

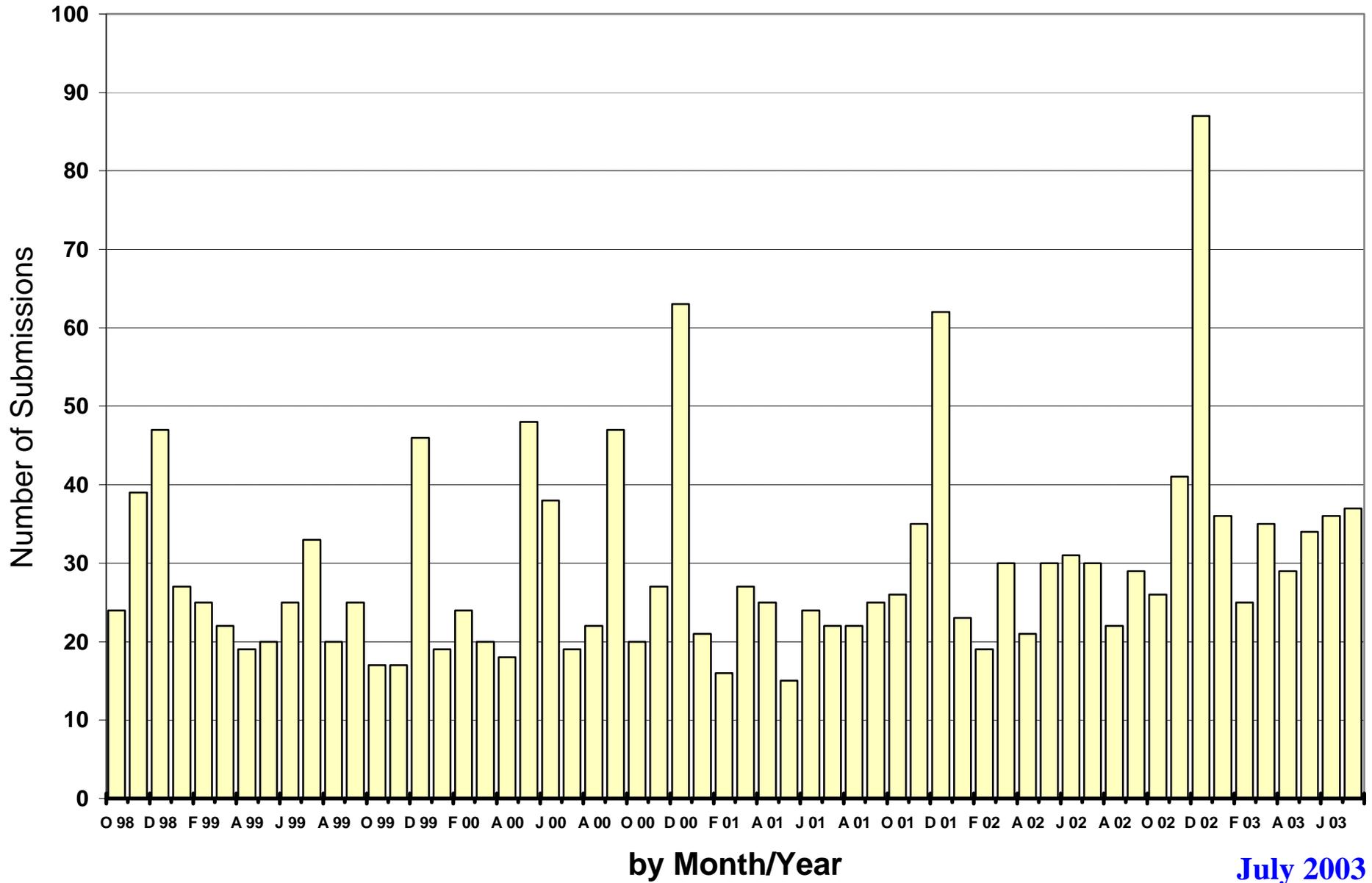
Center for Drug Evaluation and Research

Office of Generic Drugs

Monthly Quantitative Report
and Statistical Charts

