

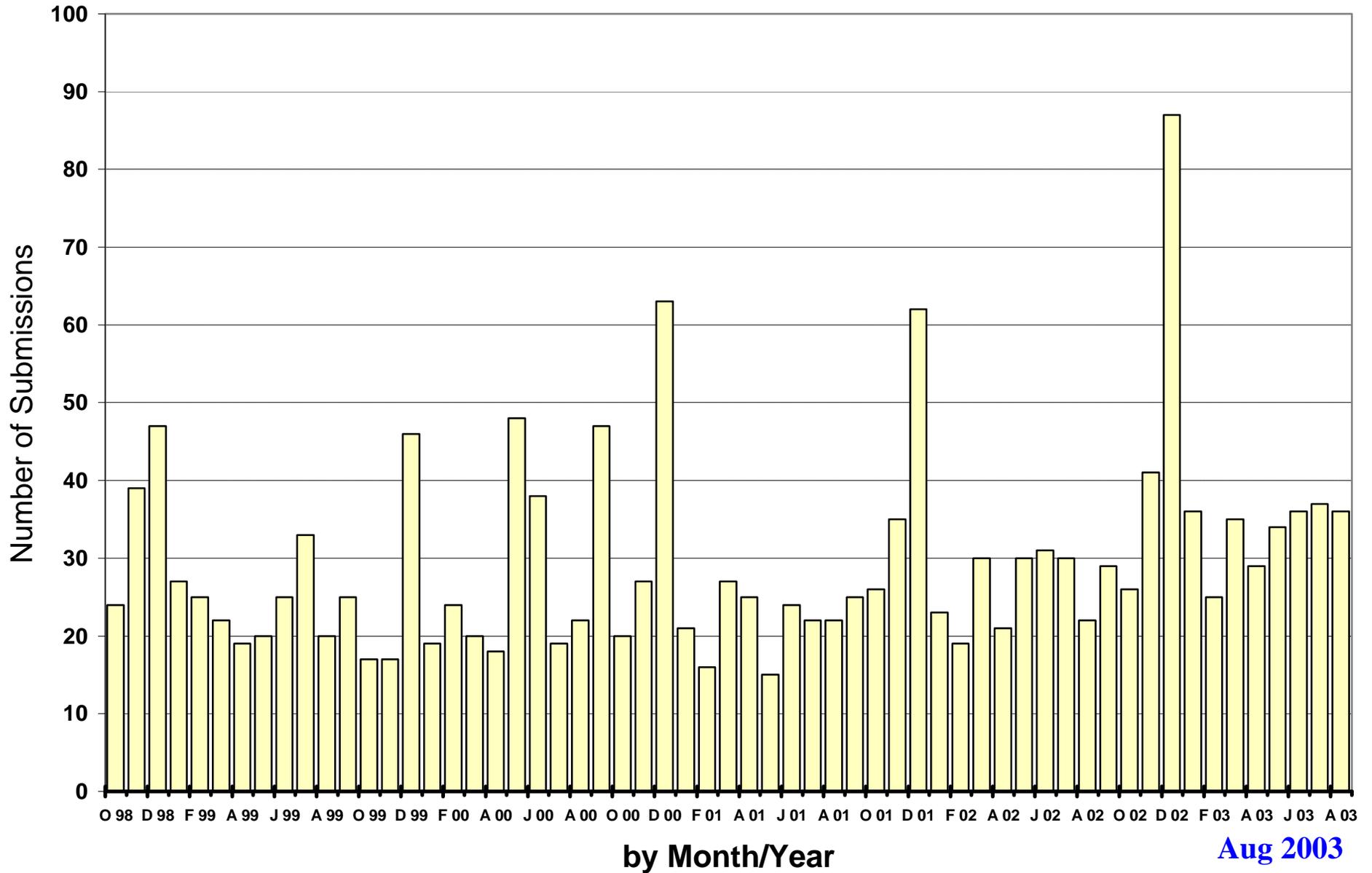
Center for Drug Evaluation and Research

# Office of Generic Drugs

Monthly Quantitative Report  
and Statistical Charts

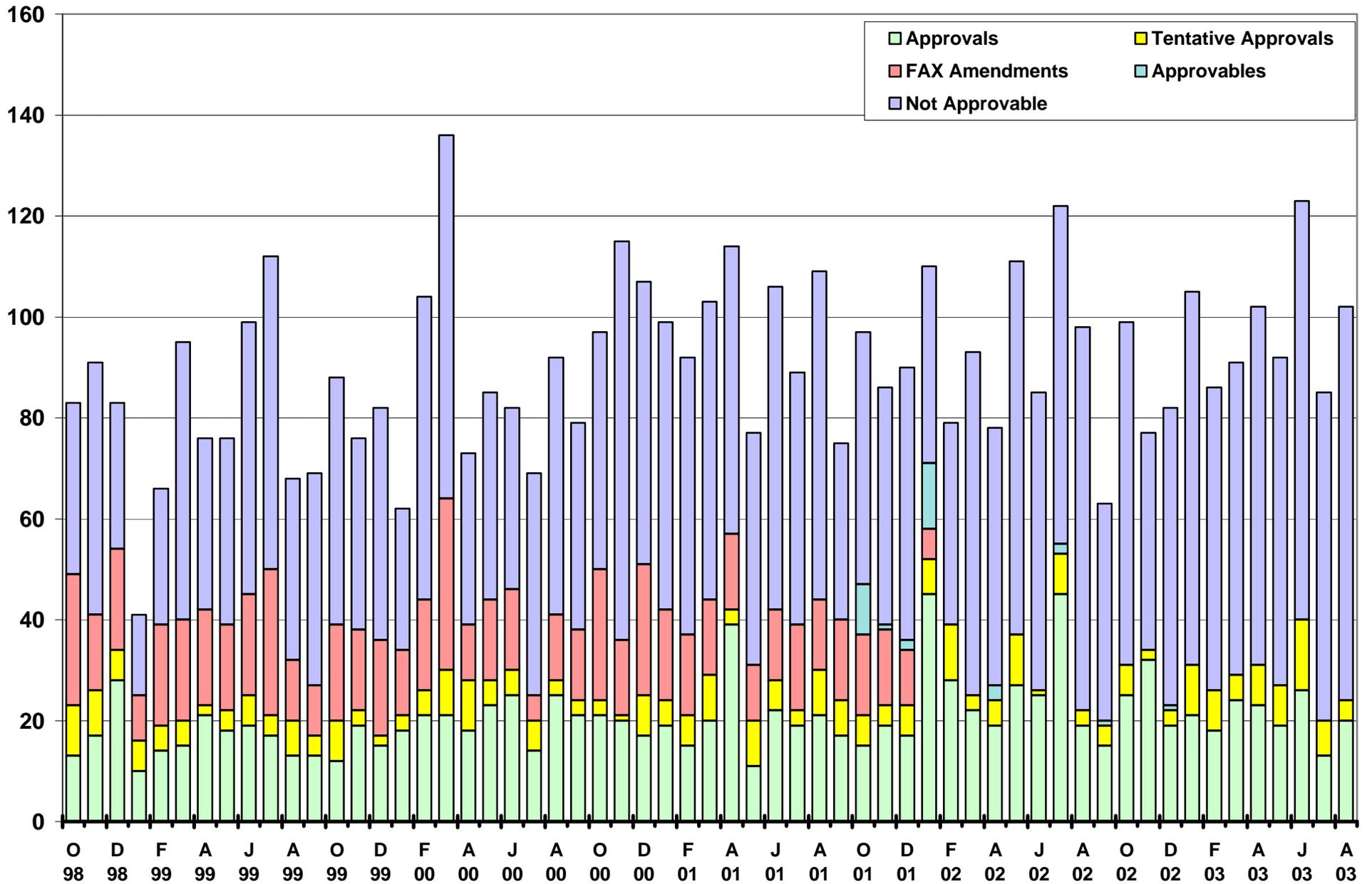
August 2003

# Original ANDAs Received



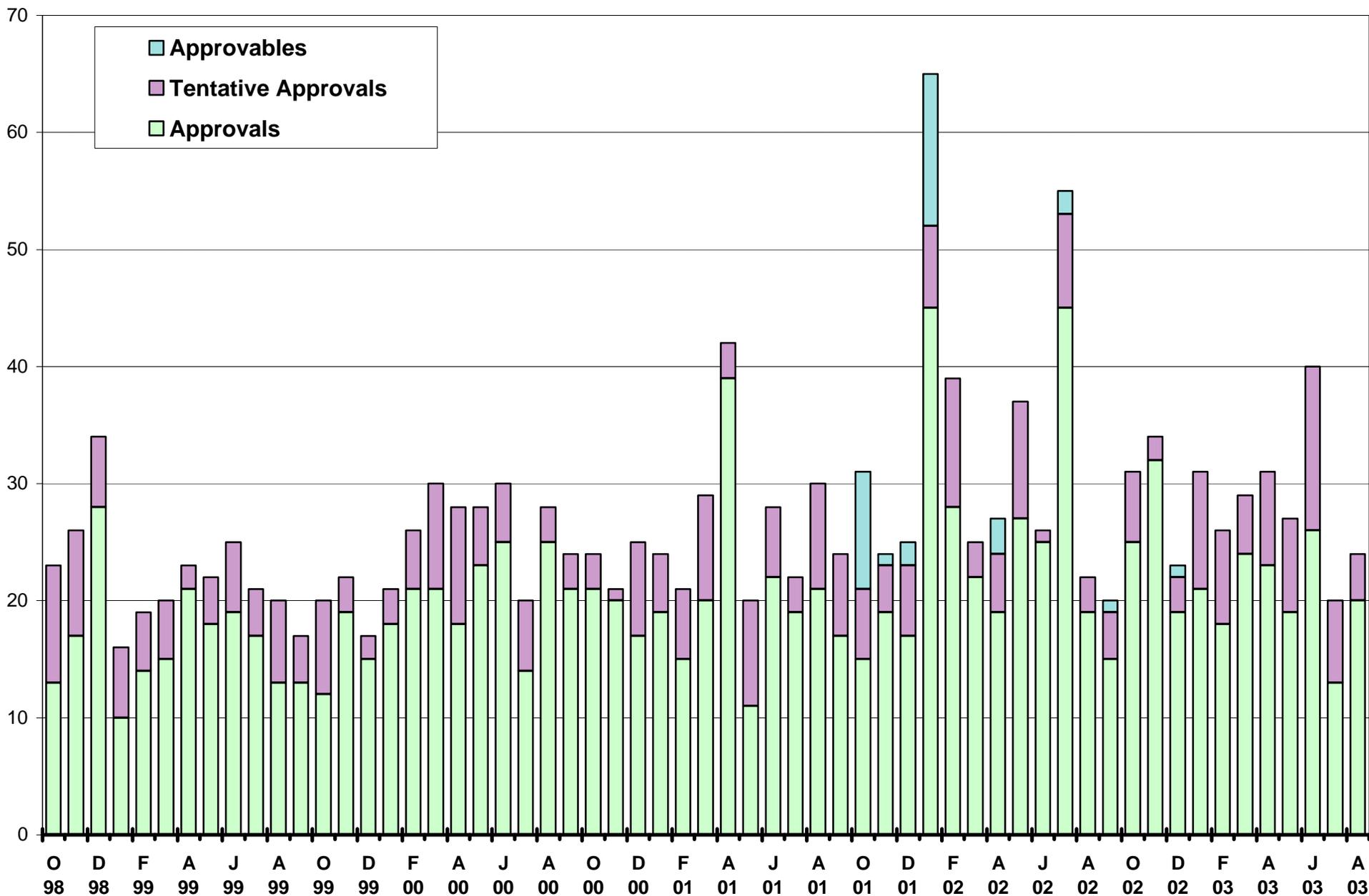
