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

5131 '01 NOV 30 P1:52

Date: November 27, 2001

To: Dockets Management Branch (HFA-305)

From: Melissa Lamb
Office of Generic Drugs

Subject: Update from the Office of Generic Drugs

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: FDA/GphA Fall Technical Workshop

Date Presented: October 29, 2001

Presented by: Gary J. Buehler, R.Ph.,
Director, Office of Generic Drugs

Number of Pages: 20

Melissa Lamb

Attachment

90S-0308

N 724

FDA/GPhA Fall Technical Workshop

Update from the Office of Generic Drugs

Gary J. Buehler, R.Ph.,
Director, Office of Generic Drugs

October 29, 2001

Topics

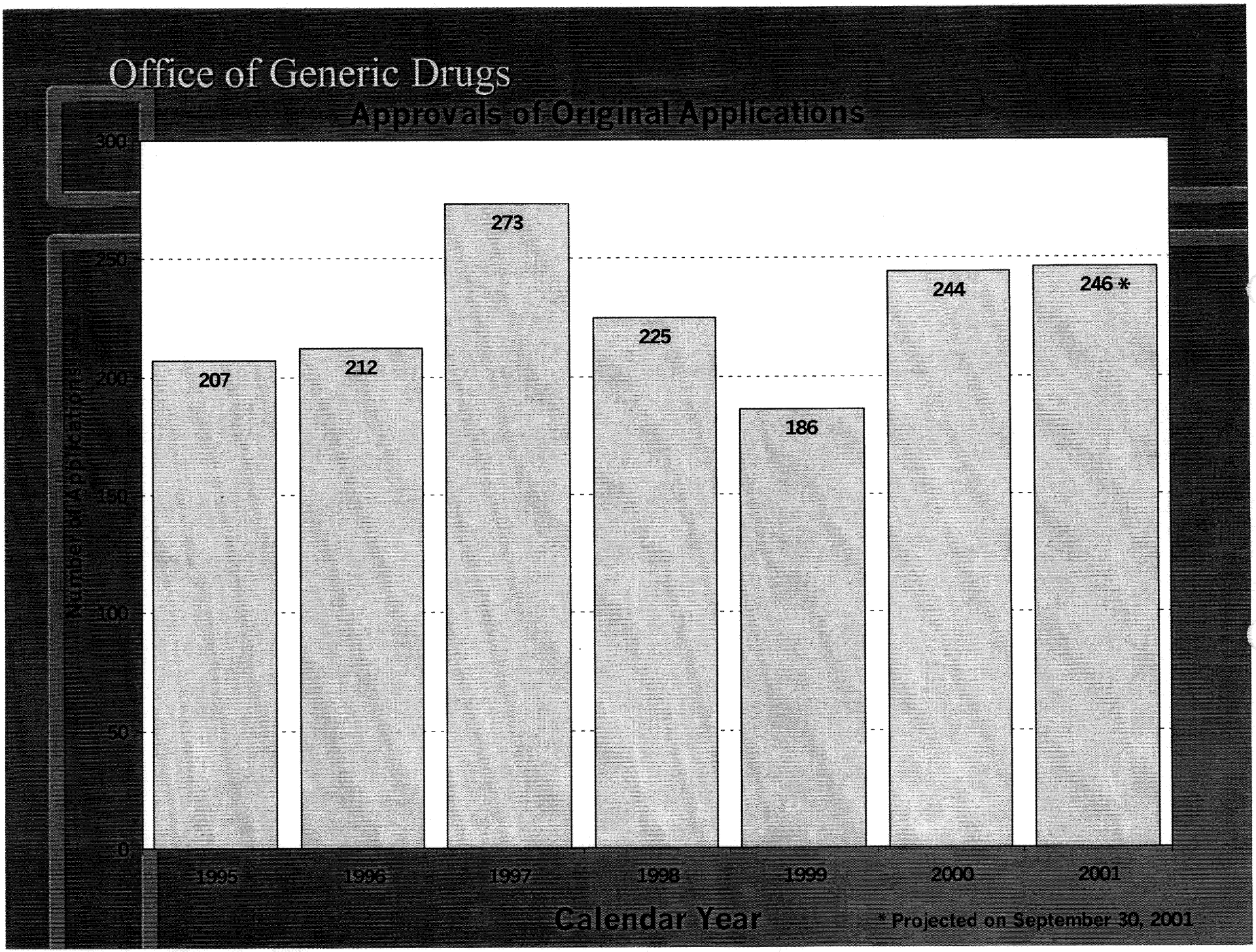
- Productivity
- Review Backlog
- FTE Initiatives
- Challenges

