

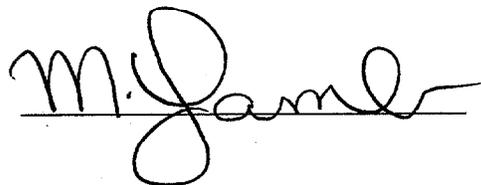
M E M O R A N D U M

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

Date: February 8, 2000
To: Dockets Management Branch (HFA-305)
From: Melissa Lamb
Office of Generic Drugs
Subject: Office of Generic Drugs Update

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: Office of Generic Drugs Update
Presented for: 1999 Fall Technical Workshop
Date Presented: 10/18&19/99
Presented by: Douglas L. Sporn
Number of Pages: 16



Attachment

90S-3860 '00 FEB 11 A9:25

90S-0308

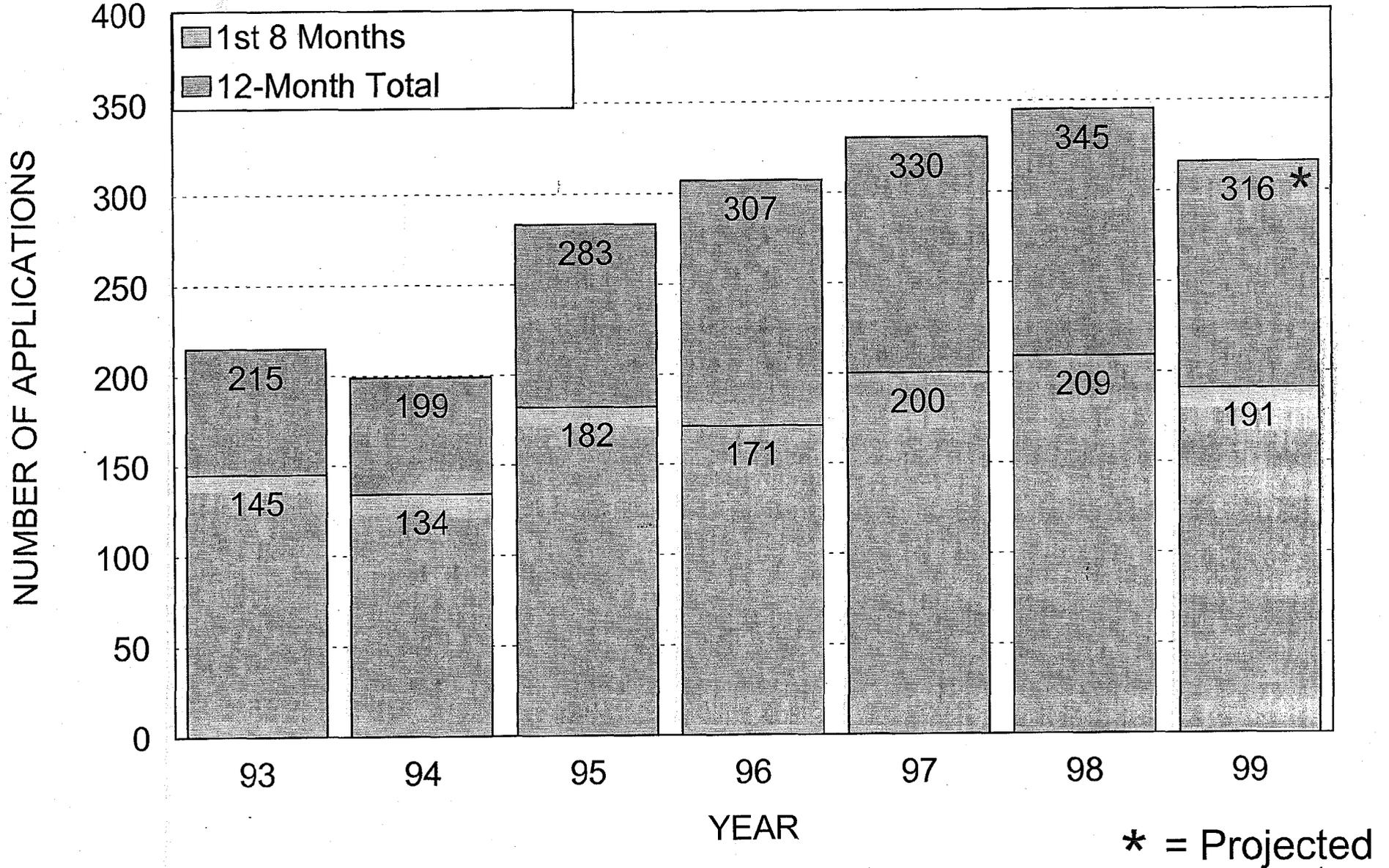
M657

1999 Fall Technical Workshop