Aug 2003

# Actions on Original ANDAs



Note: Tentative Approvals (TA) are applications that have been approved by the office pending patent expiration. TAs and Approvables(AE) are counted as approvals subsequently when approved.

# Original ANDAs Approved or Tentatively Approved

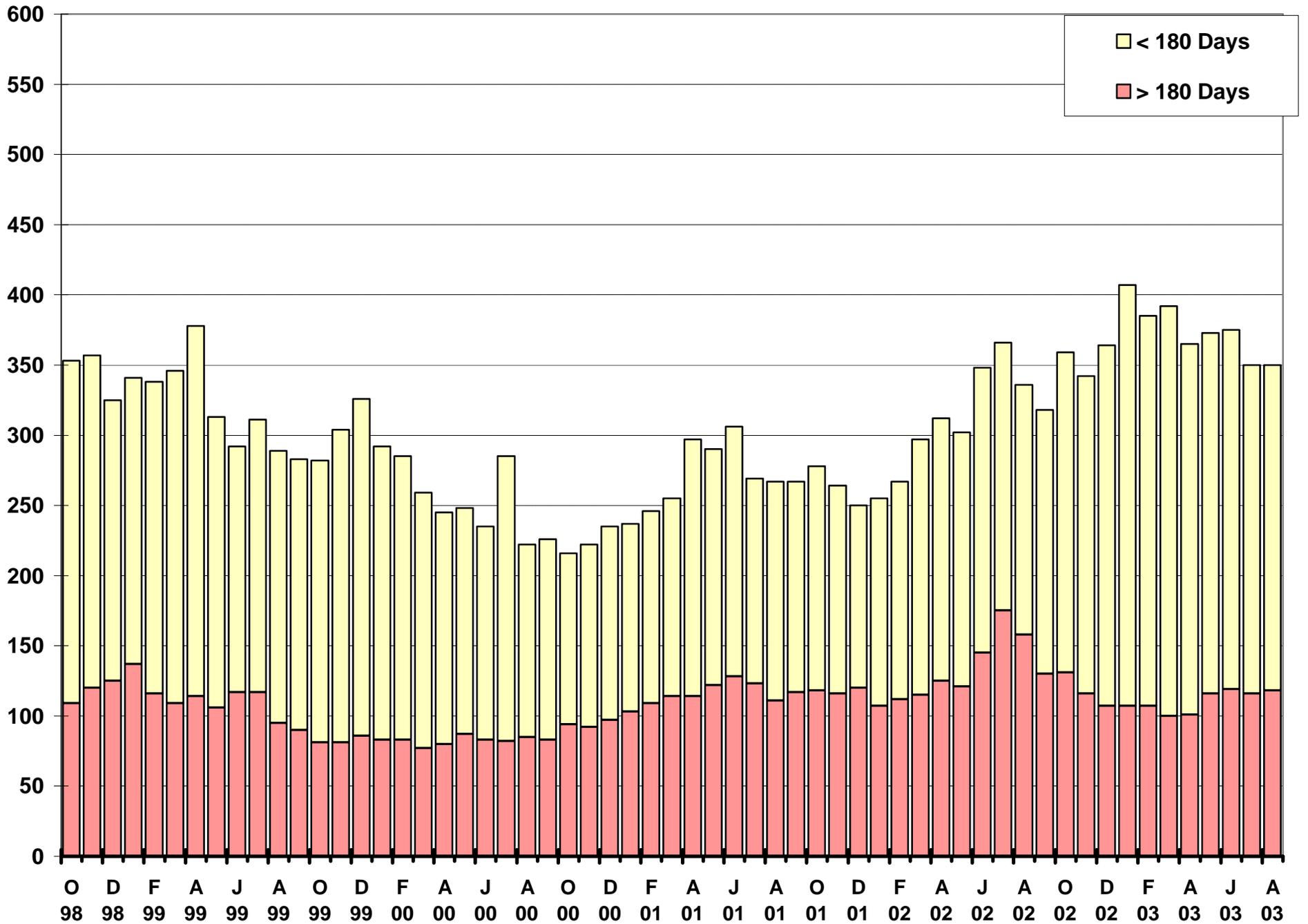


Note: Tentative Approvals (TA) are applications that have been approved by the office pending patent expiration. TAs and Approvables (AE) are counted as approvals subsequently when approved.