September 11, 2001

- Many have been in contact with OGD (Harvey Greenberg)
- Working with firms to develop risk plans
- Will involve expediting some supplemental applications
- Appreciate your cooperation

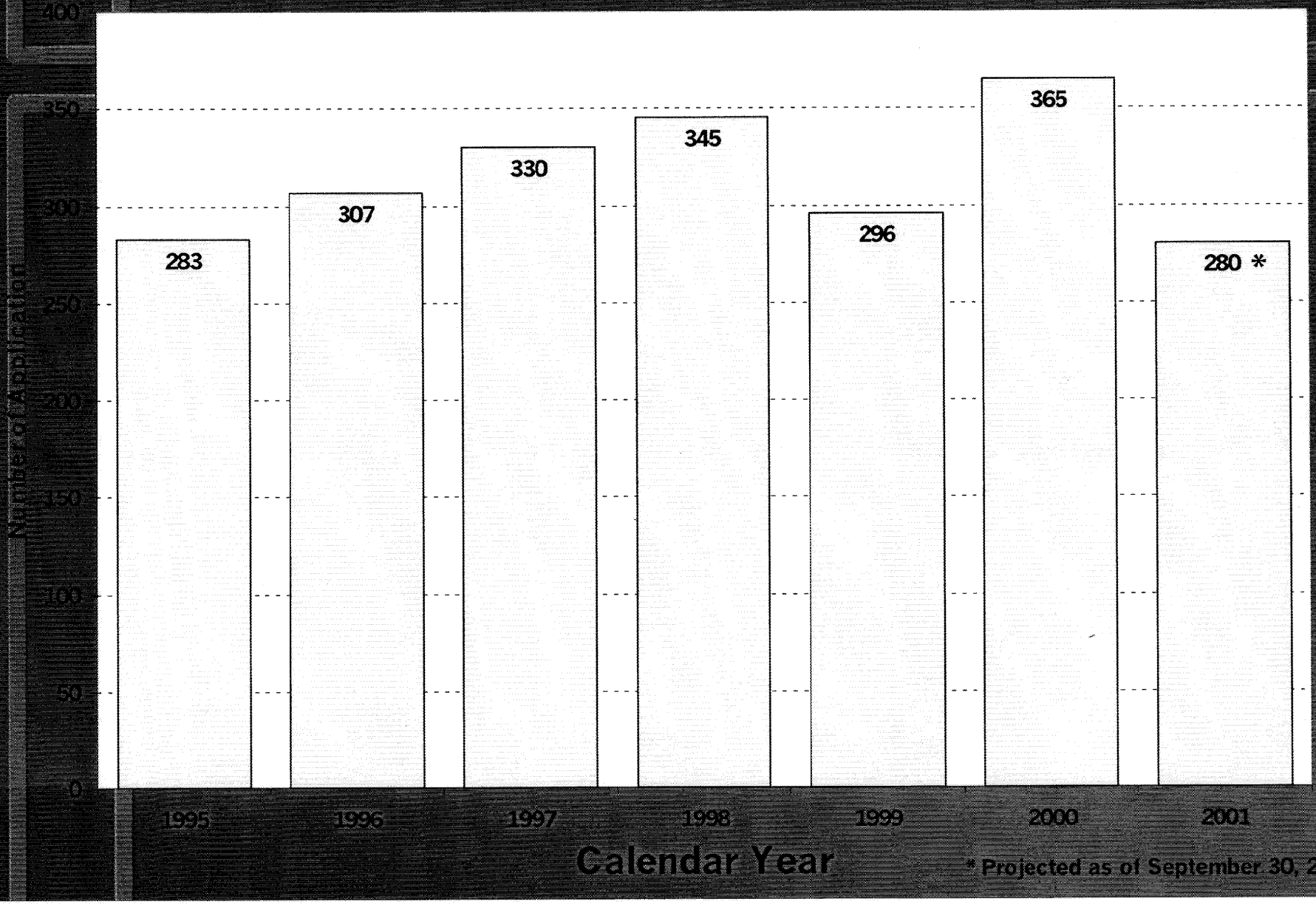
Office of Generic Drugs

Approvals of Original Applications



Office of Generic Drugs

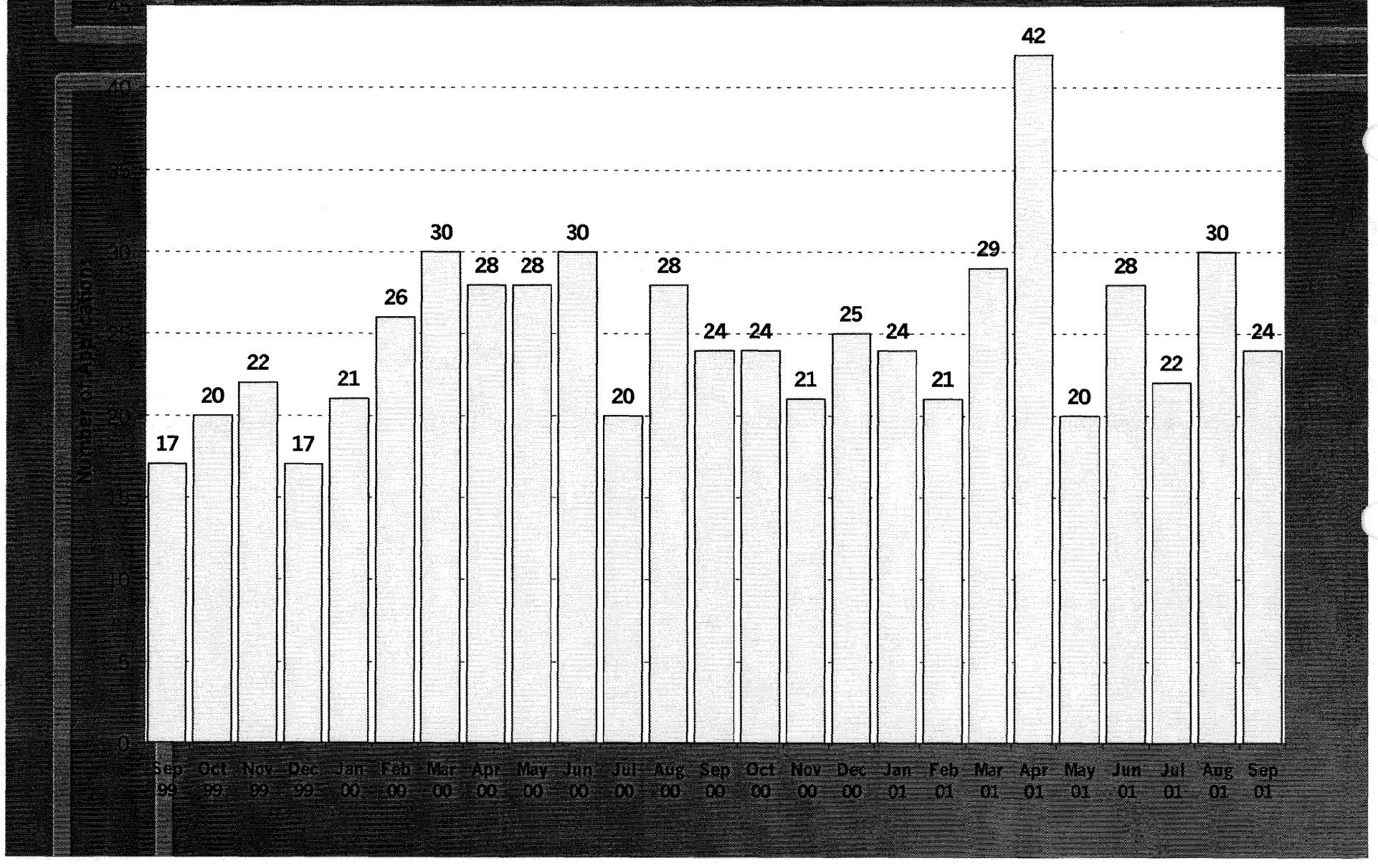
Receipts of Original Applications