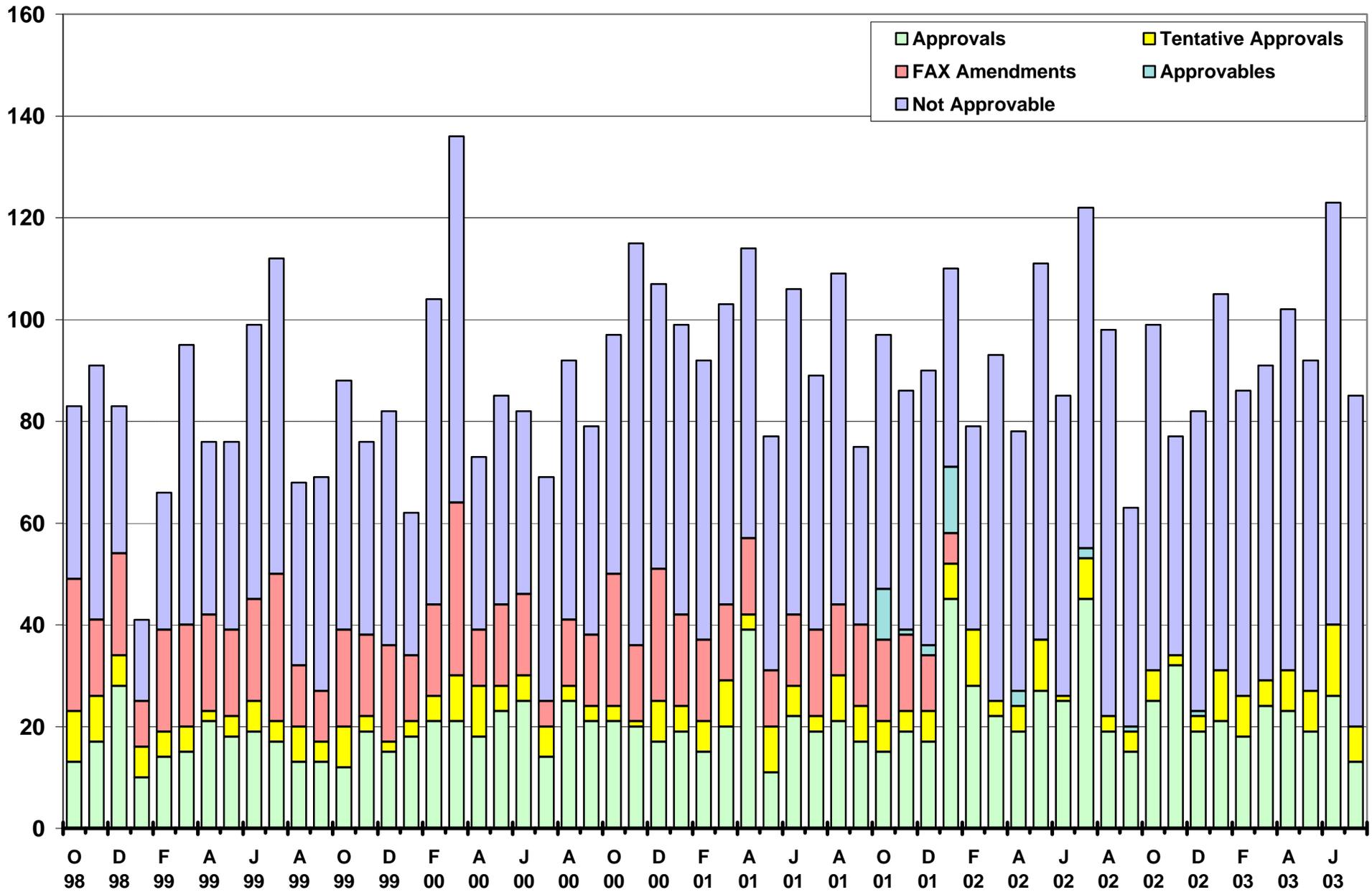
July 2003

Original ANDAs Received

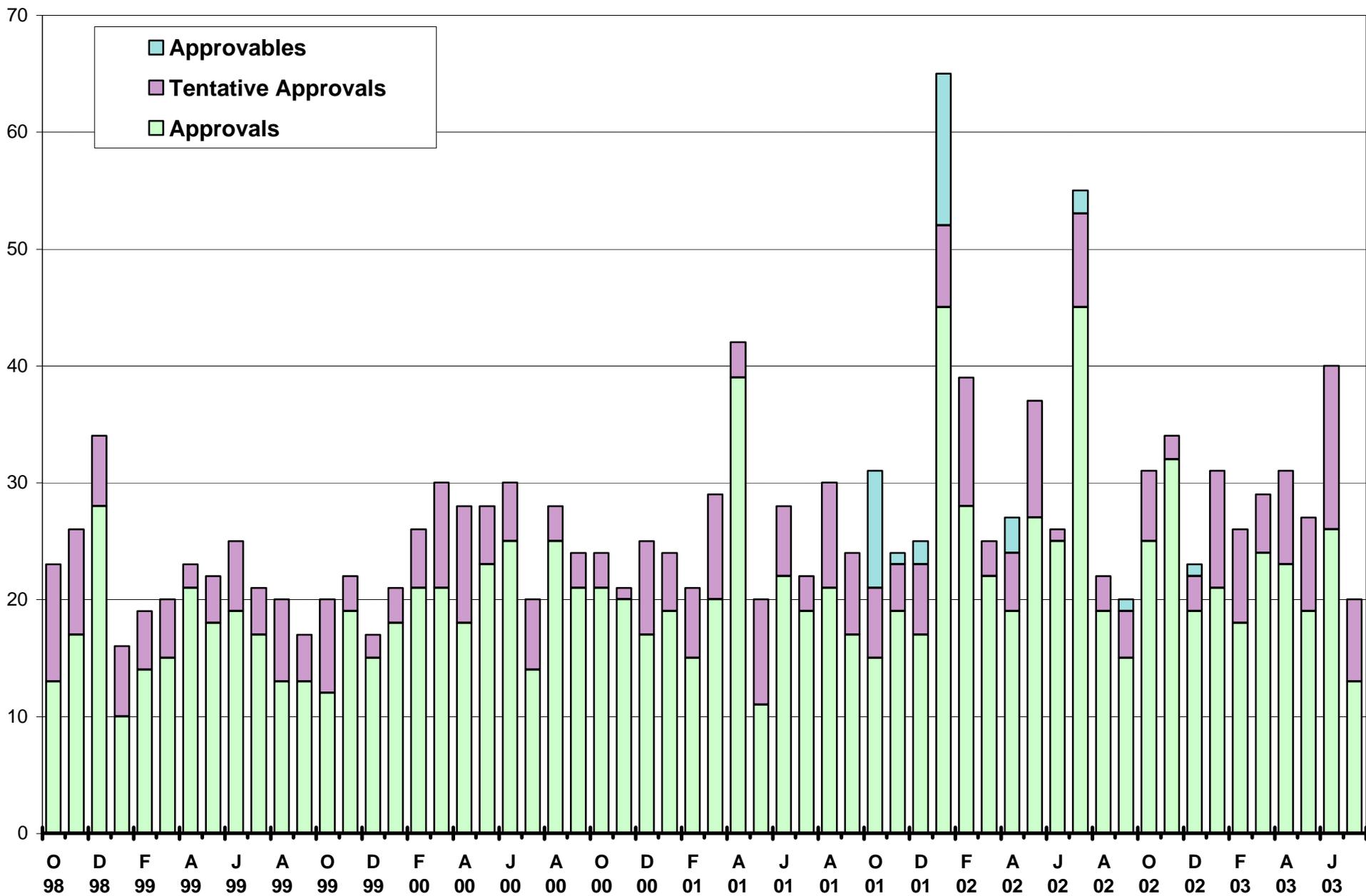


July 2003

Actions on Original ANDAs