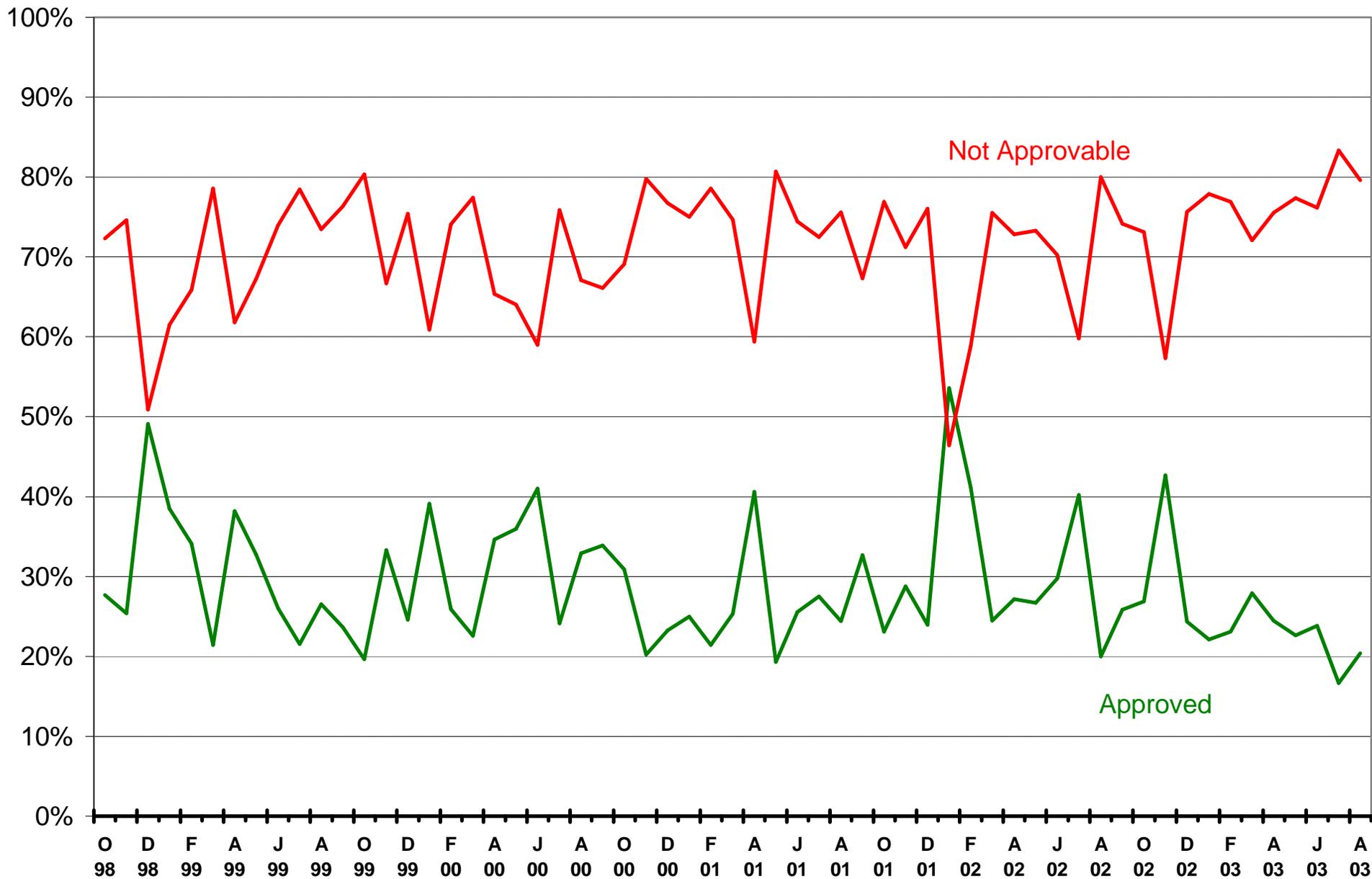




## *Labeling Supplements Awaiting OGD Action*

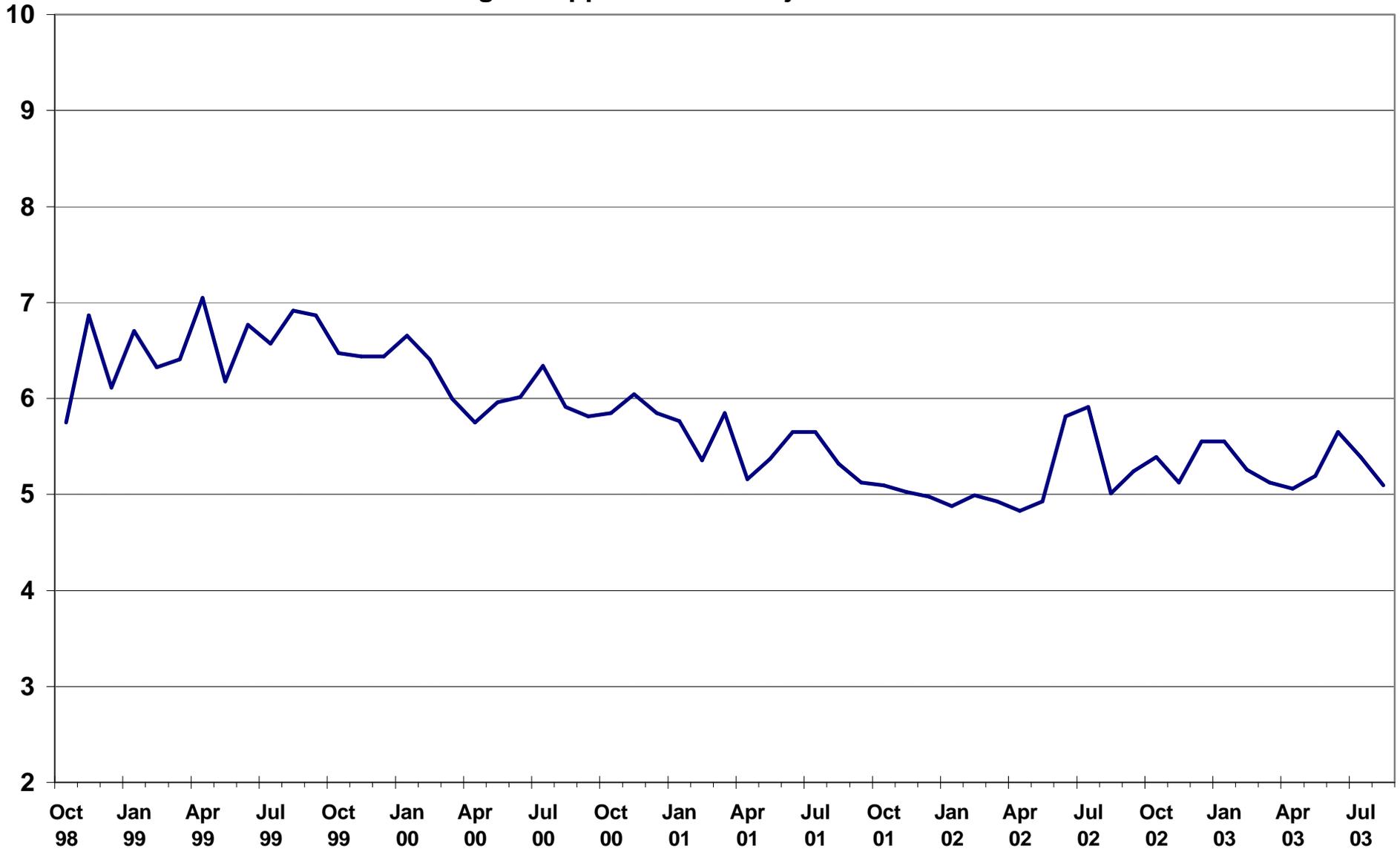


ANDA Originals  
Percent **Approved** and **Not-Approvable**  
By Month



# Median ANDA Review Cycle (Months)

## Original Applications & Major Amendments