Office of Generic Drugs

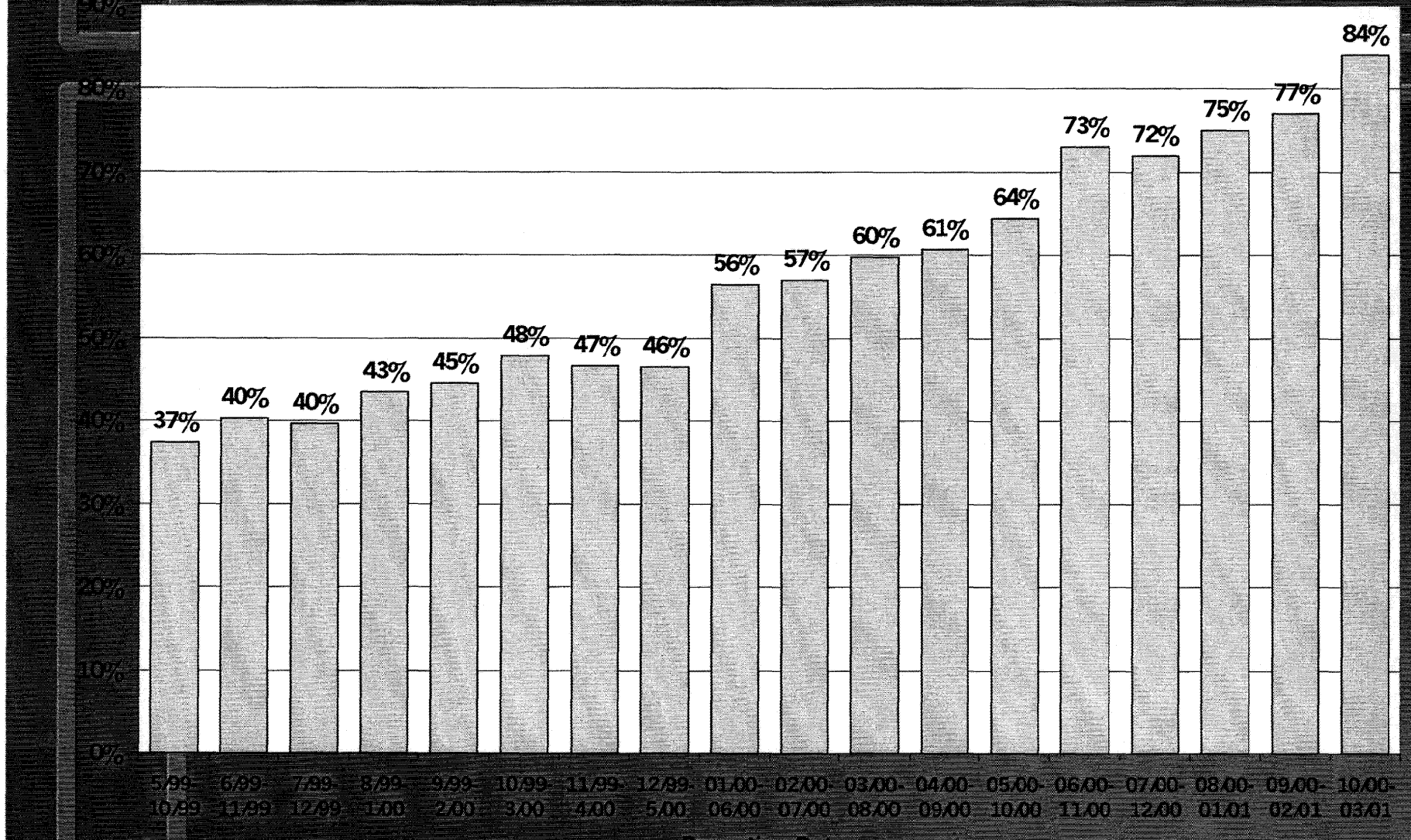
Approvals and Tentative Approvals

By Month



Office of Generic Drugs

GPRA Measure - % Originals Acted Upon < 180 Days

