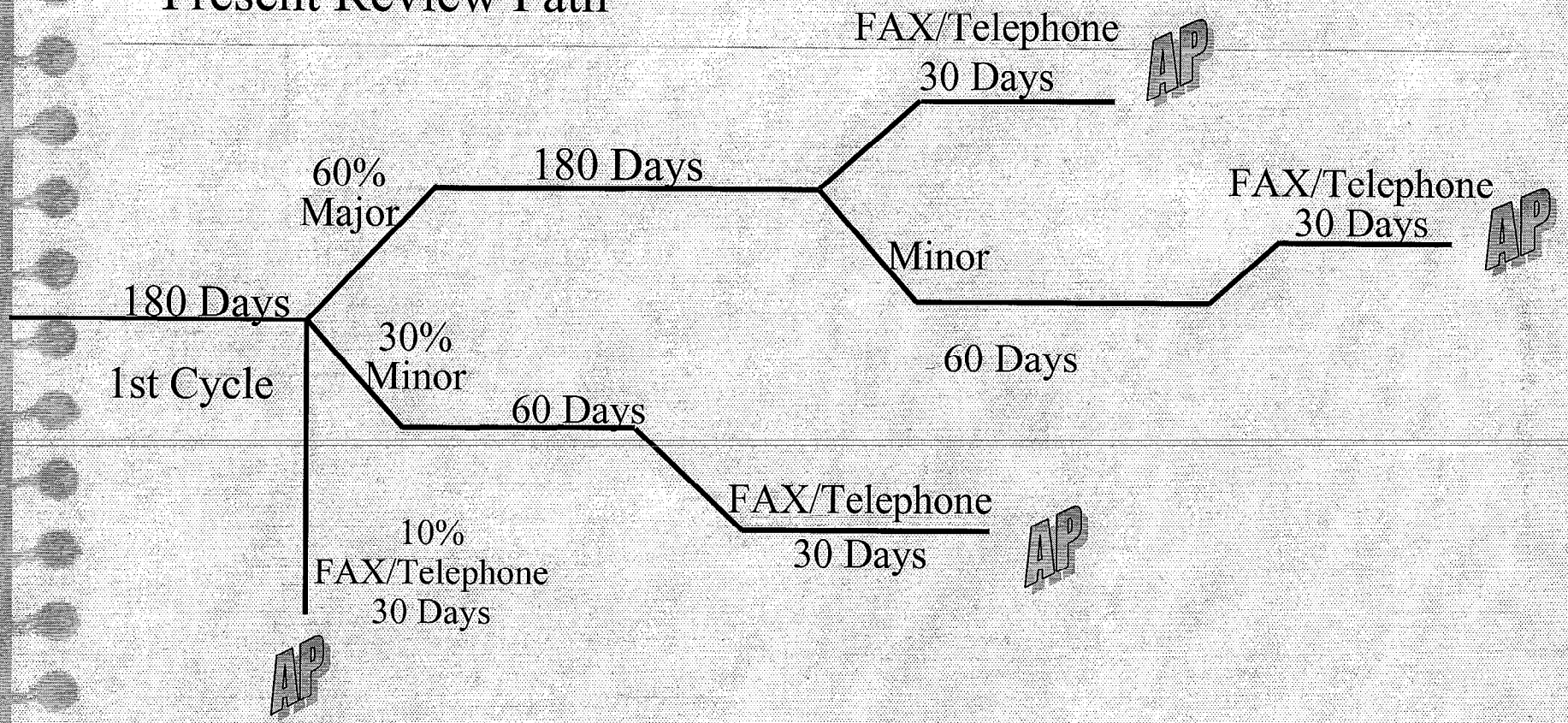
- ✓Continue Focus on Productivity
- ✓Improve Total Approval Time
- ✓Continue Quality of Worklife Initiatives
- ✓Focus on Science Base