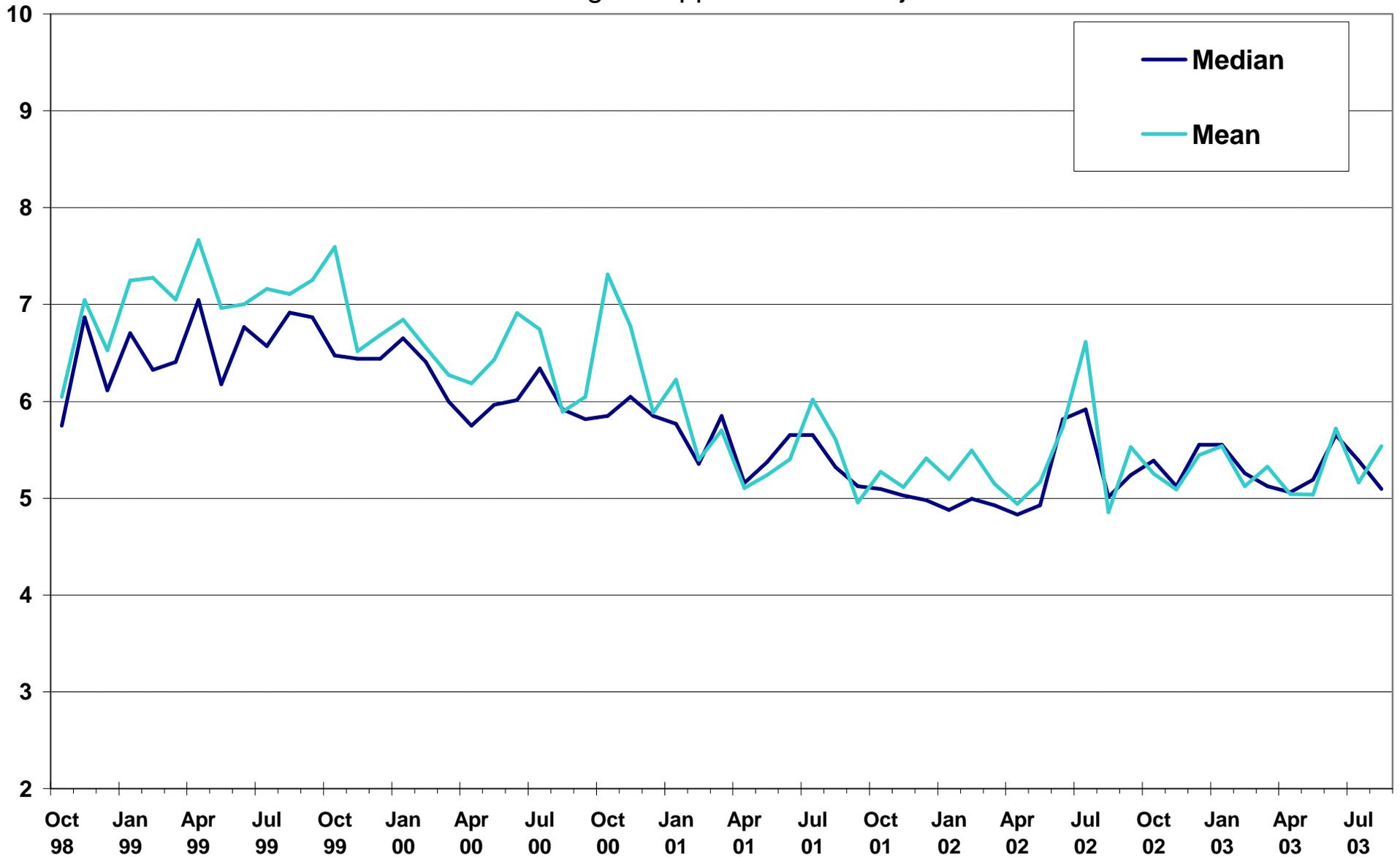


1 - Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

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 therefore, been subtracted from review time 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 reflected in the above chart.