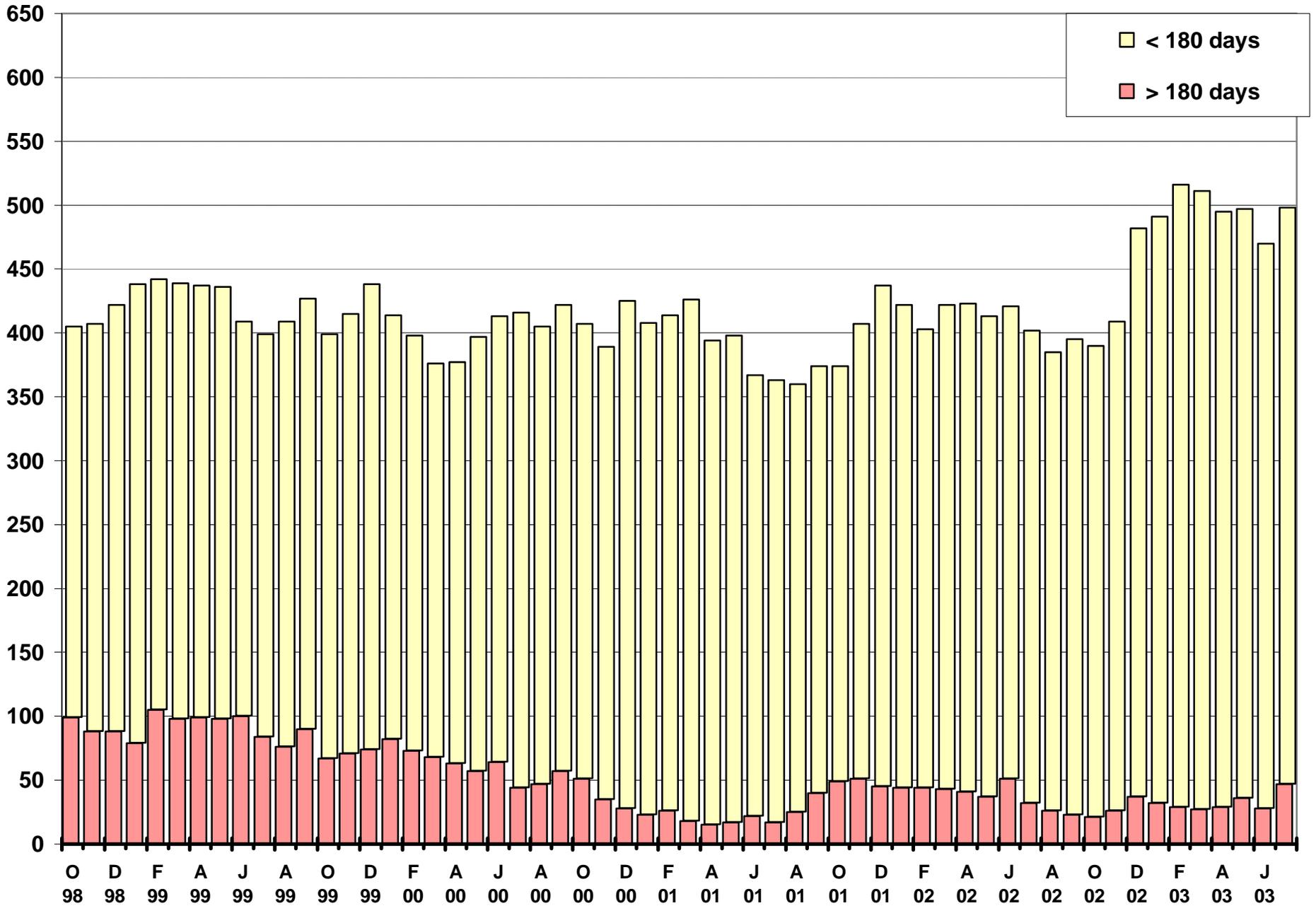


Original ANDAs Approved or Tentatively Approved

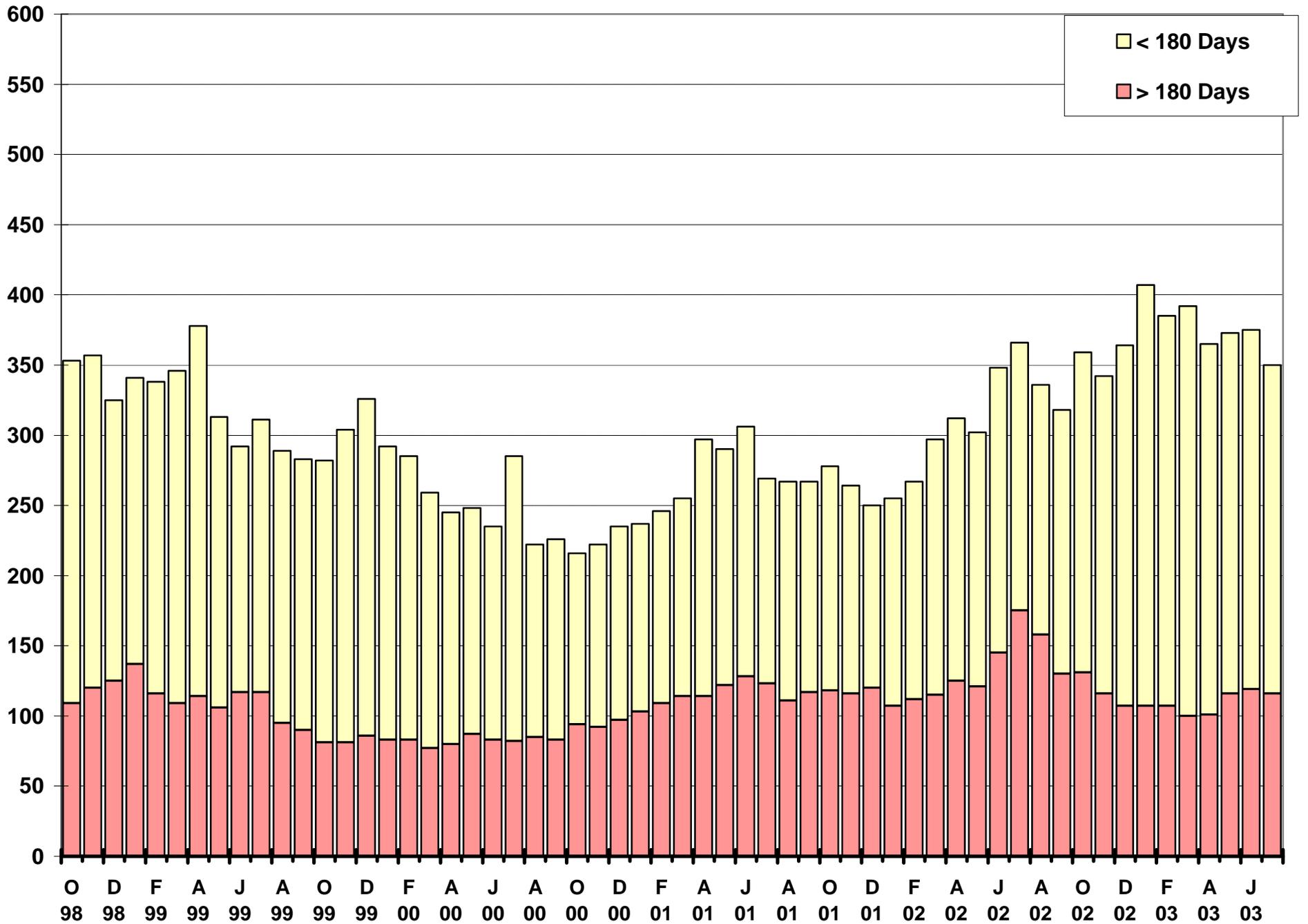


Note: Tentative Approvals (TA) are applications that have been approved by the office pending patent expiration. TAs and Approvables (AE) are counted as approvals subsequently when approved.