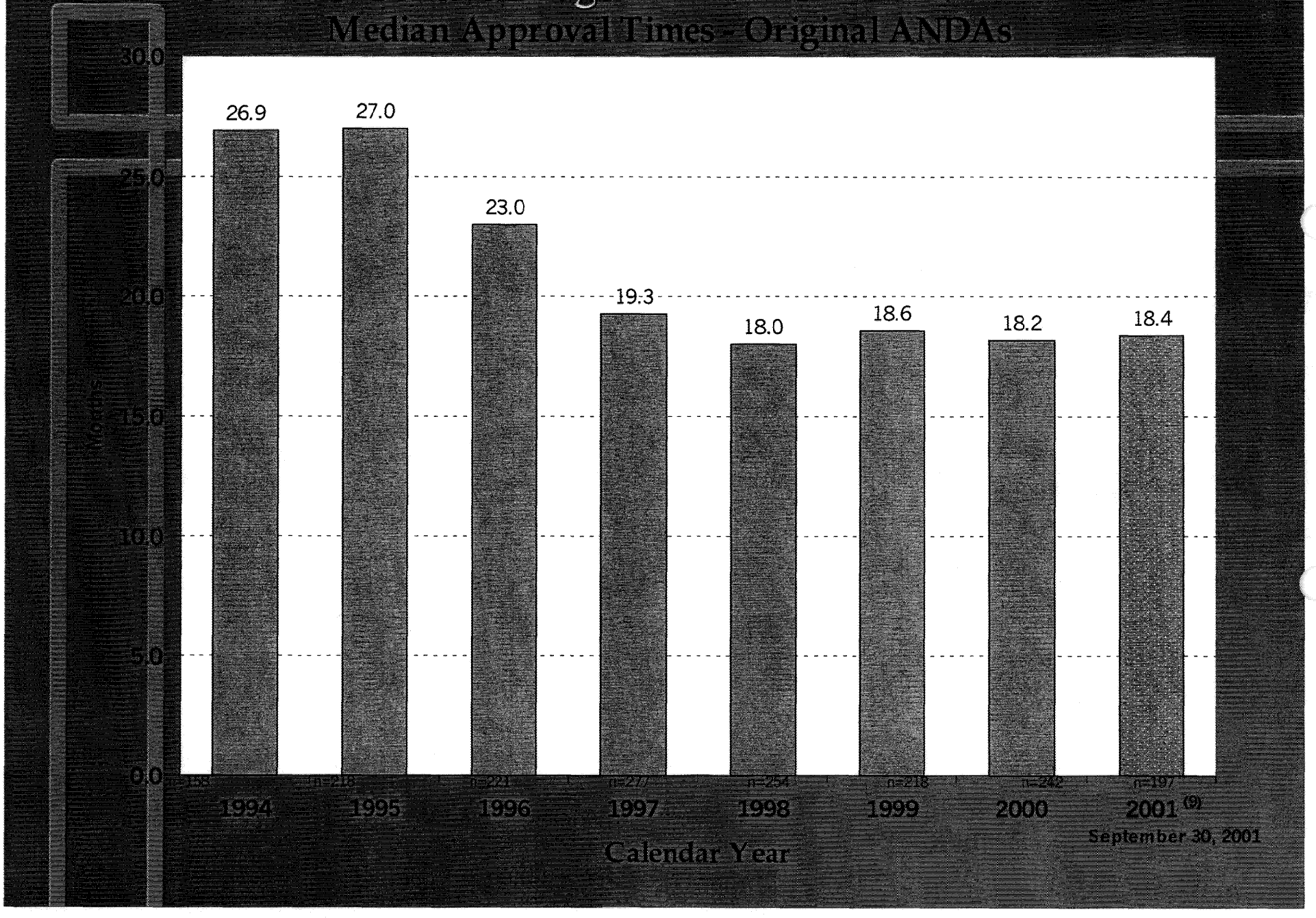


September 30, 2001

Government Performance & Results Act

Office of Generic Drugs

Median Approval Times - Original ANDAs



June 2000--Chemistry Review Backlog