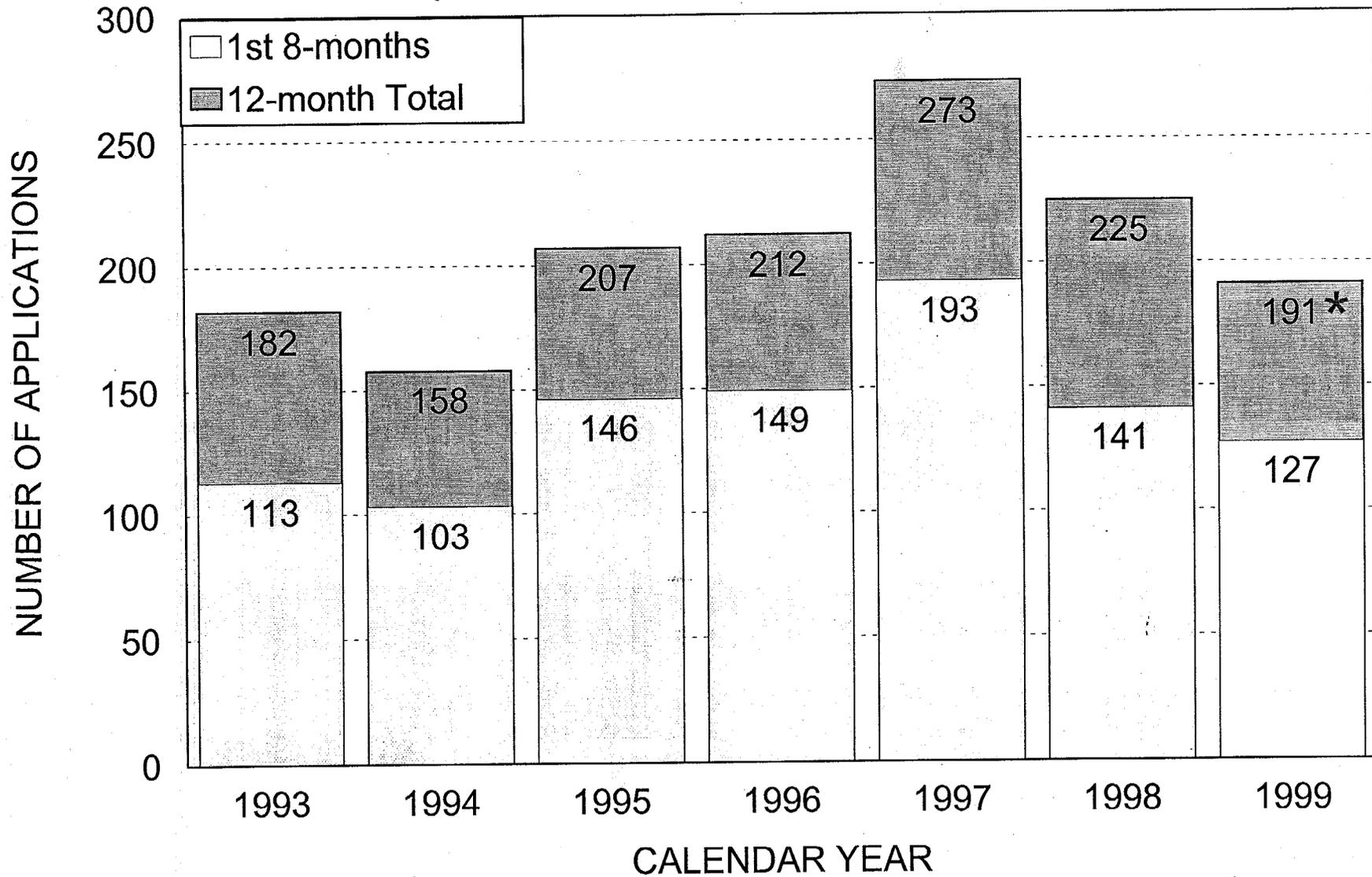
Office of Generic Drugs
Update

Douglas L. Sporn, Director
Office of Generic Drugs
October 18-19, 1999
Bethesda, MD

Calendar Year Receipts (New Counting System)



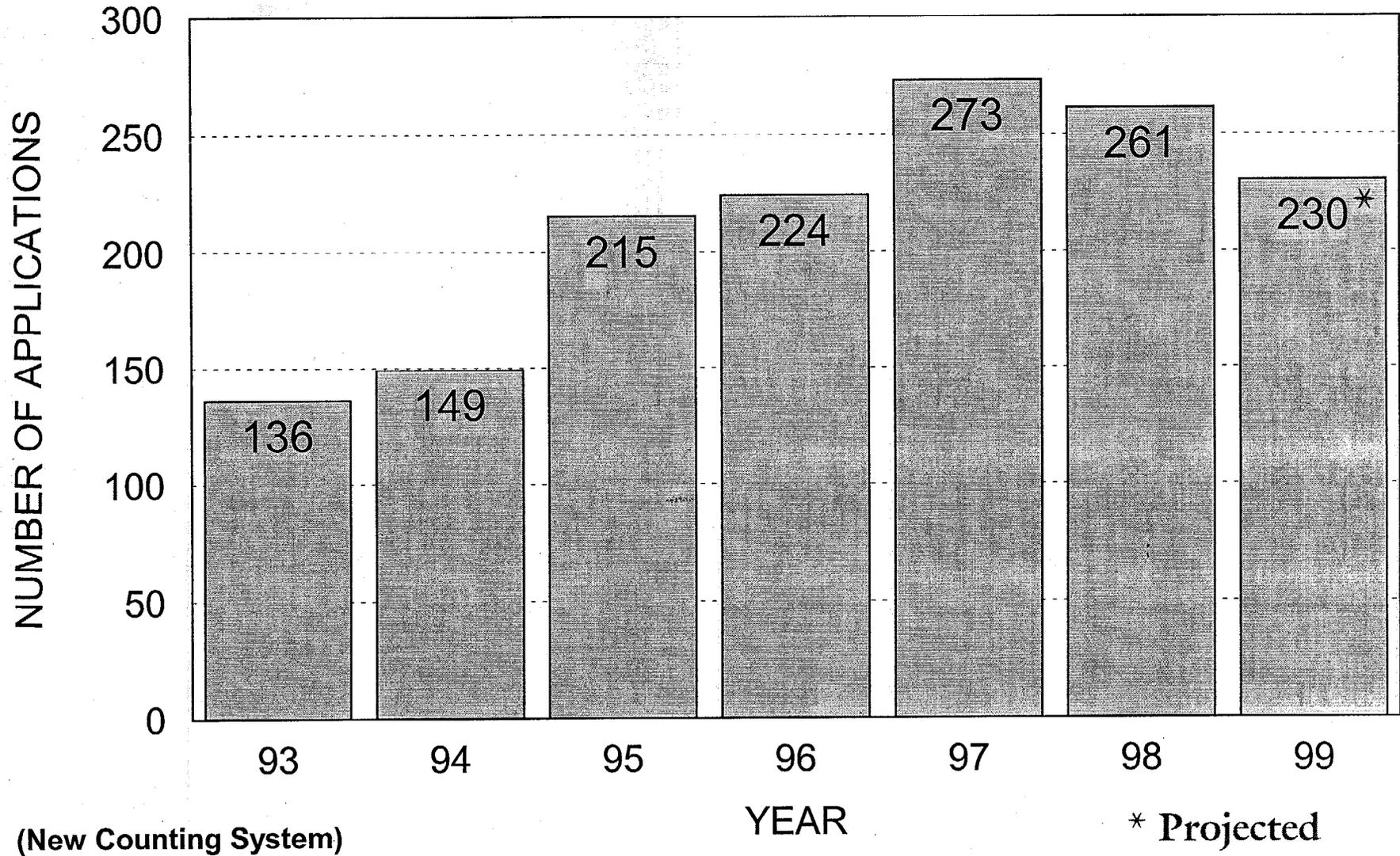
Calendar Year Approvals (New Counting System)



