MDUFMA Performance Update

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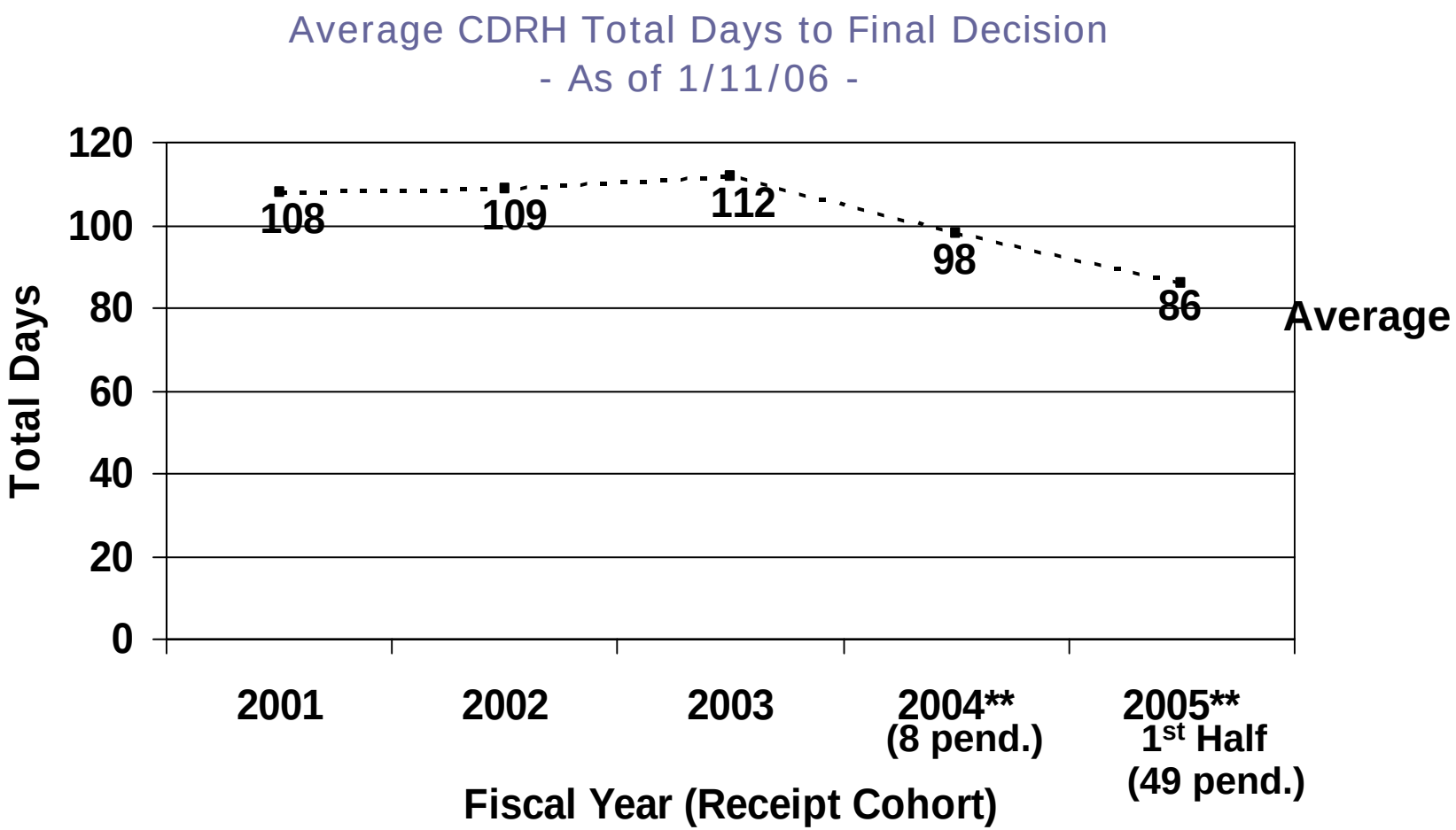
Objectives of MDUFMA

- Sustainable review program with:
  - Increased predictability in review times
  - Increased timeliness in review process
- Overall Objective: Get safe and effective devices to patients and healthcare professionals more quickly