# Mean and Median ANDA Review Cycle (Months)

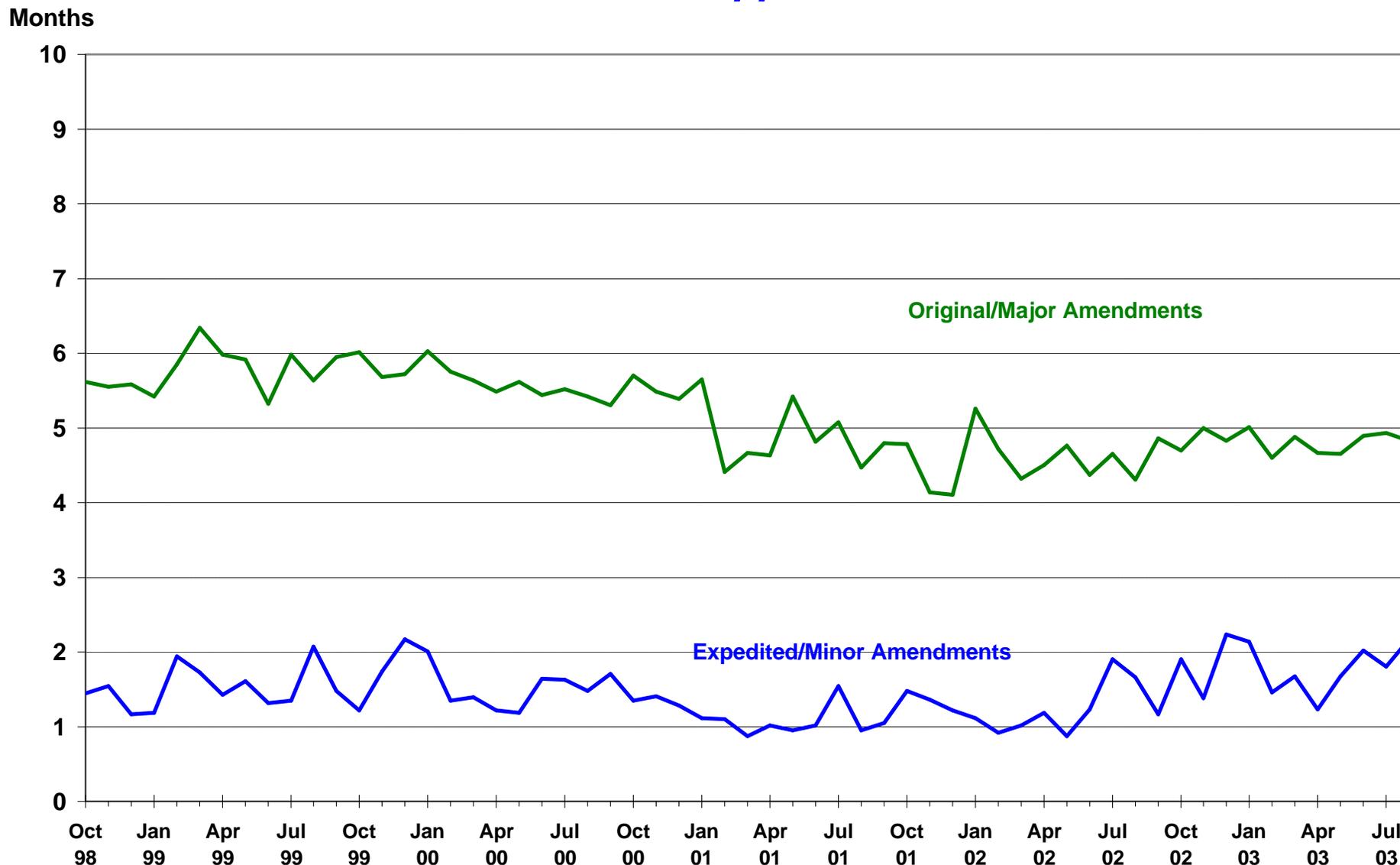
Original Applications & Major Amendments



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.

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## *Median ANDA CMC Supplement Review Time*