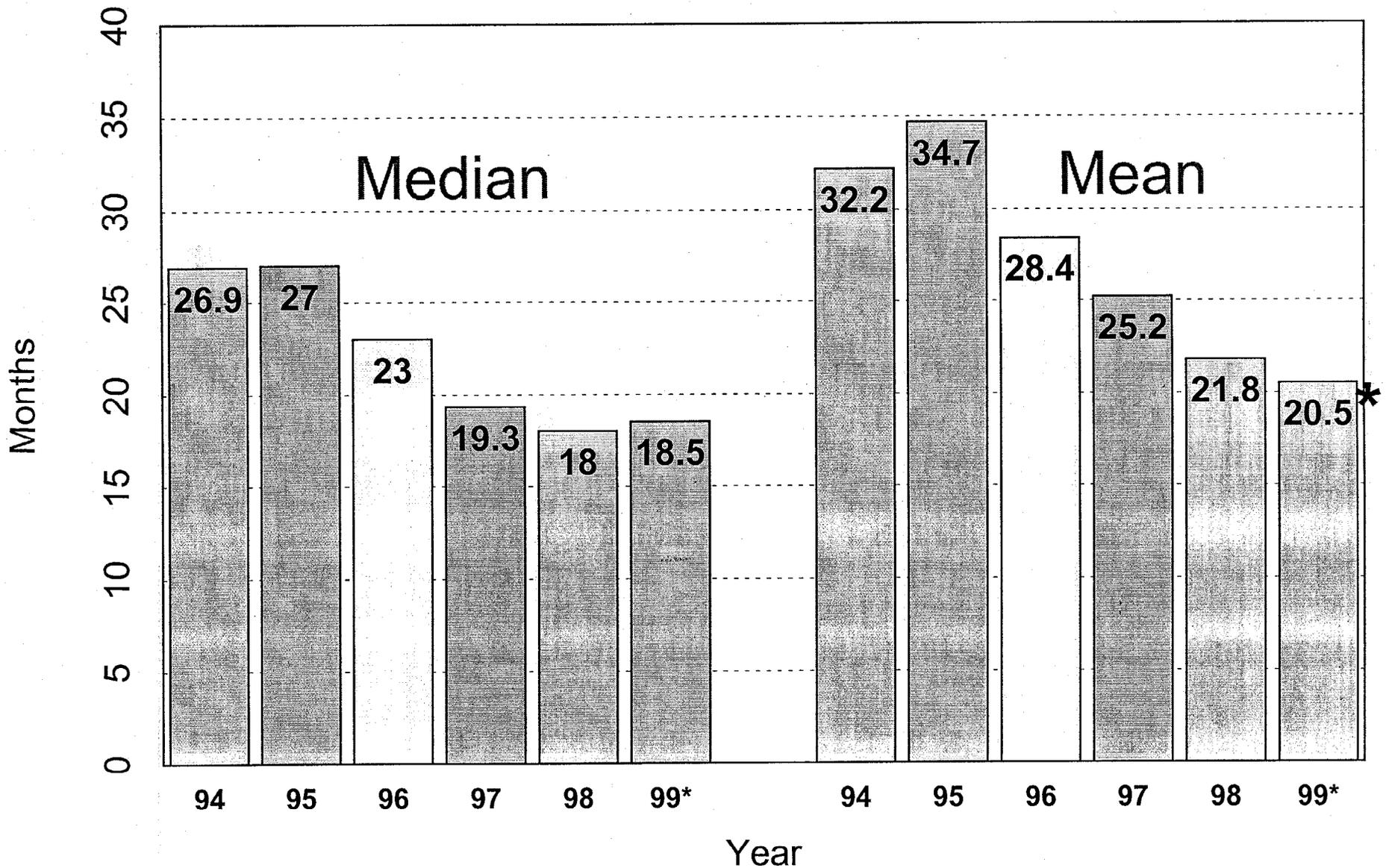
* = Projected

Calendar Year Tentative or Actual Approvals

(Subsequent approvals of TAs not counted again)