Beyond MDUFMA's Performance Goals

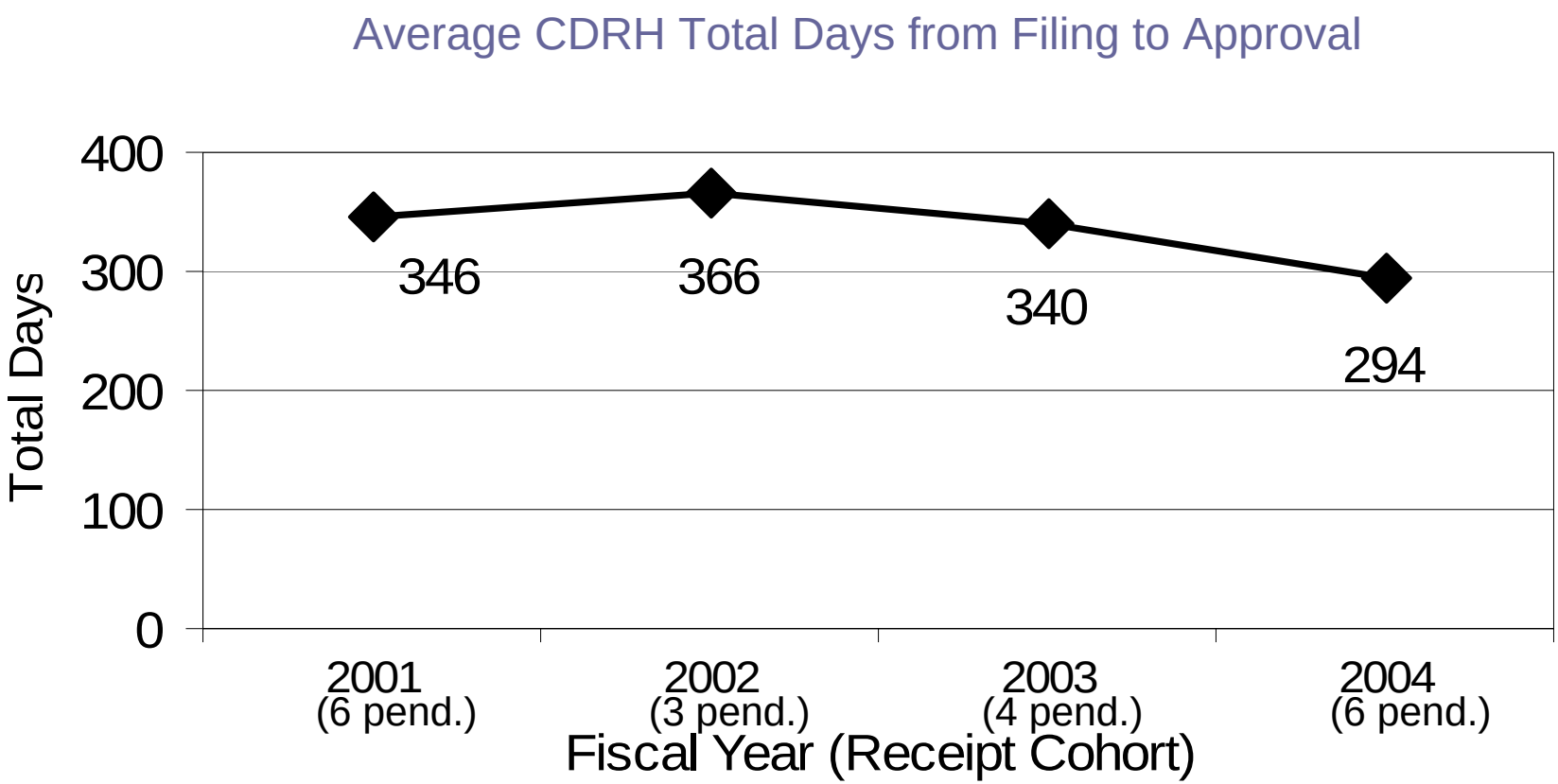
- We are meeting or exceeding nearly all of the agreed-upon performance goals
- This has brought greater consistency and predictability
- But the current performance goals do not provide a complete picture of what FDA has accomplished