Office of Generic Drugs



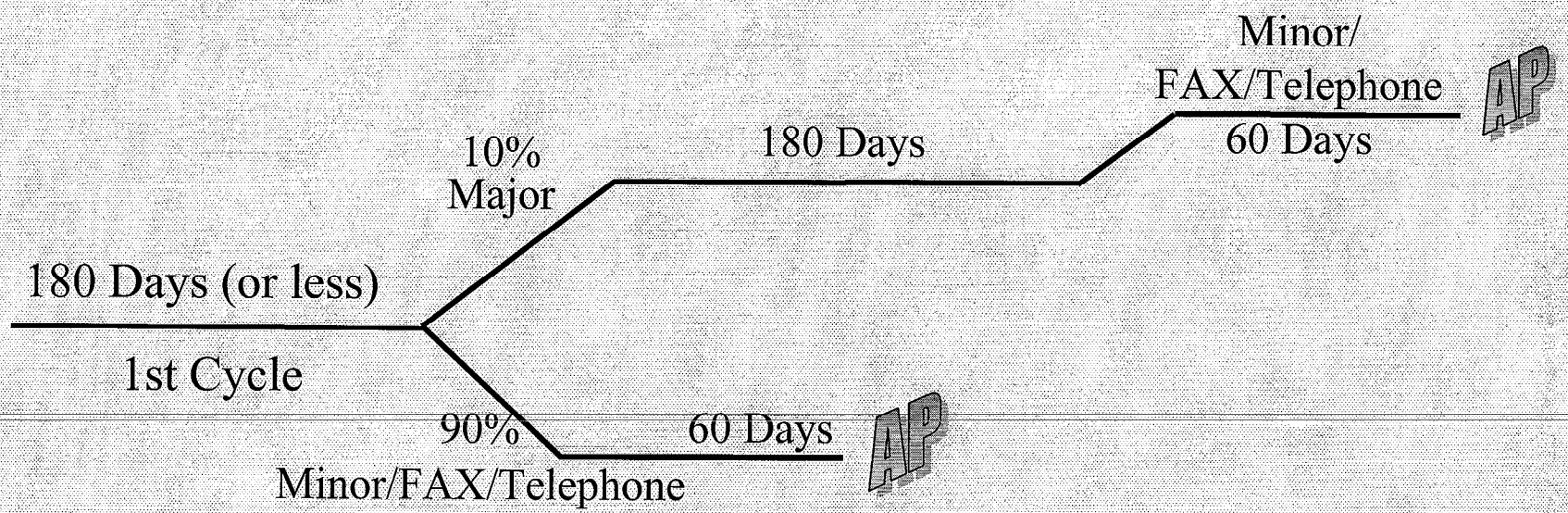
Original ANDAs

Present Review Path



Original ANDAs

Proposed Review Path



Revision of Guidance on Amendment Determination

- ✓Goal: Decrease time to final action on applications and supplements
  - Decrease or eliminate requests for re-designation
  - Keep application on reviewer's radar screen
  - Most amendments will be Minor---FAX category eliminated
  - Other rules, such as complete responses, still apply

Amendment Determination

- ✓Major
  - New Batch for any reason
  - New analytical methods and full validation data needed
- ✓Minor
  - Nearly everything else
  - Outside applicants control
- ✓Telephone
  - Clarification of data already submitted
  - During division or office level final review

Consistency

- ✓Major Goal of OGD
- ✓46 Chemistry Reviewers
  - Different educational backgrounds
  - Different personalities
- ✓New Major/Minor Policy will improve consistency with respect to result:
  - Most reviews will result in minors irrespective of how detail oriented the reviewer is

Industry Cooperation

- ✔ Initially -
  - – Minor reviews could take longer than 60 days
  - – Could take longer to get to original applications
- ✔ Existing amendments will not be reclassified
- ✔ There will be a period of adjustment

Revised Chemistry Telephone Procedure

- ✓Expect new procedure to increase efficiency of review process
- ✓Two general types of telephone communication by reviewers
  - Location/clarification of information
    - During initial review
  - Final resolution of technical issues
    - Usually follows review of minor amendment

Revised Chemistry Telephone Procedure

- ✓ Should not be of a nature to result in a substantial new submission
  - Deficiencies will be communicated in writing
  - Other topics will not be discussed
- ✓ Potential clarification during final division or office level review same

CAUTION: Don't Abuse

Other Guidance Endeavors

- ✓Electronic Labeling
  - Dr. Woodcock has made this a high priority
  - OGD representation on the committee
- ✓Finalizing guidance on referencing discontinued labeling

Pediatric Labeling Issue

- ✓ Identified Legal Issue
- ✓ Intersection of need for pediatric labeling and 3 year exclusivity for studies that result in changes in labeling
- ✓ Working to resolve matter ASAP

- User Fees ??

Office of Generic Drugs