Original ANDAs Pending Per Month

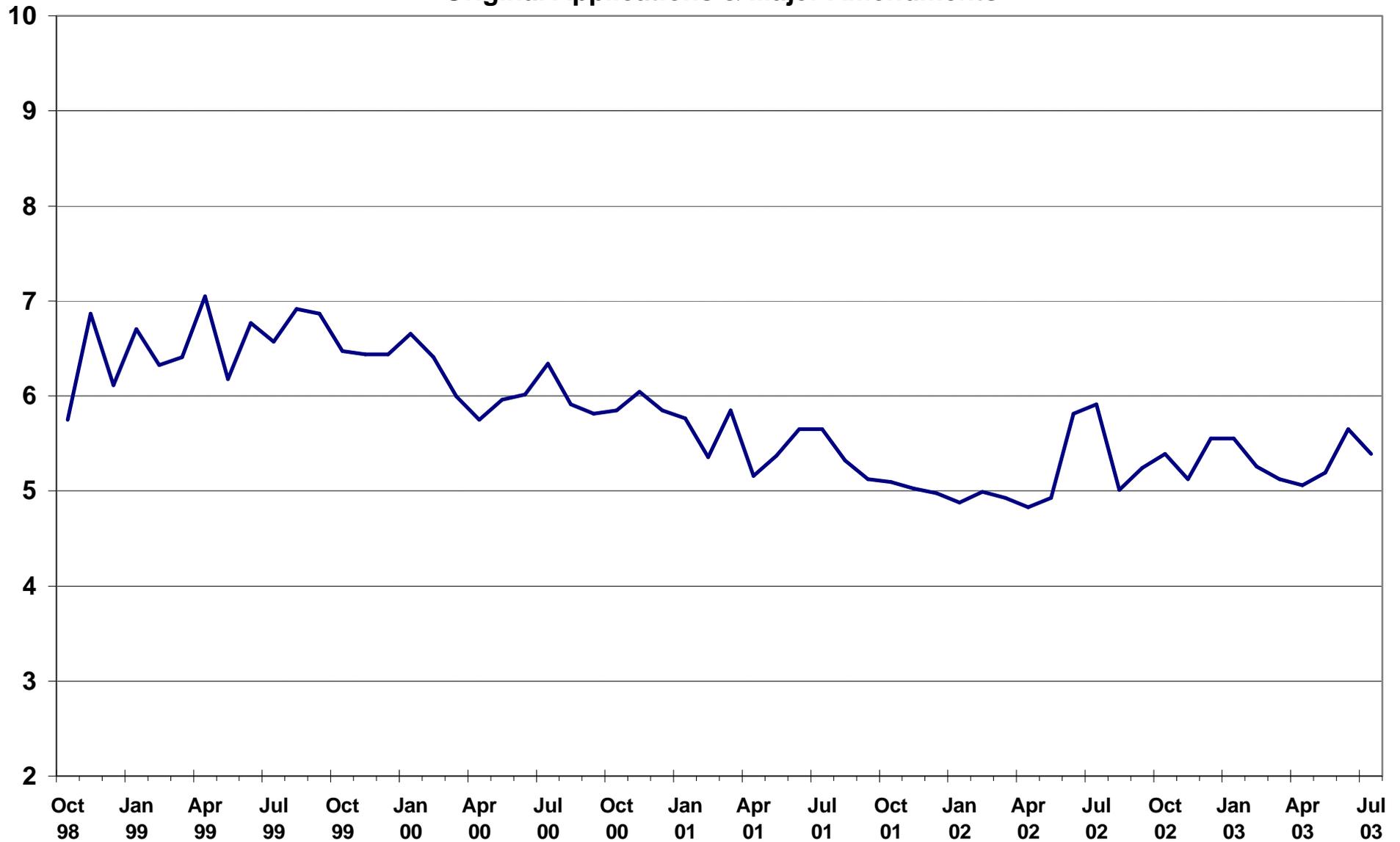


Labeling Supplements Awaiting OGD Action



Median ANDA Review Cycle (Months)

Original Applications & Major Amendments

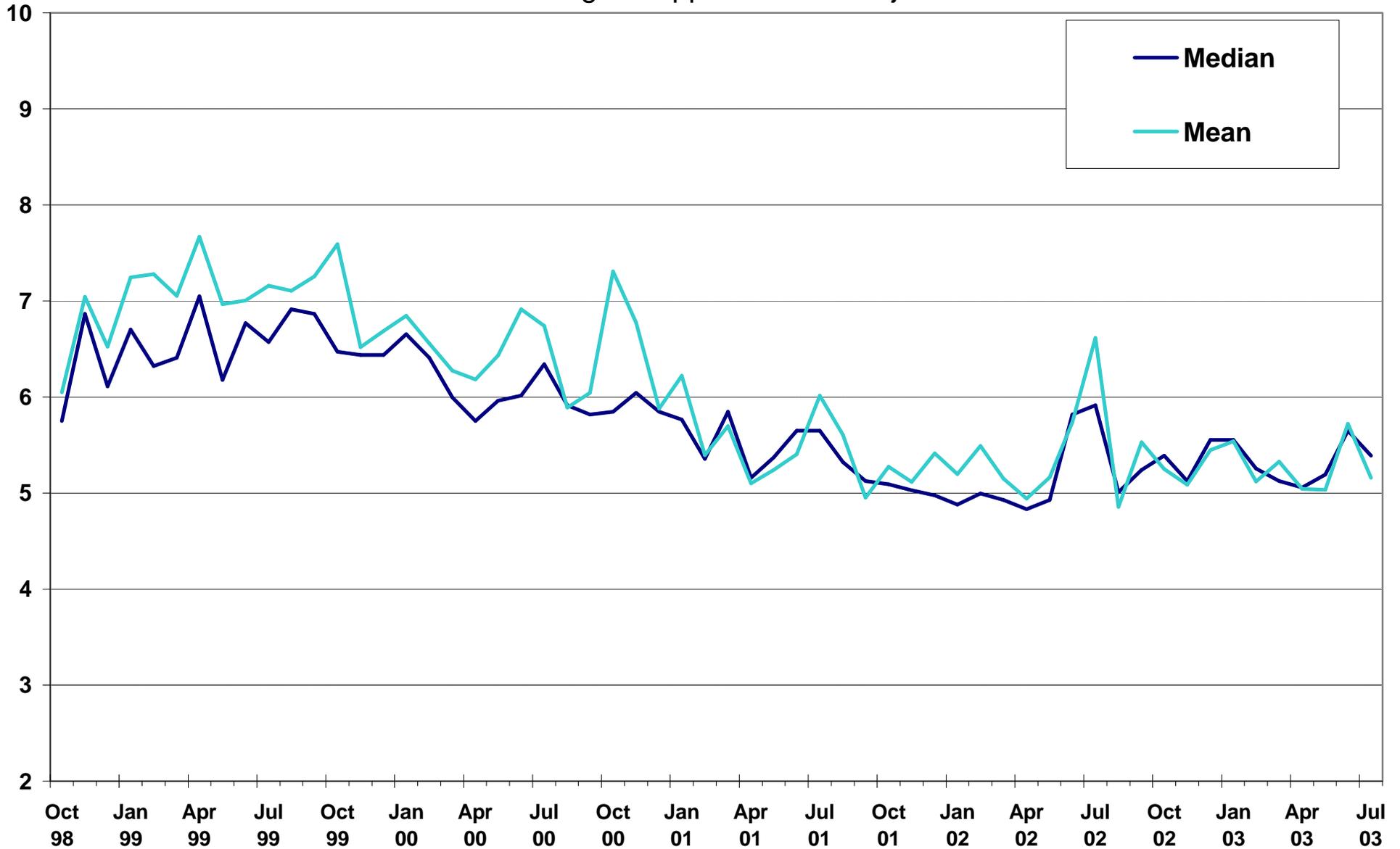


1 - Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

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)