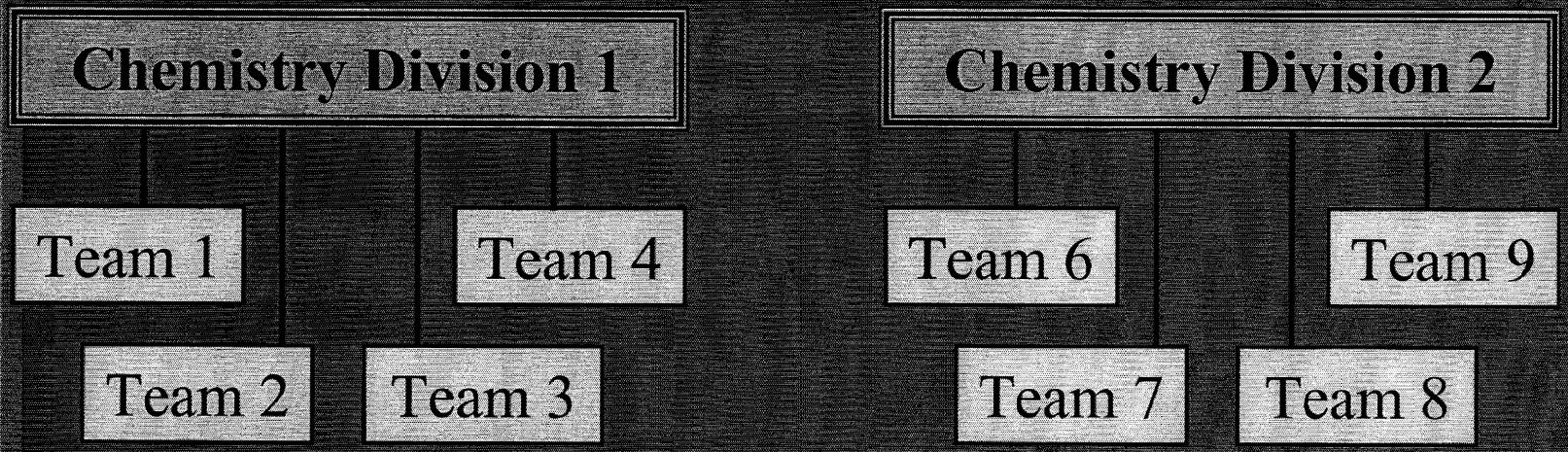
Division 1 - 122 Days		Division 2 - 125 Days	
Team 1	113 Days	Team 6	118 Days
Team 2	162 Days	Team 7	140 Days
Team 3	122 Days	Team 8	123 Days
Team 4	92 Days	Team 9	120 Days