Average Total Elapsed Time for Final Decision* for 510(k)s Has Improved

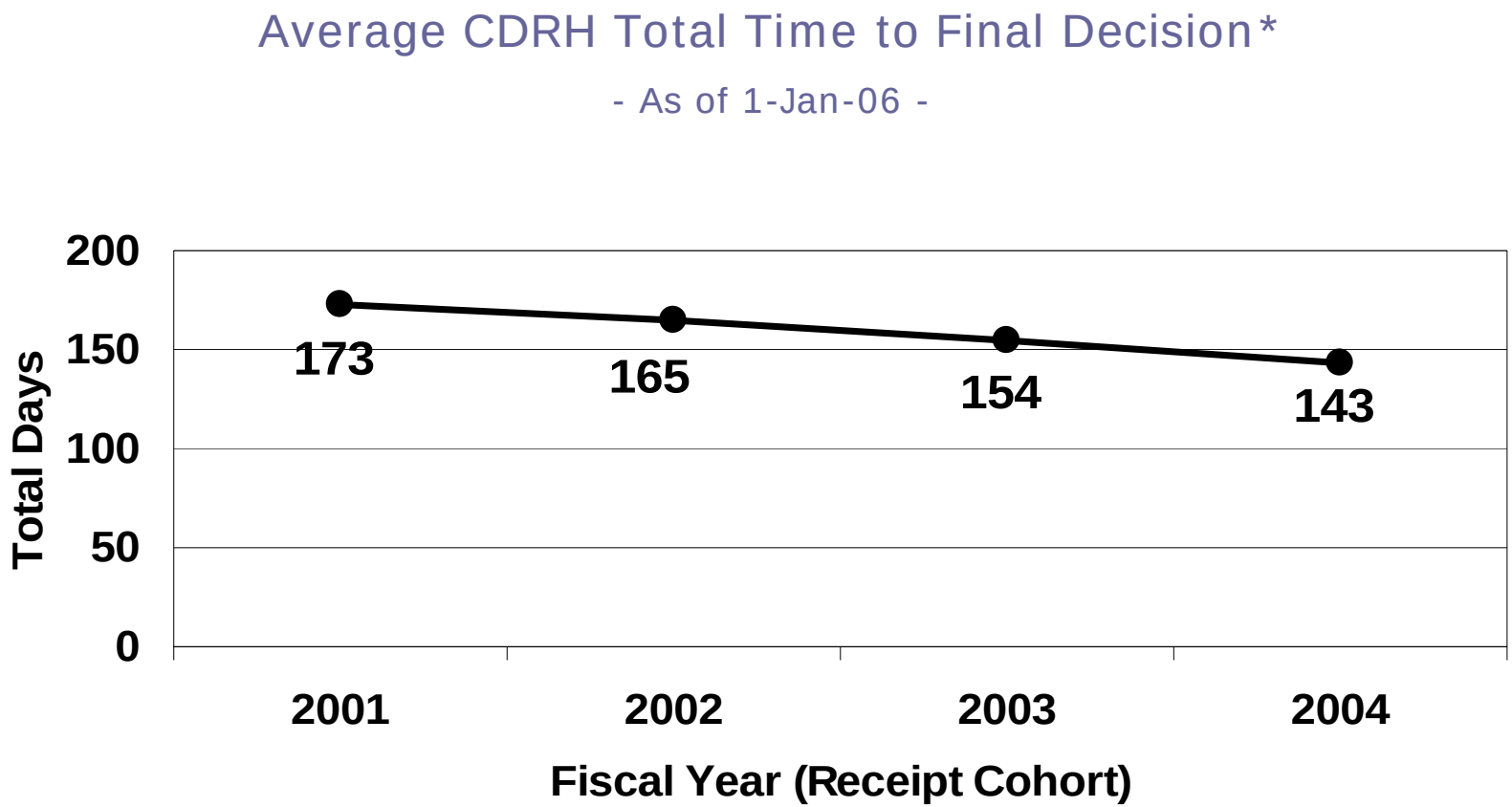


***Final Decision = SE, NSE, withdrawals, and deletions**
**** Cohort not complete; final data likely to be higher than shown**

Average Total Elapsed Time for Non-Expedited Original PMAs and P-T Supplements Has Improved