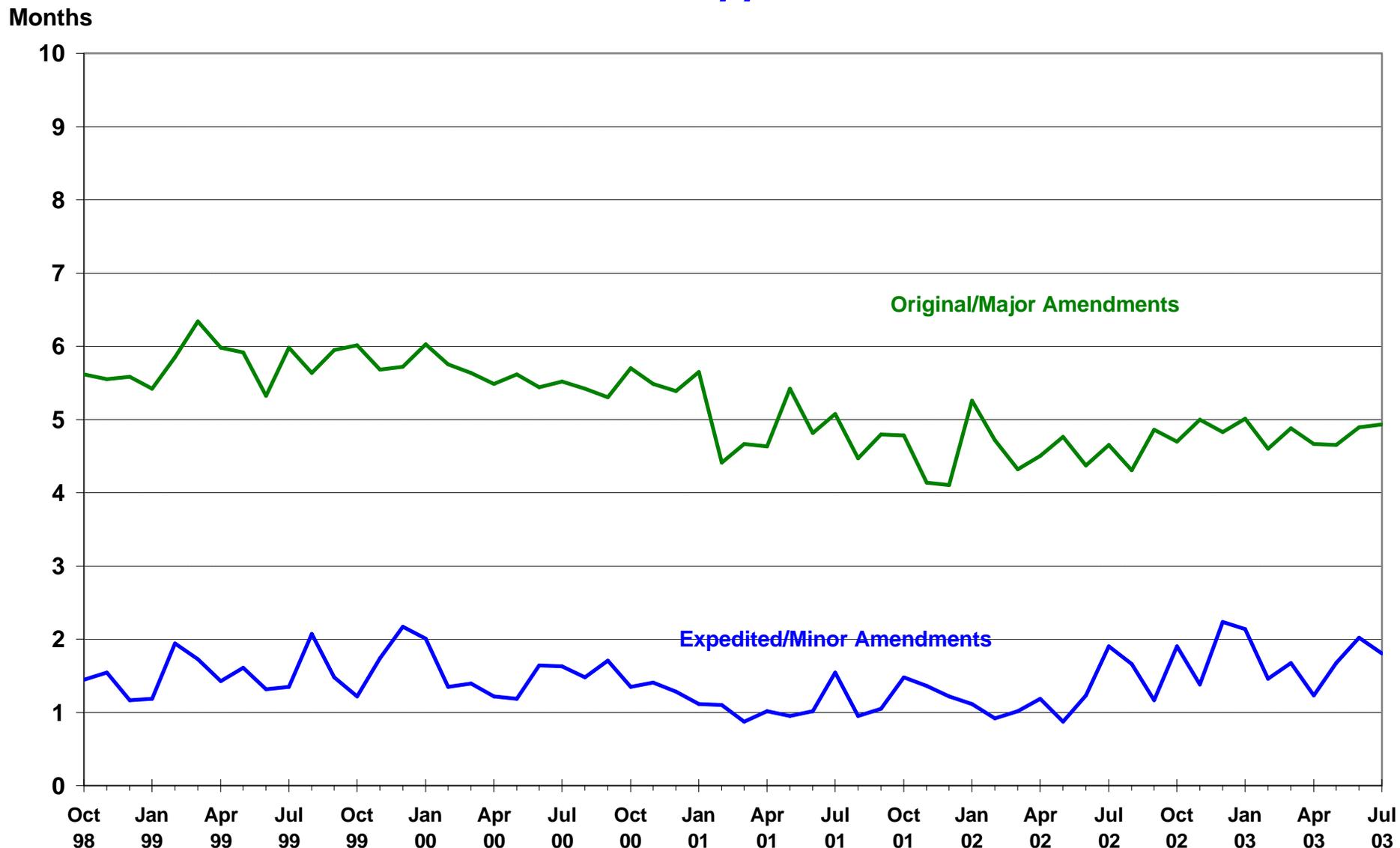
Original Applications & Major Amendments



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Median ANDA CMC Supplement Review Time