October 2001--Chemistry Review Backlog

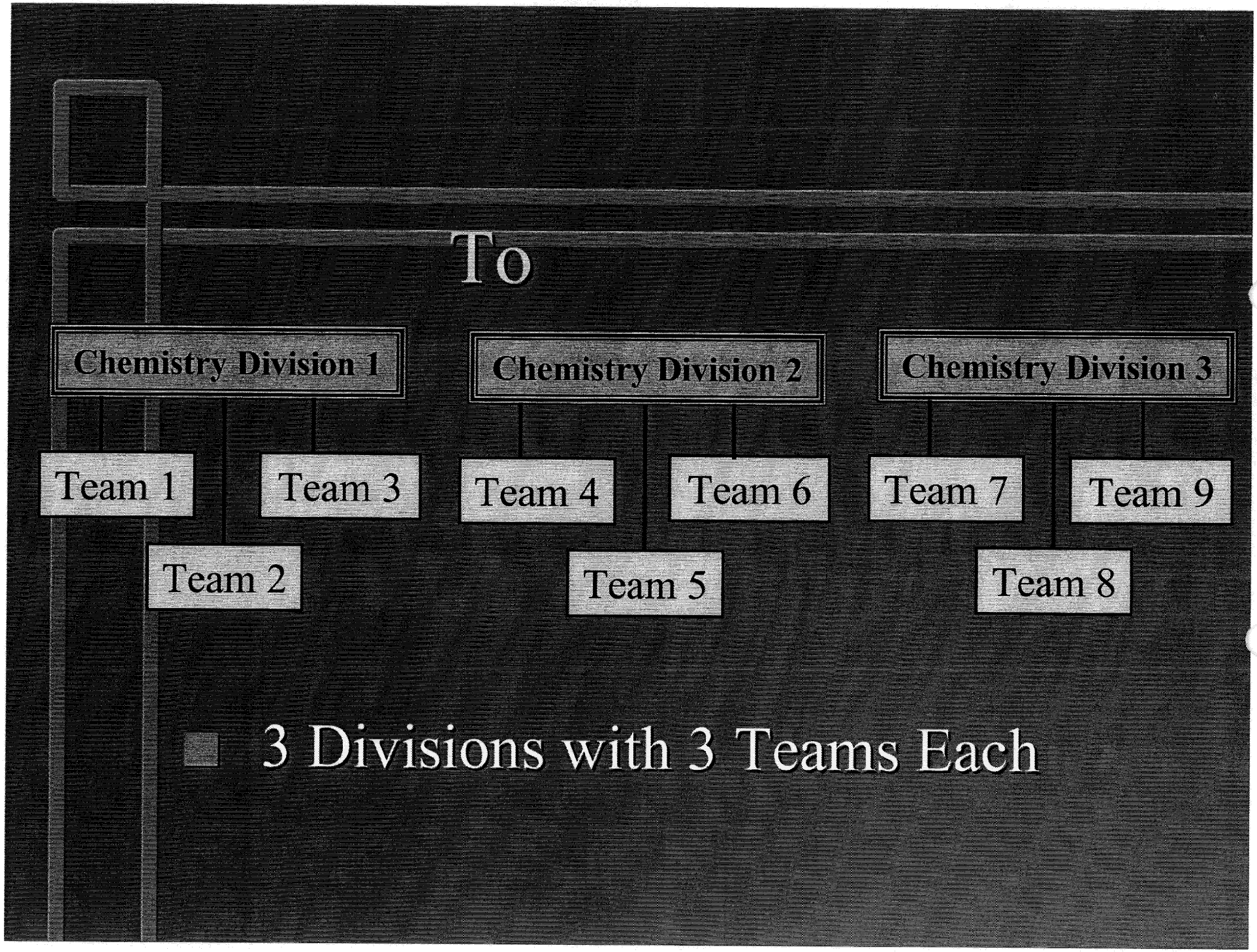
Division 1 - 73 Days		Division 2 - 80 Days	
Team 1	**84** Days	Team 6	**90** Days
Team 2	**98** Days	Team 7	**80** Days
Team 3	**0** Days	Team 8	**93** Days
Team 4	**110** Days	Team 9	**55** Days

Proposal for Change

From



- 2 Divisions with 4 Teams Each


To
Chemistry Division 1
Chemistry Division 2
Chemistry Division 3
Team 1
Team 2
Team 3
Team 4
Team 5
Team 6
Team 7
Team 8
Team 9
3 Divisions with 3 Teams Each

Question...

- DMF Team?
  - Improve quality and consistency of DMF reviews
  - Improve efficiency of chemistry review

Other Possible Initiatives

- Address review of bioequivalence trials with clinical endpoints
- Address first generic reviews
- Address scientific issues and challenges
- Address legal issues
- Address inspection delays

Labeling Issues

- Discontinued Labeling Guidance
- Pediatric Waxman-Hatch Exclusivity

Challenges

Globalization of the Pharmaceutical Industry

- Many active pharmaceutical ingredients are from foreign sources (estimated 70-80%)
- Inspections are critical to assure safe, quality products
- Inspection capability needs to be expanded to meet this demand and projected increases in review efficiency

Challenges

- Innovator Firms' Tactics to Delay Generics
  - Labeling Changes
  - Patent Listings
  - 180 Day Exclusivity
  - Lawsuits
  - Pediatric Exclusivity

Challenges

- Review Efficiency
  - 18-month average time to approval for a generic product
  - Hope to decrease to 12-14 months through staff increases and better review efficiency

Challenges

Generic Drug Education and Awareness Program

- A general bias exists against generic drugs - perpetuated by innovator industry
- Program will emphasize the quality and equivalence of generic products
- Targets medical professionals as well as lay public
- Consists of presentations, brochures, public service announcements (radio, TV)

Office of Generic Drugs