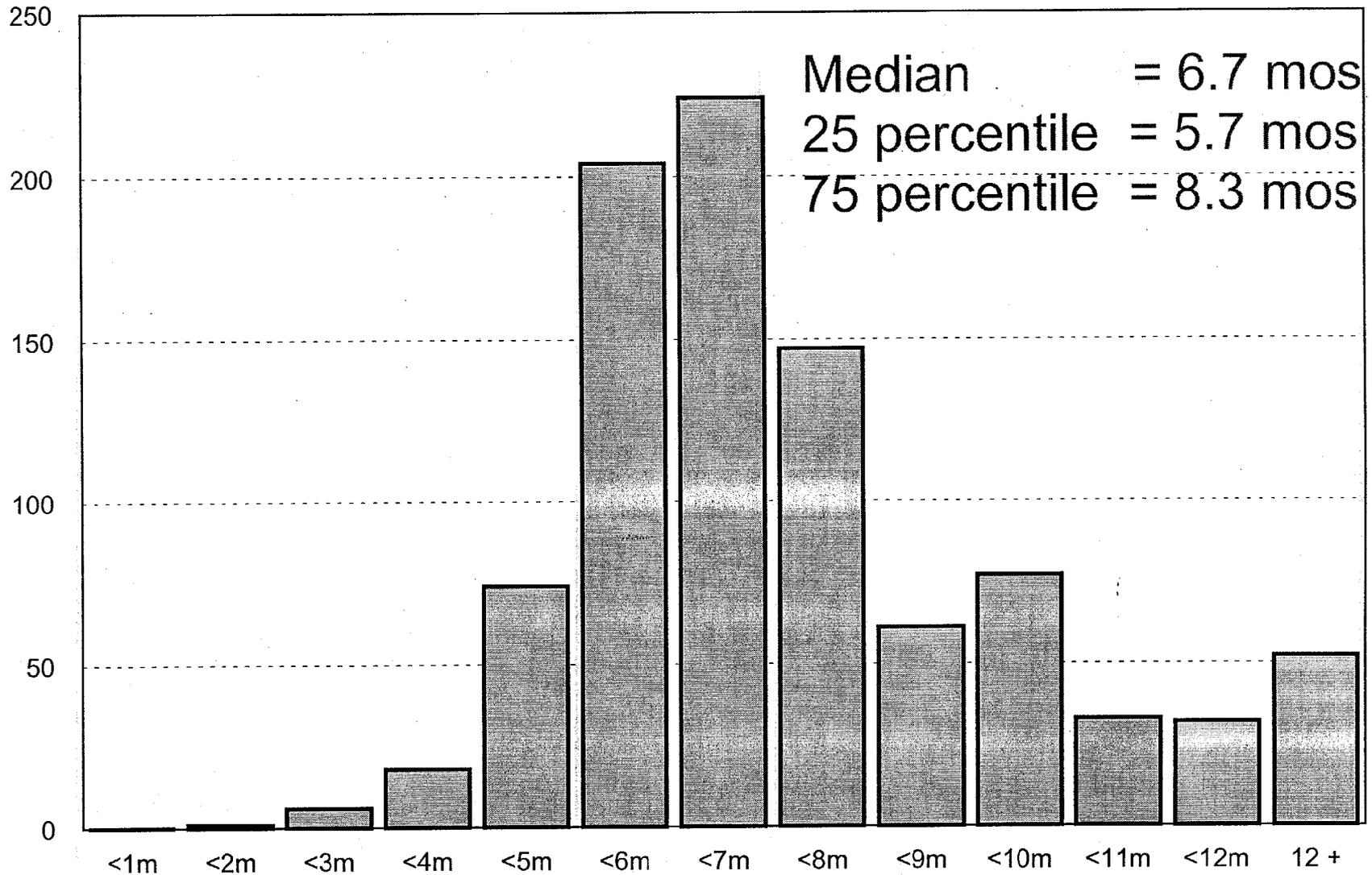
Calendar Year Approval Times



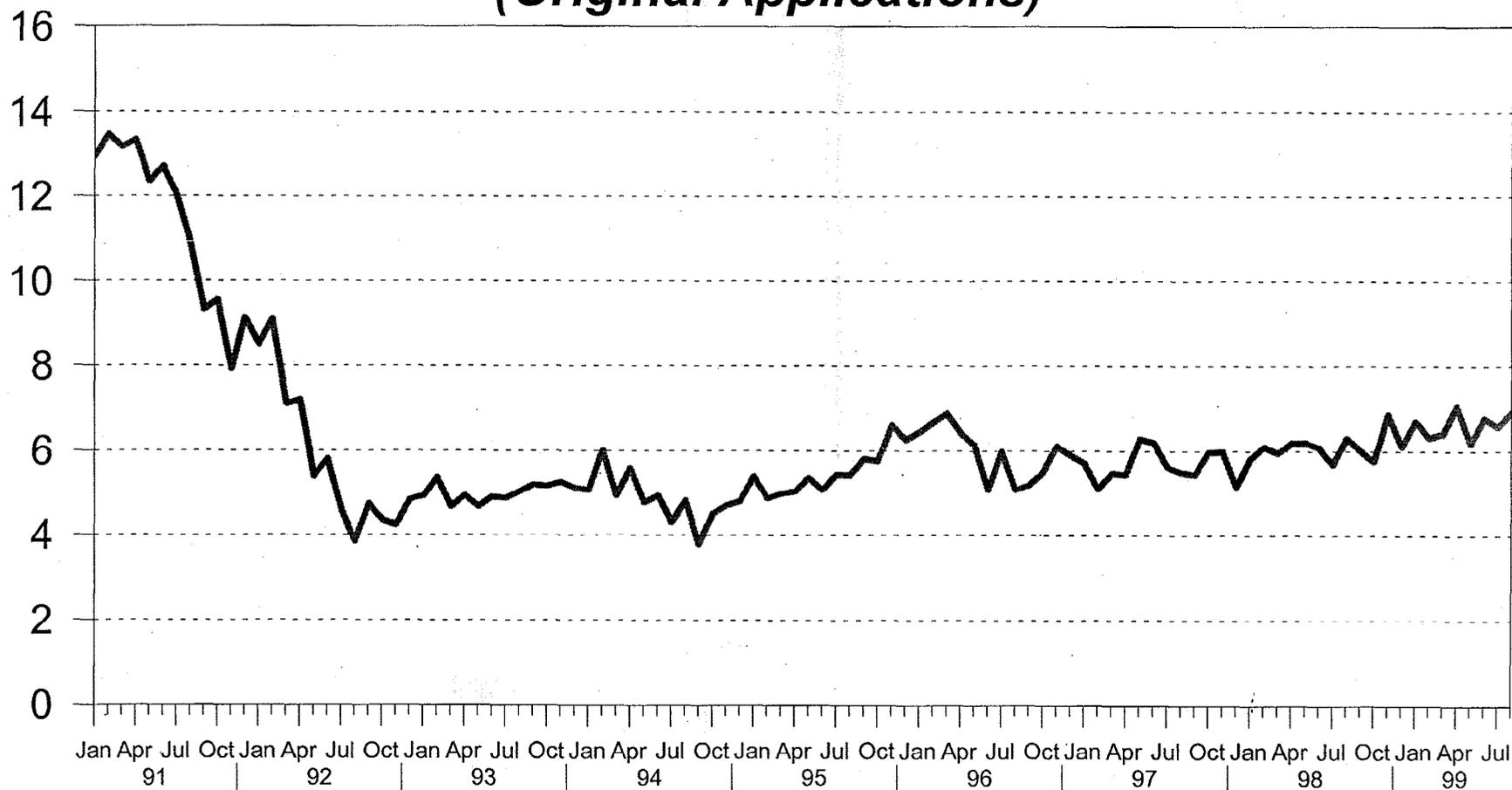
* = Through August 31, 1998

Distribution of Review Times for Original ANDAs

Major Cycles Only--1/1/98--8/31/99



Median ANDA Review Cycle (Months) **(Original Applications)**



— median

1-Times correspond to actual applications received . The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

2-In September, 1991 the OGD started implementation of the Application Integrity Policy by suspending review of applications suspected of being tainted by fraud. AIP time has been subtracted from review time above for the period after 9/91. However, before the AIP went into effect, the review of many applications suspected of containing fraudulent data were suspended. These suspensions were not recorded in the MIS and are not reflected in the above chart.