Average Total Elapsed Time to Final Decision for all 180-Day PMA/S Has Improved

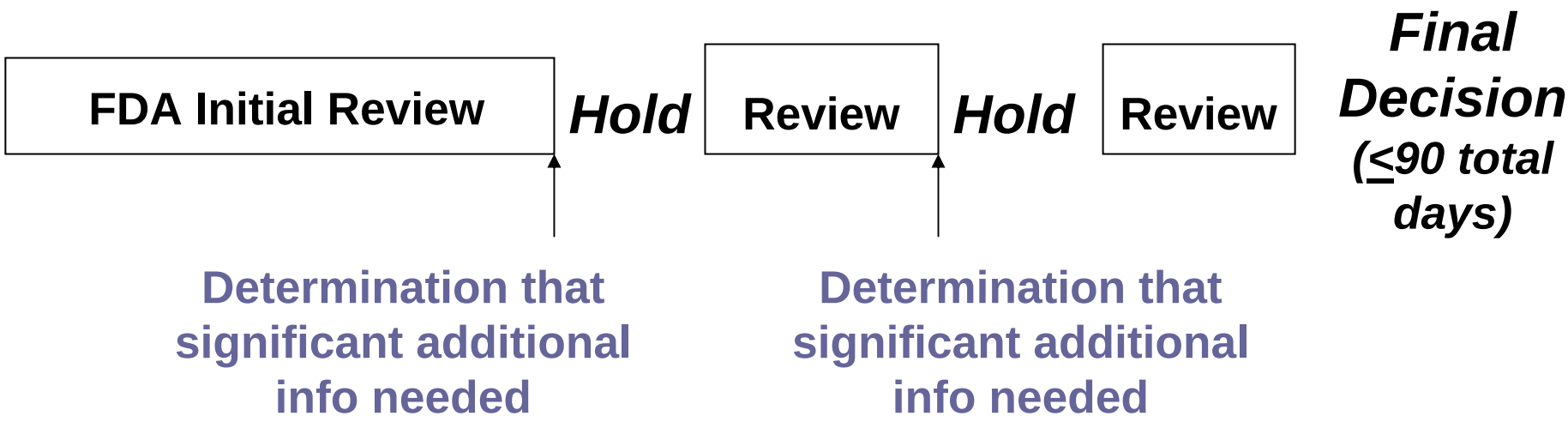


*Final Decision = Approvals, Withdrawals, and Conversions

How did we achieve these results?

Managing MDUFMA 510k goals

- We began by establishing a new 510k business process that would enable us to meet both the cycle and decision goals