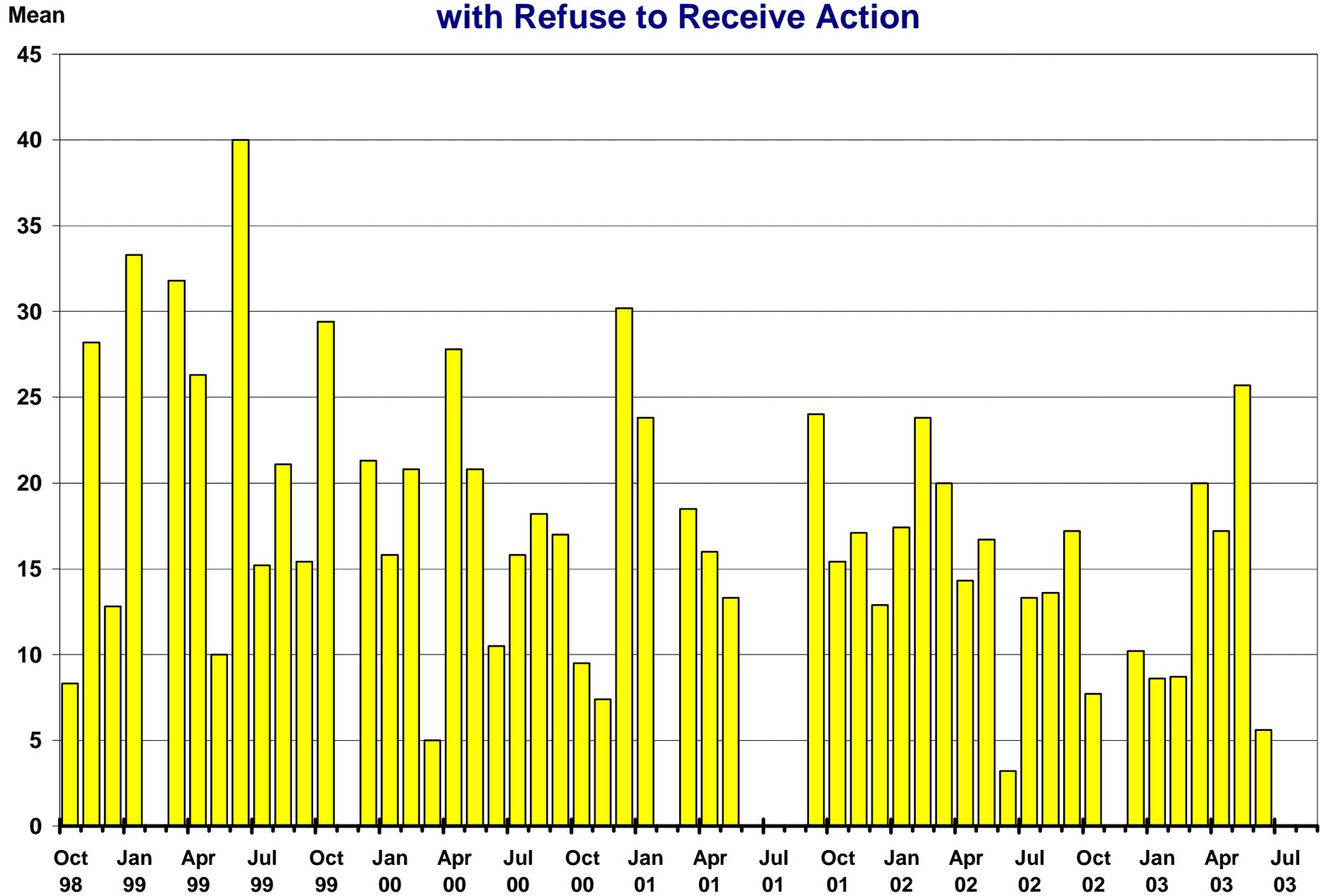


1 - Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

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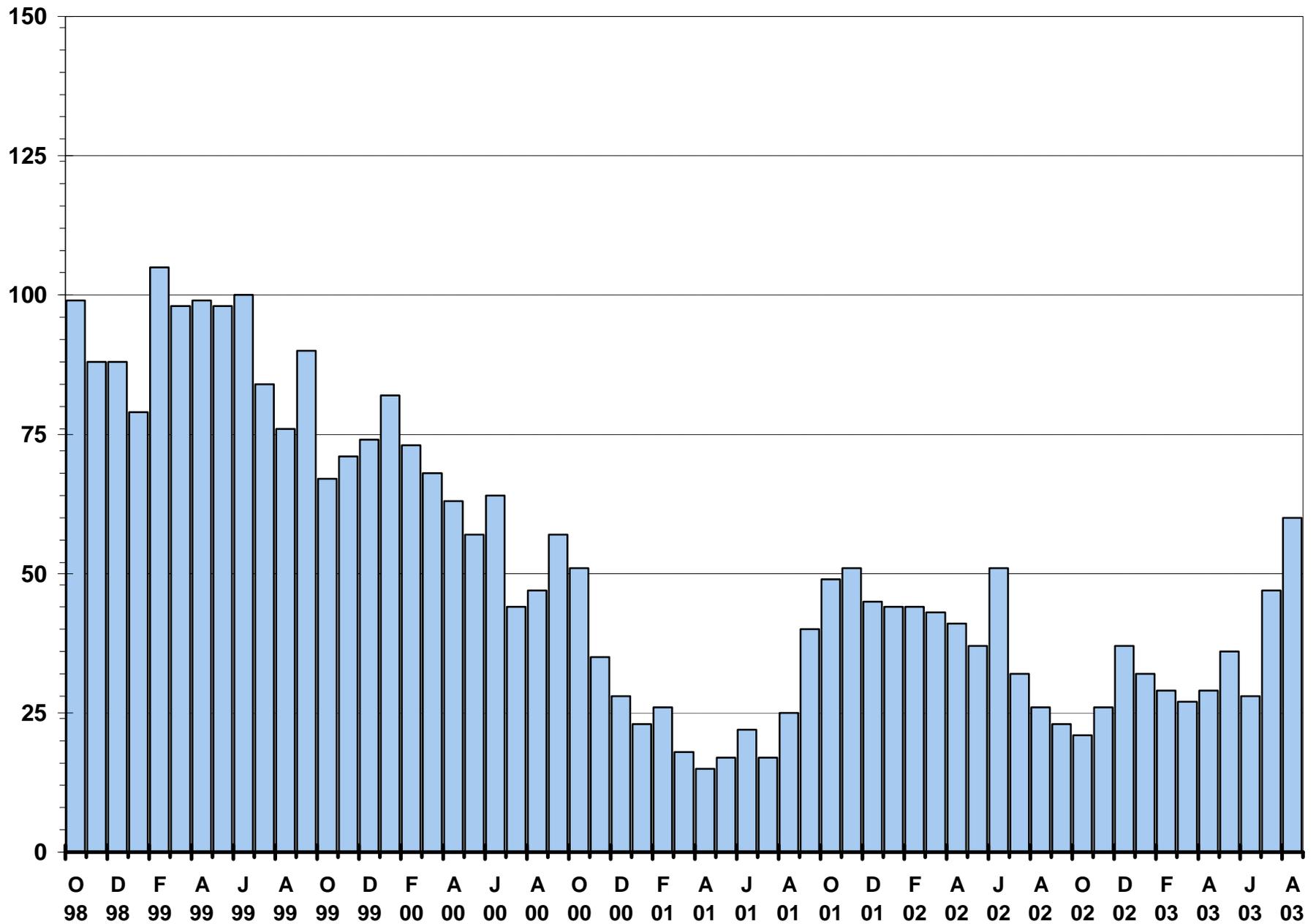
3 - Global Supplements are Collapsed