Challenges - Four Areas

- ◆ Legal
- ◆ Regulatory/Legislative
- ◆ Scientific/Pharmaceutical Use Issues
- ◆ Submission/Review Related

Legal Challenges

- ◆ Lawsuits
- ◆ Petitions

Pending Petitions & Lawsuits

Number of Pending Petitions Needing OGD Input	22	(13)
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Number of Lawsuits Involving OGD	7	(3)
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Active Citizen Petitions and Lawsuits

<u>Topic</u>	<u>Petitions</u>	<u>Lawsuit</u>
Amiodarone	✓	
Clozapine	✓	
Cyclosporine		✓
Diltiazem	✓ ✓ ✓	
Gabapentin	✓	
Estradiol	✓	
Naproxen	✓	

Active Citizen Petitions and Lawsuits

<u>Topic</u>	<u>Petitions</u>	<u>Lawsuit</u>
Phenytoin		✓
Propafenone	✓	
Propofol	✓ ✓ ✓	✓
Ursodiol	✓	

Regulatory/Legislative Challenges

- ◆ Proposed 180-Day Exclusivity Regulation
- ◆ State Legislature Efforts for NTI & Critical Care Drugs Continue
- ◆ Continue FDAMA Mandates

Scientific/Pharmaceutical Use Issues

- ◆ Post-Marketing Strategies
- ◆ New Methodologies - Need to Validate
- ◆ Variations in Reference Listed Drugs

Submission/Review Related

- ◆ Industry Training and Education
- ◆ Better Approach to Inactive Ingredients Questions
- ◆ Submit a Quality ANDA
 - ✓ Cover letters
 - ✓ Complete submissions
 - ✓ Call to clarify deficiencies
 - ✓ In house quality control
 - ✓ Sterility assurance--separate section

Submission/Review Related (continued)

- ◆ Check DMF Status
- ◆ Submit Electronic ANDAs
- ◆ QC Electronic Submissions
- ◆ Fatally Flawed Applications
- ◆ Phone Inquiries
- ◆ Use the Internet
- ◆ "Chain of Command"