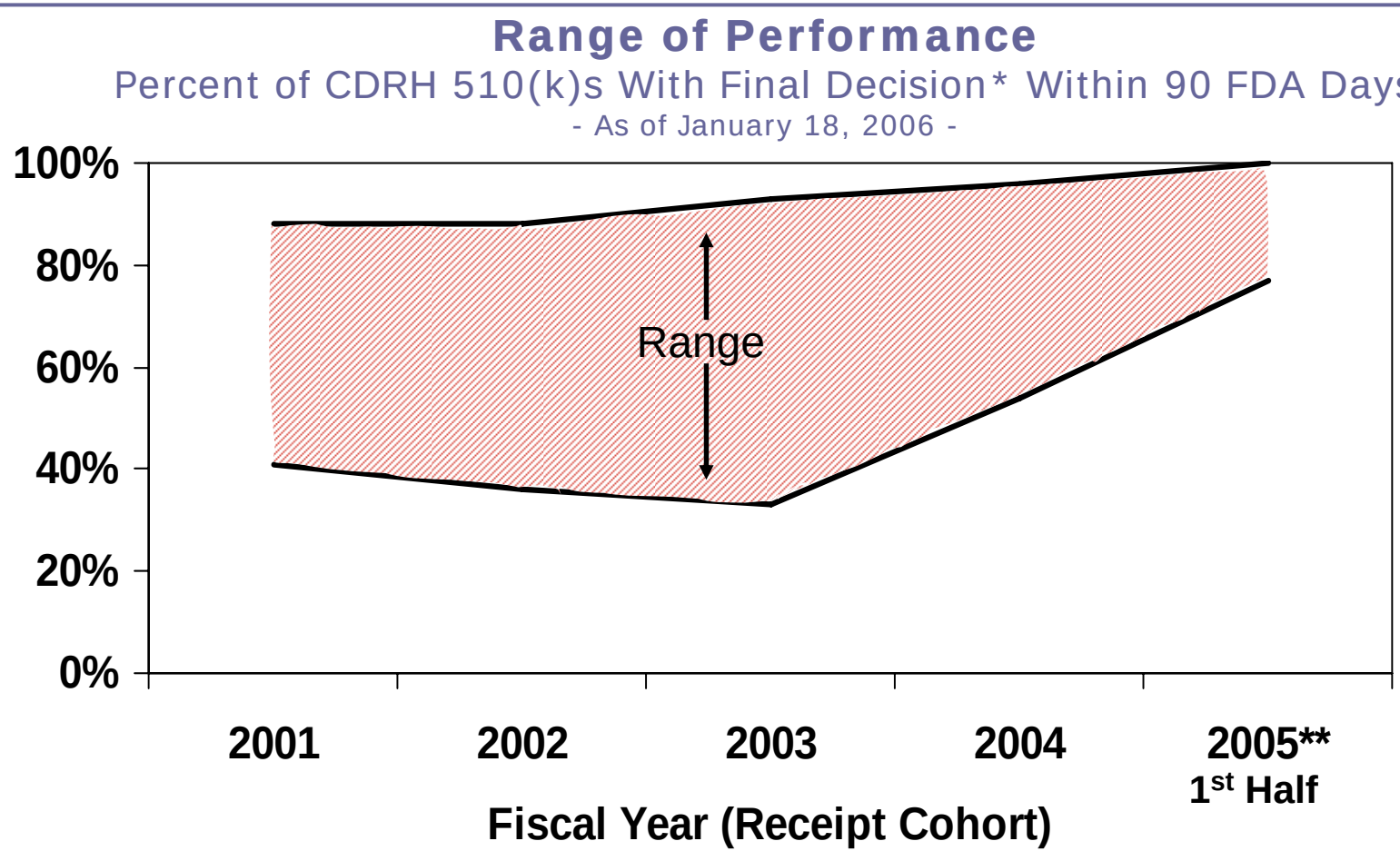
Managing the MDUFMA 510k goals

- … and as a result, we are meeting both the cycle and decision goals

	FY03	FY04	FY05	FY05 Goal
Final decision <90 days	76%	84%	93%	75%
First action <75 days	59%	79%	94%	70%
Second action < 60 days	51%	82%	93%	70%