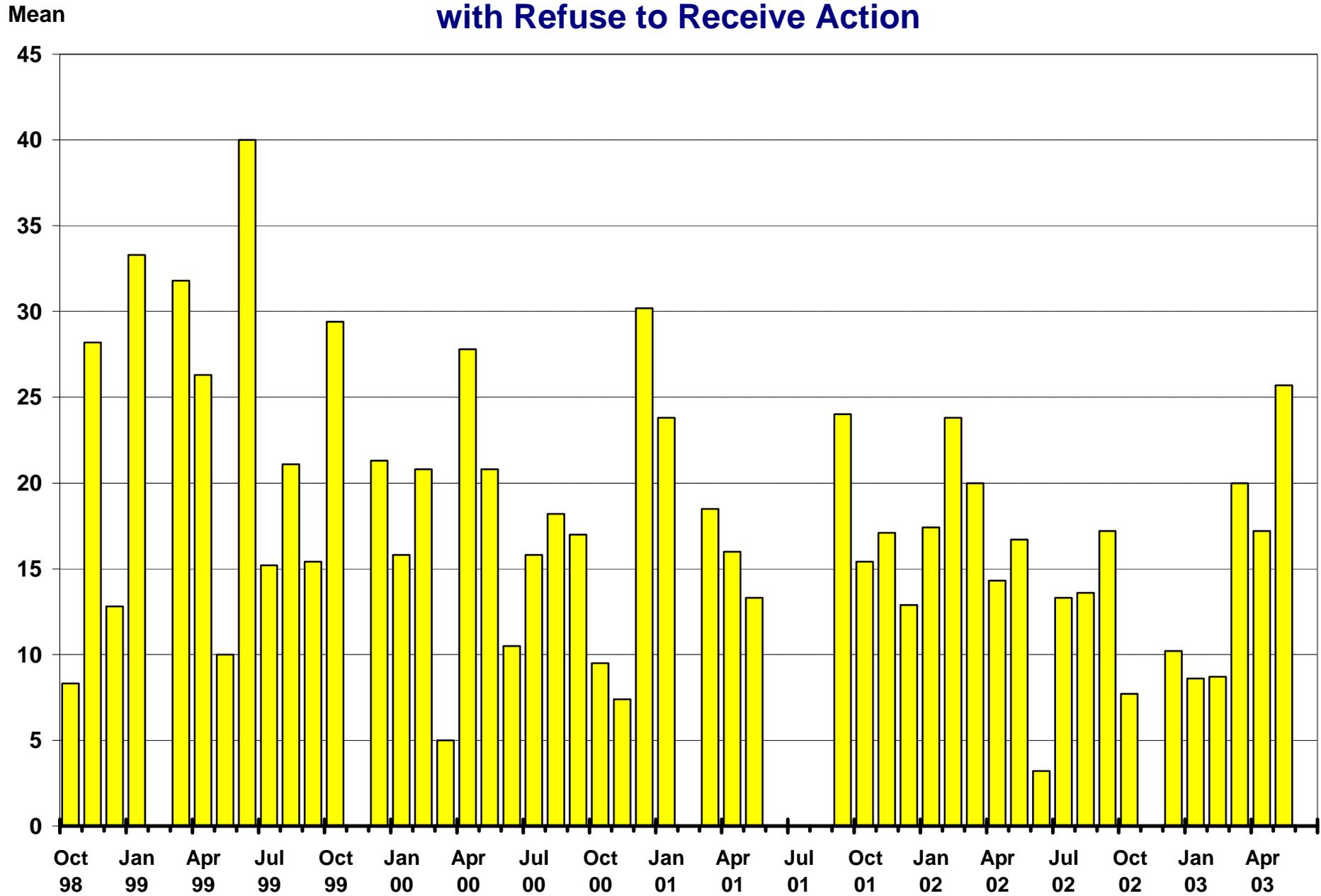


1 - Times correspond to actual applications received. The new ANDA/AADA submission policy that went into effect 1/1/91 allows certain variations in a drug product to be included in a single application.

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.