## Percent of Original Submissions with Refuse to Receive Action

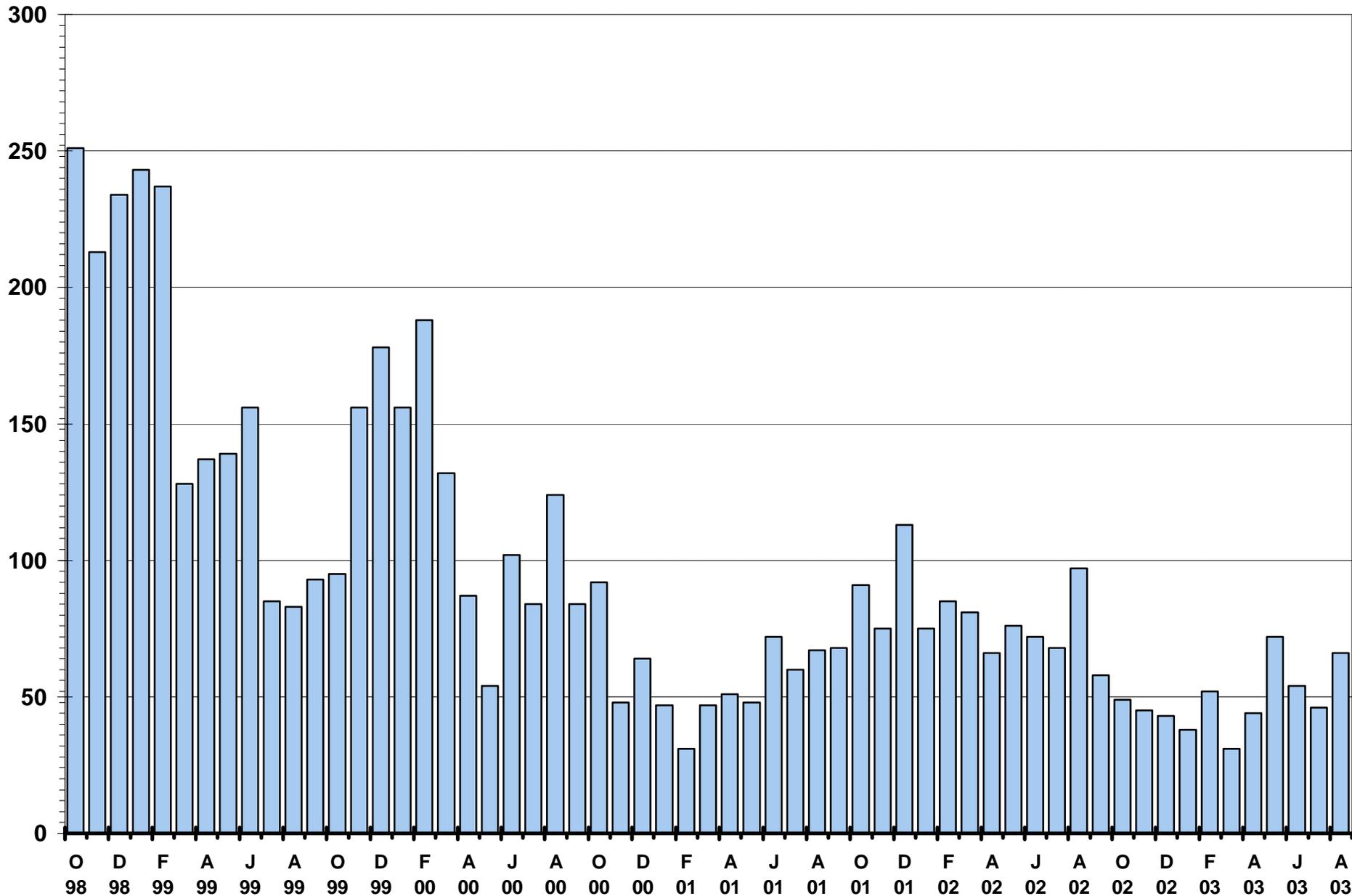


Status as of August 31, 2003. Percentages for recent months may increase due to future R/R actions

## Original ANDAs Pending > 180 Days



## ANDAs CMC Supplements Pending > 180 Days



Please note that abrupt changes in the level of pending supplements (e.g., the increase in October 1998) are the result of global submissions to all applications held by a single firm. Changes other than these will be explained separately.