FDA data

Predictability of 510(k) Review Times Across Branches Has Increased



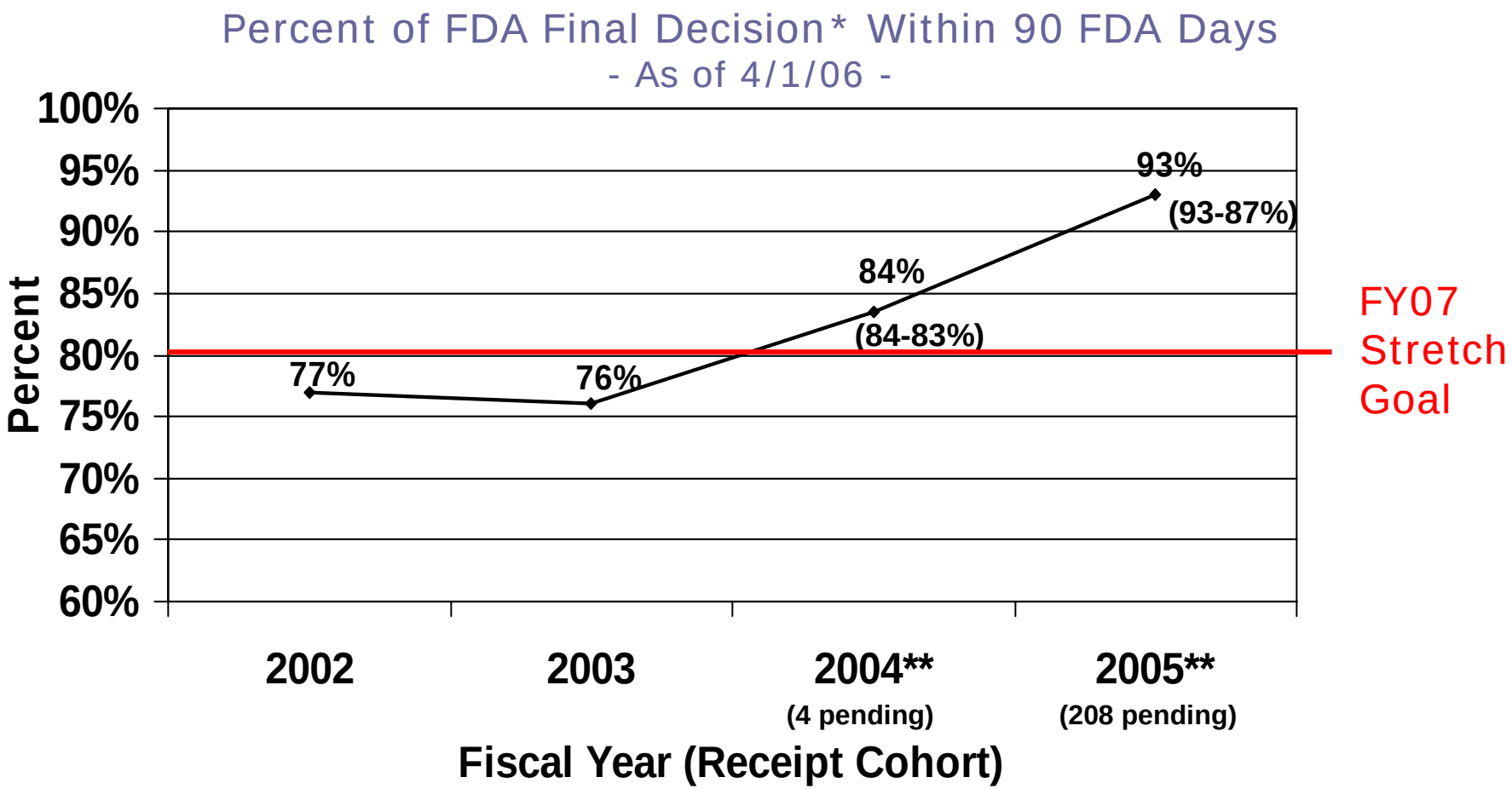
*CDRH data only; Final Decision = SE and NSE decisions only; excludes branches with fewer than 12 SE/NSE decisions in a year (i.e., <1 per month)

**Cohort not complete—uses largest possible range

Managing the MDUFMA 510k goals

- The 510k stretch goal for FY07 is:
  - 80% of 510ks will have a final decision in 90 FDA days
- We are meeting this goal