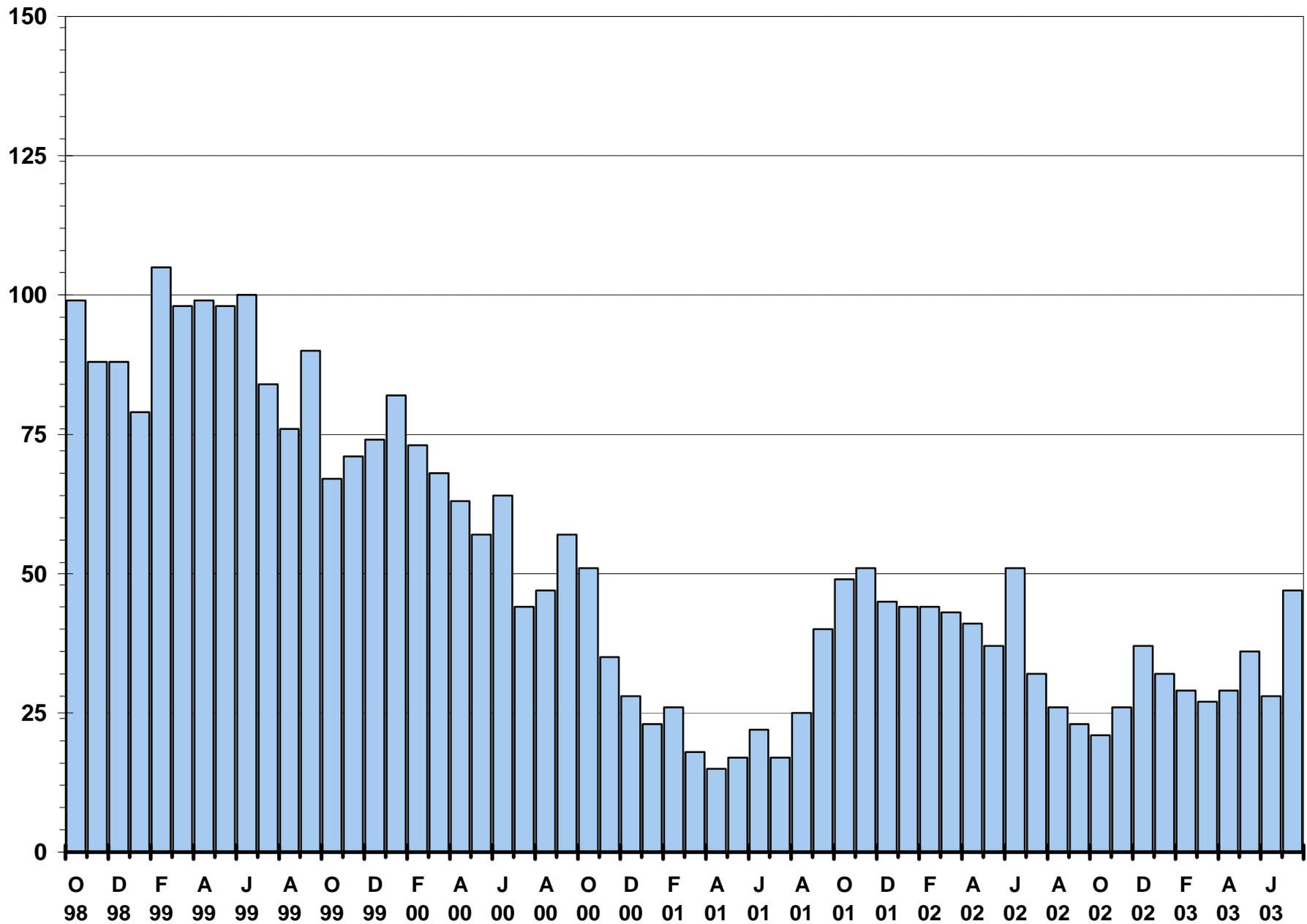
3 - Global Supplements are Collapsed

Percent of Original Submissions with Refuse to Receive Action

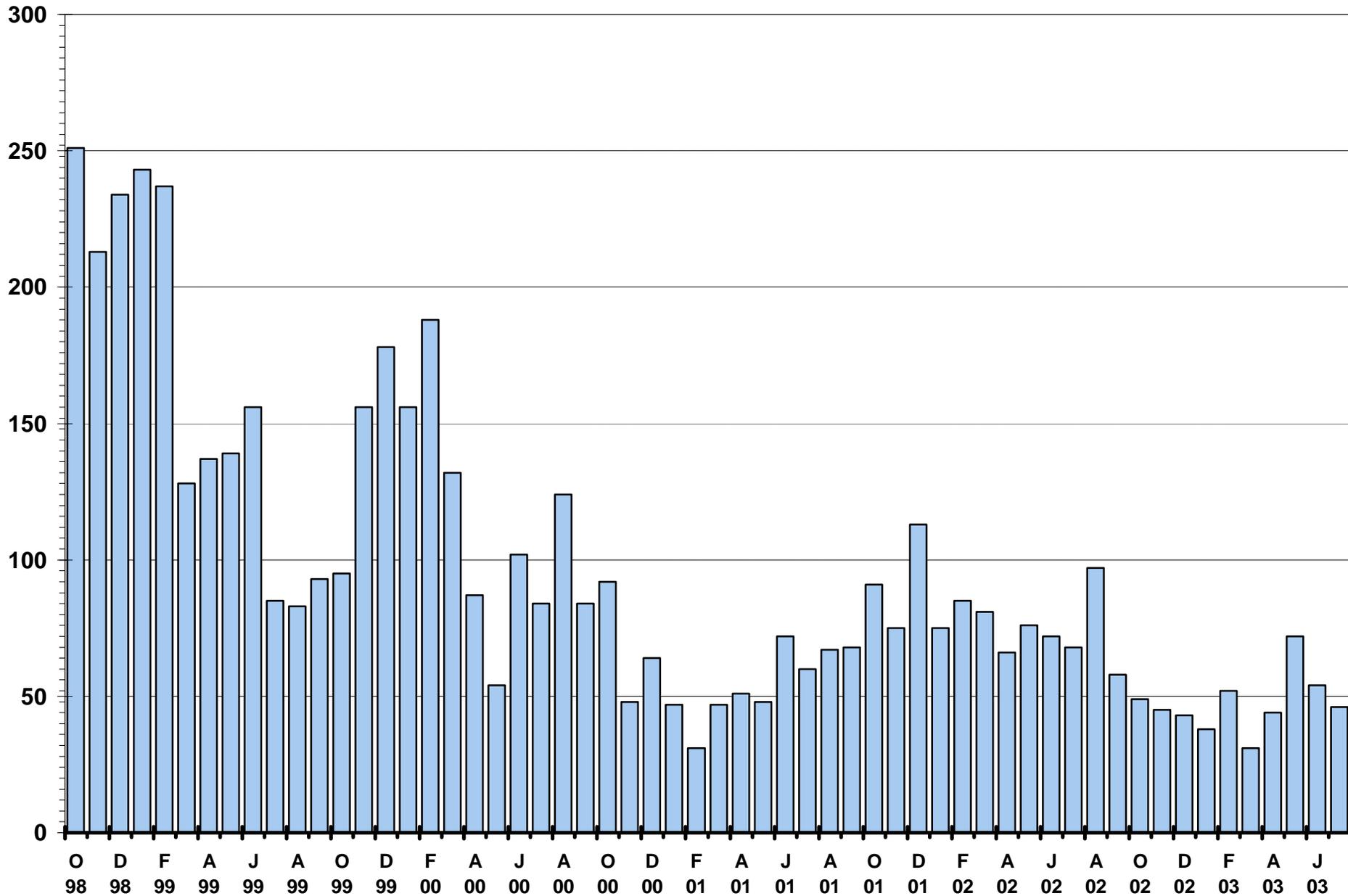


Status as of July 31, 2003. Percentages for recent months may increase due to future R/R actions

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.