Managing the MDUFMA 510k goals



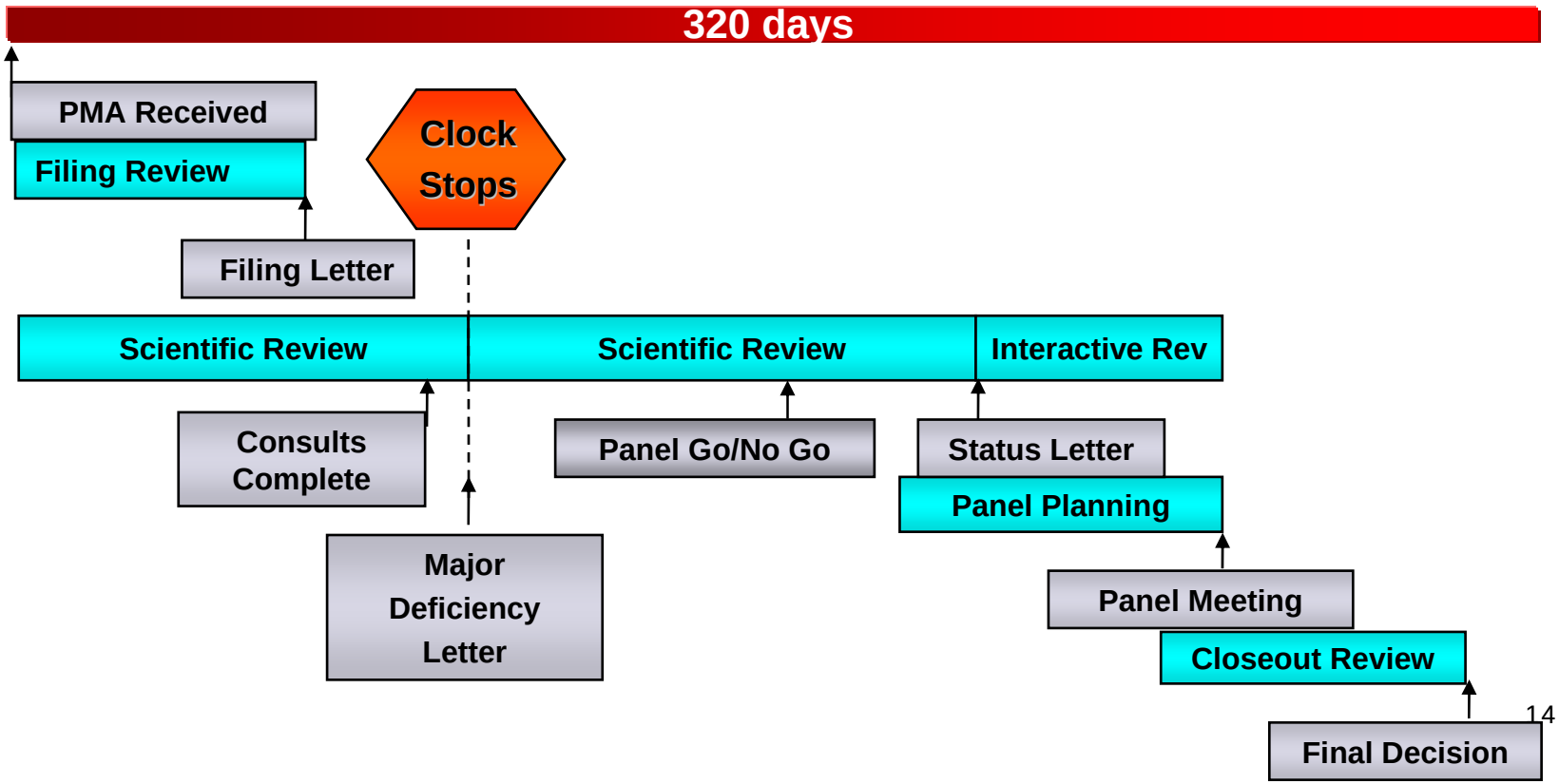
*Based on FDA SE and NSE decisions only
**Cohort not complete—data may change; range shows best-worst case possibilities for completed cohort

Managing the MDUFMA 510k goals

- Why were we able to meet the 510k stretch goal even in FY04?
  - For 510k's, the stretch goal is simply an extension of the decision goal
  - Because we had designed our business process to meet both the cycle and decision goals, we were able to meet the stretch goal.
- Our PMA results are different, because unlike the 510k stretch goal, the PMA stretch goal is not simply an extension of the decision goals

Managing the MDUFMA PMA goals

- We began by establishing a new PMA business process that would enable us to meet both the cycle and decision goals



Managing the MDUFMA PMA goals

- As a result, we are meeting both the cycle and decision goals

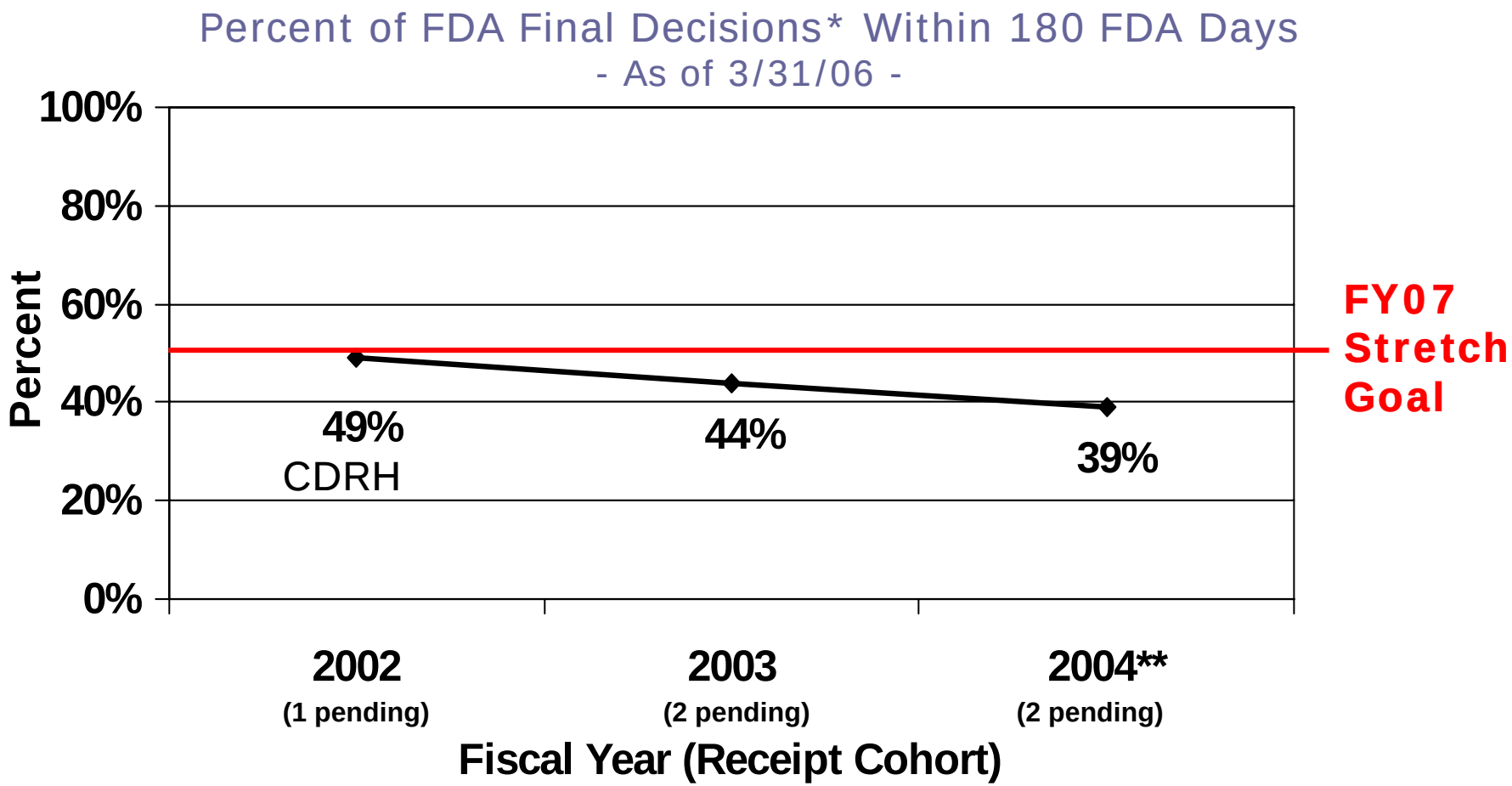
	FY03	FY04	FY05 Goal
Final decision <320 days	92%	91%	80% (FY06)
First action major deficiency <150 days	85%	82%	75%
First action other <180 days	96%	95%	75%

FDA data as of 3/31/06

Managing the MDUFMA PMA goals

- The PMA stretch goal for FY07 is:
  - 50% of PMAs will have a final decision in 180 FDA days
- We are not meeting this goal

Managing the MDUFMA PMA goals



Managing the MDUFMA PMA goals

- Why are we not meeting the PMA stretch goal?
  - We designed a new business process that enabled us to meet the MDUFMA cycle and decision goals
  - This new business process requires us to make decisions about first action major deficiency letters earlier on in the review process
  - As a result, we are more likely to issue a major deficiency letter than risk missing the cycle goal

Managing the MDUFMA PMA goals

- Why are we not meeting the PMA stretch goal?
  - The increased number of first action major deficiency letters (increased from 51% in FY02 to 68% in FY04) has decreased the number of PMAs with final decisions in 180 FDA days
  - Problems with the PMA cycle goals will require statutory changes to fix

Conclusions

- FDA is meeting or exceeding nearly all of the MDUFMA performance goals, including the FY07 510k stretch goal.
- Given the current cycle and decision PMA goal structure, which is set in statute, we are not in a position to meet the PMA stretch goal.
- Therefore, we do not intend to implement the PMA stretch goal in FY07.

We are interested in hearing your thoughts!